

PUBLIC ACCOUNTABILITY AND MEDICAL DEVICE REGULATION

Robert B. Leflar*

ABSTRACT

In enacting the Medical Device Amendments of 1976, Congress instituted a flexible system of regulatory controls over a vast array of health care products. Analyzing the complex statute and its legislative history, Professor Leflar finds at the law's core a structure designed to ensure the Food and Drug Administration's accountability to the public for its regulatory actions. Reviewing the history of FDA's implementation of the medical device law, however, the author demonstrates that FDA has strayed widely and, he contends, illegally from the congressionally mandated structure of public accountability. In particular, in its review of new-model medical devices in the most risk-laden class, the Agency has channeled the great majority of such devices into a clearance process of its own invention. This black-box "premarket notification" process circumvents statutory requirements of public advisory committee review in open meetings, published summaries of new products' safety and effectiveness data, and justification of marketing decisions—effectively insulating those decisions from administrative and judicial review and from adequate congressional and public oversight.

Professor Leflar recognizes that the medical device law is in some respects unworkable, that FDA's departure from the congressional design has been on the whole a well-intentioned effort to increase administrative efficiency, and that the Agency has undertaken noteworthy internal reforms in response to public and congressional criticism. Nevertheless, FDA's device review process departs from democratic principles. To enhance FDA's administration of the law while preserving the principle of public accountability, the author offers a number of suggestions for statutory reform.

* Associate Professor of Law, University of Arkansas, Fayetteville; Adjunct Associate Professor of Medical Jurisprudence, University of Arkansas for Medical Sciences, Little Rock; A.B. 1972, J.D. 1977, M.P.H. 1982, Harvard University. The author served as consumer representative on the FDA Immunological Devices Advisory Committee from 1982-87, and as staff attorney for Public Citizen Health Research Group from 1978-81. The author thanks Peter Hutt, Jonathan Kahan, Richard Merrill, Michael Reich, and William Schultz for their comments on a draft of this article, and acknowledges with gratitude the research support of his law school and its library staff.

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I. INTRODUCTION

The federal program of medical device regulation, an enterprise portrayed in a 1983 congressional report as an irresponsibly "neglected child" that had failed abysmally to perform its assigned statutory duties,¹ is claimed by its administrators to have attained a new maturity.² A series of often-scathing critiques, from congressional committees³ and research arms of the Congress⁴ and from consumer⁵ and industry⁶ perspectives, of Food and Drug Administration ("FDA") regulatory

1. STAFF OF SUBCOMM. ON OVERSIGHT & INVESTIGATIONS, HOUSE COMM. ON ENERGY & COMMERCE, 98TH CONG., 1ST SESS., MEDICAL DEVICE REGULATION: THE FDA'S NEGLECTED CHILD (Comm. Print 98-F, 1983) [hereinafter FDA'S NEGLECTED CHILD].

2. See, e.g., FOOD AND DRUG ADMINISTRATION, FDA'S MEDICAL DEVICE PROGRAM: PROGRESS IN CONSUMER PROTECTION (1988).

3. *FDA Oversight: Medical Devices, Hearing Before the Subcomm. on Oversight & Investigations, House Comm. on Energy & Commerce, 97th Cong., 2d Sess. (No. 97-144, 1982)* [hereinafter *1982 FDA Oversight Hearing*]; FDA'S NEGLECTED CHILD, *supra* note 1; *Health & the Environment: Miscellaneous, Part 2: Hearings Before the Subcomm. on Health & the Environment, House Comm. on Energy & Commerce, 98th Cong., 2d Sess. 273-435 (No. 98-108, 1984)* (Medical Device Amendments of 1976) [hereinafter *1984 Medical Device Hearings*]; *Failed Pacemaker Leads: Hearing Before the Subcomm. on Oversight & Investigations, House Comm. on Energy & Commerce, 98th Cong., 2d Sess. (No. 98-134, 1984)* [hereinafter *Failed Pacemaker Leads*]; *Anesthesia Machine Failures: Hearing Before the Subcomm. on Oversight & Investigations, House Comm. on Energy & Commerce, 98th Cong., 2d Sess. (No. 98-188, 1984)* [hereinafter *Anesthesia Machine Failures*]; *Pacemakers Revisited: A Saga of Benign Neglect, Hearing before the Senate Special Comm. on Aging, 99th Cong., 1st Sess. (No. 99-4, 1985)* [hereinafter *Pacemakers Revisited*]; *Medical Device and Drug Issues: FDA's Implementation of Medical Device Amendments of 1976, Hearing Before the Subcomm. on Health & the Environment, House Comm. on Energy & Commerce, 100th Cong., 1st Sess. 331-400 (No. 100-34, 1987)* [hereinafter *1987 Medical Device Hearings*].

4. COMPTROLLER GENERAL, FEDERAL REGULATION OF MEDICAL DEVICES — PROBLEMS STILL TO BE OVERCOME (1983) [hereinafter 1983 GAO REPORT]; OFFICE OF TECHNOLOGY ASSESSMENT, FEDERAL POLICIES AND THE MEDICAL DEVICES INDUSTRY (1984) [hereinafter OTA REPORT]; UNITED STATES GENERAL ACCOUNTING OFFICE, MEDICAL DEVICES: EARLY WARNING OF PROBLEMS IS HAMPERED BY SEVERE UNDERREPORTING (1986) [hereinafter 1986 GAO REPORT]; UNITED STATES GENERAL ACCOUNTING OFFICE, MEDICAL DEVICES: FDA'S 510(k) OPERATIONS COULD BE IMPROVED (1988) [hereinafter 1988 GAO REPORT].

5. E.g., Public Citizen Health Research Group (PCHRG), Comments on Proposed Procedures for Investigational Device Exemptions (Dec. 14, 1978); PCHRG, Petition to FDA to Restrict the Sale, Distribution and Use of Alpha-Fetoprotein Reagents, FDA Docket No. 79P-0143/CP (1979); J. AMCHIN & R. LEFLAR, THE HEALTH RESEARCH GROUP REPORT ON THE HAZARDS OF INTRA-OCULAR LENSES (1979); PCHRG, Petition to FDA to Remove Blood Screening Tests for Gonorrhea from the Market, FDA Docket No. 80P-0234/CP (1980); PCHRG, Petition to FDA to Require Premarket Approval Applications for Class III Neurological Devices, FDA Docket No. 82P-0151/CP (1982); *1982 FDA Oversight Hearing, supra* note 3, at 136-202 (testimony of Dr. Sidney Woife and Allen Greenberg).

6. E.g., HEALTH INDUSTRY MFRS. ASS'N. REPORT AND RECOMMENDATIONS OF THE HIMA DEVICE AND DIAGNOSTIC PRODUCT APPROVAL TASK FORCE (1985).

performance sparked a searching FDA internal review.⁷ The result has been a concerted agency effort to order in more logical fashion the processes by which FDA clears new medical devices for marketing and learns of problems with marketed products.

These internal and external critiques of FDA's regulatory enterprise also identified shortcomings in its statutory charter, the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act.⁸ In the last Congress, both the Reagan Administration and powerful Democratic legislators sponsored divergent proposals for statutory reform;⁹ one major bill passed the House with bipartisan support.¹⁰ Congress undoubtedly will consider other competing proposals in the coming year.

This Article analyzes the objectives and structure of the 1976 medical device law and concludes that one of the statute's core values is the principle of public accountability for Agency actions (Part II). The Article then reviews the twelve-year record of FDA's implementation of the law, including recent internal reforms (Part III). The lawfulness of the Agency's practices under the statute is analyzed in light of recent case law concerning judicial review of Agency statutory interpretations (Part IV). Finally, the Article evaluates the proposed reform legislation, with a particular emphasis on mechanisms for ensuring public accountability of the Agency's actions, and offers suggestions for needed changes consistent with both democratic principles and scientific decision-making.

The thesis of the Article is that FDA's past policies concerning pre-

7. FOOD AND DRUG ADMINISTRATION, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (FDA CDRH), REPORT OF THE PRE-AMENDMENTS PMA CRITICISMS TASK FORCE (1984); FDA CDRH, REPORT OF THE RECLASSIFICATION CRITICISMS TASK FORCE (1984); FDA CDRH, REPORT OF THE PMA CRITICISMS TASK FORCE (1985); FDA CDRH, REPORT OF THE GMP CRITICISMS TASK FORCE (1985); FDA CDRH, REPORT OF THE PREMARKET NOTIFICATION CRITICISM TASK FORCE (1985); FDA CDRH, REPORT OF THE TASK FORCE ON INVESTIGATIONAL DEVICE EXEMPTIONS (IDES) (1985); FDA CDRH, EXECUTIVE SUMMARY OF THE CRITICISMS TASK FORCES' REPORTS (1985).

As Dr. Kshitij Mohan, head of FDA's Office of Device Evaluation, observed at a June 24, 1987 conference of the Food and Drug Law Institute, "We had had enough of being a slow target and bleeding profusely when hit, so we undertook a uniquely honest self-appraisal."

8. Pub. L. No. 94-295, 90 Stat. 539 (1976).

9. E.g., H.R. 4640, 100th Cong., 2d Sess., *approved by voice vote*, 134 CONG. REC. H5848-53 (daily ed. July 26, 1988) (Reps. Waxman & Dingell); H.R. 1226, 100th Cong., 2d Sess., 201-211, *approved by voice vote*, 134 CONG. REC. H5853-57 (daily ed. July 26, 1988) (appending H.R. 4640 to the FDA Act of 1987, previously passed by the Senate); S. 1808, 100th Cong., 2d Sess., *favorably reported out of committee*, 134 CONG. REC. 5929 (daily ed. July 14, 1988) (Sens. Kennedy & Hatch); H.R. 4784, 100th Cong., 2d Sess., Title V, at 69, *approved*, 134 CONG. REC. S10,408 (daily ed. July 29, 1988) (contact lens reclassification provision introduced by Sen. Bumpers); S. 1928, 100th Cong., 1st Sess., 133 CONG. REC. S17,436 (daily ed. Dec. 8, 1987) (then-Sen. Quayle, for the Reagan Administration).

10. H.R. 4640, *supra* note 9.

market clearance of medical devices have departed widely from both the spirit and the letter of the law. Congress in 1976 designed a three-tier regulatory system, mandating premarket approval through an open public process for the most risk-laden class of devices and calling for performance standards for devices of intermediate risk. FDA, however, contrived a separate "premarket notification" system for review of products claimed to be "substantially equivalent" to devices marketed before the 1976 legislation—a review system bypassing the open process for premarket approval that Congress had designed. The Agency has channeled the vast majority of new-model devices proposed for introduction on the market, including most devices in the highest-risk class, into this alternate review system, which is closed off from public scrutiny. FDA has also virtually foregone the writing of standards for devices of intermediate risk, regulating them for most purposes like low-risk devices.

The Agency's intentions in departing from the process Congress envisioned have been honorable, because the law is in some respects unworkable and the Agency's adopted procedures have proved relatively efficient. But a major cost of FDA's efficient extralegal administration of the law has been the routine subversion of a principle at the heart of the congressionally mandated scheme: the Agency's responsibility to practice open government and justify its decisions to the public. Medical innovation sometimes entails hazard and under the law the Agency should be accountable to the public when deciding how the risk-benefit tradeoffs are made.

II. THE MEDICAL DEVICE LAW: WHAT CONGRESS INTENDED

A. Background

Until Congress enacted the Medical Device Amendments in 1976, federal regulation of medical devices was a catch-as-catch-can affair.¹¹

11. The brief summary of the medical device law's background that follows draws in large part on the House committee report, H.R. REP. NO. 853, 94th Cong., 2d Sess. 5-12 (1976) [hereinafter HOUSE REPORT]. The House Report is for most purposes the best source of legislative history on the Medical Device Amendments, since the House bill (H.R. 11,124) served as the "basis for the conference substitute" that was ultimately enacted. See H.R. REP. NO. 1090, 94th Cong., 2d Sess. 51 (1976) (Conference Report on S. 510, Medical Device Amendments of 1976), reprinted in 1976 U.S. CODE CONG. & ADMIN. NEWS 1103 [hereinafter CONFERENCE REPORT].

For an overview of device hazards recognized by the mid-1970's, see generally Foote, *Loops and Loopholes: Hazardous Device Regulation Under the 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act*, 7 ECOLOGY L.Q. 101, 102-06 (1978).

The Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA")¹² authorized FDA to seize adulterated or misbranded devices and to seek injunctions or criminal prosecutions against manufacturers or distributors of violative articles. But the Agency could act only after the articles had been introduced on the market. In the absence of a premarket review system, FDA bore the burden of proving that each item was unsafe or misbranded. Considerable agency time and resources were required to remove even relatively simple fraudulent products from the market,¹³ and, pending litigation, product sellers could generally continue marketing. As medical technology advanced, necessitating more sophisticated risk-benefit judgments for useful, but potentially dangerous products (such as the Dalkon Shield IUD), the inadequacy of existing law from the perspective of public health protection became more obvious.

FDA asserted premarket review authority over some types of products commonly thought of as medical devices and courts upheld the Agency's creative classification of the products as "new drugs."¹⁴ However, these rulings covered only a small corner of the rapidly expanding medical device field, leaving many potentially hazardous or useless products virtually free of regulatory oversight. A 1970 report by the blue-ribbon Cooper Committee,¹⁵ pointing to 10,000 device-related injuries and 751 deaths over the previous ten years, recommended replacement of the existing patchwork system by a comprehensive but flexible regulatory structure.¹⁶ The concepts embodied in the Cooper Committee

12. Act of June 25, 1938, ch. 675, 52 Stat. 1040.

13. The classic example is FDA's protracted attempt to remove from the market the Diapulse device, a heat-generating device promoted (without valid scientific evidence of efficacy) for over 100 therapeutic claims. It took FDA from the initial enforcement action in 1965 until well into the 1970's to obtain injunctions against the marketing of the device. See *United States v. Diapulse Mfg. Corp. of Am.*, 389 F.2d 612 (2d Cir.), *cert. denied*, 392 U.S. 907 (1968); *United States v. Diapulse*, 1 Med. Devices Rep. (CCH) ¶ 3044.64 (D. Idaho 1973); *United States v. Diapulse*, 1 Med. Devices Rep. (CCH) ¶ 3044.25 (S.D. Ohio 1974); *United States v. Diapulse*, 1 Med. Devices Rep. (CCH) ¶ 3040.23 (M.D. N.C. 1974); *United States v. Diapulse*, 1 Med. Devices Rep. (CCH) ¶ 3040.235 (D. Iowa 1974); HOUSE REPORT, *supra* note 11, at 7.

14. E.g., *United States v. Bacto-Unidisk*, 394 U.S. 784 (1969) (disc to determine antibiotic sensitivity); *AMP v. Gardner*, 389 F.2d 825 (2d Cir.), *cert. denied*, 393 U.S. 825 (1968) (nylon suture); HOUSE REPORT, *supra* note 11, at 8-9.

15. The "Cooper Committee" was the Study Group on Medical Devices, convened in 1969 by the Secretary of Health, Education and Welfare and chaired by the then-Director of the National Heart and Lung Institute, Dr. Theodore Cooper. The committee was charged with devising recommendations for a law for the regulation of medical devices. See Cooper, *Device Legislation*, 26 FOOD DRUG COSM. L.J. 165 (1971); HOUSE REPORT, *supra* note 11, at 9.

16. STUDY GROUP ON MEDICAL DEVICES, DEPARTMENT OF HEALTH, EDUCATION & WELFARE, MEDICAL DEVICES: A LEGISLATIVE PLAN (1970) [hereinafter COOPER COMMITTEE REPORT].

Report ultimately formed much of the basis for the 1976 Medical Device Amendments.

B. Divisions Among Devices

The FDCA's comprehensive definition of "device"¹⁷ applies to a vast array of medical products—"from bedpans to brainscans."¹⁸ The definition's catch-all quality covers virtually any product for which a claim of usefulness in promoting health or preventing or curing illness is advanced, except for products regulated as drugs due to their chemical or metabolic mode of action. Health concerns raised by these thousands of products range from nonexistent to critical. On the Cooper Committee's recommendation,¹⁹ Congress attempted to craft the law to provide for regulatory controls of differing stringency, depending on the degree of risk or need for proof of effectiveness characteristic of each type of medical device.

The major substantive objectives of the law were protection of public health through risk prevention and encouragement of technological innovation²⁰—goals that in many cases are mutually contradictory, since innovation often will involve risk. Secondary objectives of the law probably included avoidance of market disruption for products currently in use and marketing equity among product sellers.²¹

To achieve these objectives, Congress erected two sets of regulatory partitions among the legions of existing and future devices. The first divides all the realm of devices into three parts.²² Class I devices are those relatively simple products for which "general controls" relating to adulteration, misbranding, registration, premarket notification, good manufacturing practices, and reporting are deemed sufficient to provide reasonable assurance of safety and effectiveness.²³ Class II devices are those for which mandatory performance standards are to be established to provide such assurance.²⁴ Class III devices, the most risk-laden, are those needing "premarket approval"—a term of art designating an

17. Food, Drug, and Cosmetic Act (FDCA) § 201(h), 21 U.S.C. § 321(h) (1982).

18. FDA'S NEGLECTED CHILD, *supra* note 1, at 1.

19. COOPER COMMITTEE REPORT, *supra* note 16, at 11.

20. HOUSE REPORT, *supra* note 11, at 12.

21. See *infra* text accompanying notes 28 & 174.

22. FDCA § 513(a)(1).

23. The standard example of the Class I device is the tongue depressor. 21 C.F.R. § 880.6230 (1988). Other examples are the "burn sheet" in which burn victims are wrapped, *id.* § 880.5180, and the viscometer for cervical mucus to help determine the time of ovulation. *Id.* § 884.1040.

24. Illustrations of Class II devices are X-ray machines and paraphernalia, 21 C.F.R. § 892.1600-1770; bone-conduction hearing aids, *id.* § 874.3300(b)(2); and condoms, *id.* § 884.5300.

agency licensing process that may actually take place long after the product is introduced on the market.²⁵ The licensing process, conducted with public participation and subject to review on the record, requires the device's sponsor to prove the product's safety and effectiveness in a manner similar to that prescribed for new drugs.²⁶ This three-tier classification scheme was at the center of both the Cooper Committee recommendations and the congressional descriptions of the medical device law.²⁷

The second kind of partition, not suggested by the Cooper Committee Report and explained only briefly in the legislative history, has turned out to be far more important in FDA regulatory practice. This is the partition between "new" devices introduced after the date of enactment of the Amendments (May 28, 1976)—which are automatically placed in Class III and must go through the review and licensing process unless reclassified to Classes I or II—on the one side, and products on the market before enactment and (most significantly) their postenactment "substantial equivalents," on the other.²⁸ This second kind of partition was probably designed to avoid market disruptions by freeing those with an existing stake in the lightly regulated preenactment status quo from the application of various new regulatory strictures for a temporary grace period.²⁹ Moreover, apparently to provide marketing equity for prospective sellers of new-model "me-too" devices equivalent to (and competitive with) preamendment products, the new-but-equivalent devices were to be given a retroactive preamendment status, qualifying them also for lenient treatment by FDA during the grace period.³⁰

25. Examples of Class III products include implanted cardiac pacemakers. 21 C.F.R. § 870.3610 (1988); replacement heart valves, *id.* § 870.3925; intraocular lenses for implantation in cataract patients' eyes, *id.* § 886.3600; certain blood tests for cancer detection, *e.g.*, *id.* § 866.6010 (carcinoembryonic antigen test kits); and penile inflatable implants, *id.* § 876.3350.

26. See *infra* notes 43–44 and accompanying text; *but see* notes 72–76 and accompanying text.

27. See COOPER COMMITTEE REPORT, *supra* note 16, at 10–15; HOUSE REPORT, *supra* note 11, at 34–42.

28. FDCA § 513(f)(1). The phrase "'new' device" is found not in the statute but in the legislative history. See, *e.g.*, CONFERENCE REPORT, *supra* note 11, at 56; HOUSE REPORT, *supra* note 11, at 31, 36.

For a helpful table describing and giving examples of the various device categories—"new" or postenactment devices, preenactment devices, and substantial equivalents of the latter, as well as implanted, custom, investigational, and transitional devices, see Kessler, Pape & Sundwall, *The Federal Regulation of Medical Devices*, 317 NEW ENG. J. MED. 357, 358 (1987).

29. See *infra* note 174 and accompanying text.

30. For an explanation of the grace period, see *infra* text accompanying notes 187–91.

As explained below,³¹ FDA is extending the grace period for most preenactment Class III devices to the far horizon. The key regulatory question for most new-model devices,³² therefore, is whether FDA deems them "substantially equivalent" to a preamendment device and clears them for immediate marketing, or finds them to be "new" in the special statutory sense and requires them to go through the licensing process. In fact, through internal agency determinations, FDA has determined that the overwhelming majority of new-model products in Class III device types are substantially equivalent to preenactment products, rather than "new" in the statutory sense.³³ Thus the medical device law's variation on the traditional grandfather clause, as administered by FDA, has operated in a uniquely self-propagating way. Despite the congressional intent that new Class III devices undergo premarket licensing or reclassification in a publicly accountable fashion, most of these devices today receive marketing clearance through a private, unexplained and virtually unreviewable determination granting them quasi-grandfathered status for a period of indefinite duration.³⁴

C. The Premarket Approval Process for Class III Devices

1. Scope of the Premarket Approval Requirement

All Class III devices are required to undergo premarket approval.³⁵ A

31. See *infra* notes 252-63 and accompanying text.

32. The phrase "new-model device" is used in this article to denote any medical device that varies from previously marketed devices, regardless of whether the seller views it as a new model or as a minor modification of a marketed device. The phrase covers products incorporating significantly new technology or design, products with only minor variations from previously marketed products, and exact copies of a marketed product that are offered for sale by competing firms. The phrase is to be distinguished from the term of art "new" device," which (as explained in the text) is used in the legislative history to mean a new-model device not substantially equivalent to a device marketed before the enactment of the Medical Device Amendments.

33. See *infra* notes 266-68 and accompanying text. For an explanation of "device type," see *infra* note 36.

34. See *infra* notes 265-338 and accompanying text.

35. This requirement is established in FDCA sections 513(a)(1)(C), 515(a) and 515(b). The first of these provisions states that a device that meets the statutory tests for Class III "is to be subject, in accordance with section 515, to premarket approval to provide reasonable assurance of its safety and effectiveness." Section 515(a) states that a Class III device that is subject to a section 515(b) regulation calling for safety and effectiveness data, or is a "new" (i.e., not substantially equivalent) device in the statutory sense, "is required to have . . . an approval under this section of an application for premarket approval," unless it falls under an investigational device exemption. Section 515(b), which applies to preamendment Class III devices and their postamendment substantial equivalents, states that the agency "shall by regulation . . . require that such device have an approval under this section of an application for premarket approval."

The absolute character of the premarket approval requirement for Class III devices is

device can attain Class III status in any of four ways. First, if it was marketed prior to enactment of the Medical Device Amendments, it could fall within a generic "type of device"³⁶ classified in Class III by notice-and-comment rulemaking following FDA's receipt of a recommendation by a nongovernment expert advisory panel.³⁷ Second, if the device is a new-model device first marketed after May 28, 1976, it could be found "substantially equivalent" to a preenactment device within a Class III device type.³⁸ Sponsors of devices within these two categories receive the benefit of the grace period mentioned above; FDA cannot require premarket approval for about two and a half years after final classification into Class III.³⁹ Third, if a device is a postenactment product found not substantially equivalent to a preenactment device—if it is "new" in the statutory sense—it is automatically in Class III and immediately subject to the premarket approval requirement, although its sponsor has an opportunity to request reclassification or to obtain an investigational device exemption.⁴⁰ Fourth, products regulated as drugs before enactment—so-called "transitional" devices such as bone cements, intraocular lenses, and soft contact lenses—are also automatically considered Class III devices requiring premarket approval, absent reclassification or an investigational device exemption.⁴¹

Congress envisioned the premarket approval process as the primary mechanism for premarket clearance of Class III devices, as even leading

emphasized in the legislative history. See, e.g., HOUSE REPORT, *supra* note 11, at 30–31.

36. A "generic type of device" is "a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness." 21 C.F.R. § 860.3(i) (1988).

For example, all electroshock machines marketed before enactment of the device law, whatever their design or construction, fall within the "type of device" called "electroconvulsive therapy devices" and are currently classified in Class III. *Id.* § 882.5940. By contrast, contact lenses are divided into three "types of device": soft (hydrophilic) contact lenses, rigid gas permeable (RGP) contact lenses, and polymethylmethacrylate (PMMA, or "hard") contact lenses. As of this writing, the first two types of device are regulated in Class III. *Id.* §§ 886.5925 (soft), 886.5916 (RGP), whereas FDA has postponed the final classification of "hard" lenses. Ophthalmic Devices, 52 Fed. Reg. 33,346, 33,347 (1987).

The terms "type of device," "generic type of device," and "device type" are used interchangeably in this Article.

37. FDCA § 513(b)-(d). A type of device initially placed in Class II could also be moved to Class III following reclassification proceedings. *Id.* § 513(e).

38. See *infra* notes 151–70 and accompanying text.

39. *Id.* §§ 501(f)(2)(B), 515(a)(1). (b); see *infra* text accompanying notes 187–91.

40. *Id.* §§ 513(f)(1), 515(a)(2). If a "new" device is reclassified to Class I or II, other postamendment devices found substantially equivalent to that device receive the same classification and avoid the premarket approval requirement. *Id.* § 513(f)(1)(A)(i)(II), (ii).

41. *Id.* § 520(1).

attorneys for the industry have acknowledged.⁴² This process bears considerable similarity to that for review of new drug applications.⁴³ However, as a close examination of the structure of the device law demonstrates, Congress tailored the process to respond to scientific concerns specific to devices, and to ensure public accountability of agency decision-making in a more explicit fashion than is provided for in the drug law.

2. *Premarket Approval and Public Accountability*

As is the case with firms seeking marketing clearance for new drugs, persons seeking premarket approval of a device must submit applications containing full reports on investigations—both laboratory studies and clinical investigations involving human subjects—concerning: the device's safety and effectiveness; a description of the device, its principles of operation, and the methods used in its production; proposed labeling for the device, which would prescribe its licensed conditions for use; and other information required by the Agency.⁴⁴ As in the drug law, the device's sponsor bears the burden of demonstrating its safety and effectiveness, although the standard of proof differs from that applied to new drugs.⁴⁵

Upon receipt of a premarket approval application containing all required information, FDA must refer the application to an advisory panel for scrutiny.⁴⁶ This is the first element of public accountability that Congress built into the premarket review process. The advisory panel is composed of nongovernment experts "in such fields as clinical and administrative medicine, engineering, biological and physical sciences, and other related professions."⁴⁷ It also has nonvoting consumer and industry representatives.⁴⁸ A panel is required to review each premarket approval application and to submit to the Agency a report and recommendation for approval, approval with conditions, or disapproval, giving reasons for its conclusions.⁴⁹ While the panel recommendations are not

42. *E.g.*, Cooper, *Clinical Data under Section 510(k)*, 42 FOOD DRUG COSM. L.J. 192, 193 & n.8 (1987); Kahan, *Medical Device Reclassification: The Evolution of FDA Policy*, 42 FOOD DRUG COSM. L.J. 288, 288 (1987).

43. *See* FDCA § 505.

44. *Id.* § 515(c)(1); 21 C.F.R. § 814.20 (1988).

45. *See infra* notes 78–82 and accompanying text.

46. FDCA § 515(c)(2).

47. *Id.* § 513(b)(2).

48. Panel members are nominated by scientific, trade, and consumer organizations. *Id.*

49. *Id.* § 515(c)(2).

binding on the Agency, in general they have been remarkably influential.⁵⁰

Panel meetings are conducted primarily in open session, in accordance with the Federal Advisory Committee Act.⁵¹ Spurred by a House committee report critical of FDA for improper closure of advisory committee meetings,⁵² Congress also decided, over the opposition of the Department of Health, Education and Welfare,⁵³ to require that transcripts of advisory panel meetings be made available to the public after deletion of any trade secret or confidential commercial information.⁵⁴

The requirement of advisory panel review, hotly debated in the Congress,⁵⁵ was an innovation not previously incorporated into federal premarket clearance statutes such as the drug law.⁵⁶ In providing for participation by nongovernment experts in medical device licensing decisions,⁵⁷ in making such participation mandatory rather than discretionary, and in requiring that panel meetings be conducted primarily in public and that participants' remarks be transcribed, Congress made clear its commitment to the principle of agency accountability to the

50. See *infra* notes 346-49 and accompanying text.

51. 5 U.S.C. app. 1-15 (1982). Meetings are closed only for discussion of trade secret matters such as manufacturing techniques. Discussions of clinical data on human subjects are ordinarily conducted in open session. See 21 C.F.R. § 14.27 (1988).

52. HOUSE COMM. ON GOVERNMENT OPERATIONS, USE OF ADVISORY COMMITTEES BY THE FOOD AND DRUG ADMINISTRATION, H.R. REP. NO. 787, 94th Cong., 2d Sess. (1976); *Use of Advisory Committees by the Food and Drug Administration: Hearings Before a Subcomm. of the House Comm. on Government Operations*, 93d Cong., 2d Sess., pt. 1, 94th Cong., 1st Sess., pts. 2-3 (1974-75). Young, *Recent Developments Under FOIA and FACA Directly Affecting the Pharmaceutical Industry*, 31 FOOD DRUG COSM. L.J. 507, 508-09 (1976).

53. See 122 CONG. REC. 5854 (1976)(HEW analysis of H.R. 11,124)(statement of HEW Undersec'y Lynch).

54. FDCA § 520(i).

55. The major opponents of advisory panel review were the consumer groups, which feared excessive industry influence over the panels. See Patton, *Consumer Protection and the Medical Device Amendments: Assessing the Gains*, 9 ENVTL. L. 519, 548-51 (1979). As one leading scholar with an industry background observed, "it is well to remember that industry chose the advisory panel process." O'Reilly, *Reading the Tea Leaves: The Past and Future of FDA's Medical Device Advisory Committees*, 35 FOOD DRUG COSM. L.J. 604, 616 (1980).

56. See O'Reilly, *supra* note 55, at 609. Expert drug panels, though not expressly authorized in the drug regulatory provisions of the FDCA, had been used as a matter of agency discretion. The practice had been upheld by the courts. See, e.g., *Weinberger v. Hynson, Wescott & Dunning, Inc.*, 412 U.S. 609, 614-15 (1973); *Weinberger v. Bentex Pharmaceuticals*, 412 U.S. 645, 647-49 (1973).

57. The advisory panels' initial task was to recommend classification of each type of device into Class I, II or III. FDCA § 513(b)-(c). The panels' additional duty of providing recommendations on premarket approval applications became their central responsibility once the classification process was completed. *Id.* § 515.

scientific community and to the public at large in premarket review proceedings.⁵⁸

After consideration of a premarket approval application and of the panel's recommendations, FDA issues an order approving the application or denying it because of one or more statutorily specified inadequacies.⁵⁹ An approval order may impose postapproval requirements such as: restrictions on the sale, distribution, or use of the device;⁶⁰ continuing evaluation of, and periodic reporting on, the device's safety and effectiveness;⁶¹ and information and warnings to patients or physicians in the labeling or advertising of the product.⁶² Both denials and approvals may be administratively contested—denials by the applicant or by any others who can show standing,⁶³ and approvals by "any interested person."⁶⁴

Further embedding the public accountability principle in the statutory structure, Congress required the Agency to issue, at the time of its approval or denial order, a detailed summary of the safety and

58. The House Committee Report stated:

[I]t is important that the Secretary of Health, Education, and Welfare have the benefit of the scientific knowledge and experience of national experts in implementing his authority under the proposed legislation. . . .

Thus, the proposed legislation requires the Secretary to establish panels of experts, organized according to medical and scientific specialties, to review medical devices on the market before the date of enactment and those intended for marketing in the future. . . . To encourage thorough and scientific evaluation on the parts of the panels as well as to facilitate review by the Secretary and oversight activities by the Congress and the general public, the proposed legislation requires each panel to maintain a transcript of its proceedings, from which proprietary information would be deleted prior to disclosure to the public.

HOUSE REPORT, *supra* note 11, at 39. See also Rogers, *Medical Device Law—Intent and Implementation*, 36 FOOD DRUG COSM. L.J. 4 (1981). Former Congressman Rogers was chairman of the committee that drafted the law.

59. FDCA § 515(d)(1)-(2).

60. 21 C.F.R. § 814.44(e)(1)(iii); see FDCA §§ 515(d)(1)(B)(ii), 520(e)(1).

61. 21 C.F.R. §§ 814.82(a)(2), 814.84(b) (1988); *Premarket Approval of Medical Devices*, 51 Fed. Reg. 26,342, 26,359 (1986).

62. 21 C.F.R. § 814.82(a)(3) (1988).

63. FDCA § 515(d)(3); 5 U.S.C. § 702.

64. FDCA § 515(d)(3). Parties requesting review of FDA orders must first exhaust either of two specified administrative review procedures, *id.* § 515(g), and then may seek judicial review of final agency decisions. *Id.* § 517(a).

The explicit statutory grant of standing to "any interested person" to administratively contest product approvals is another indication of the emphasis Congress placed on the axiom of agency accountability. No similar explicit grant is found in the drug law, although the agency in its drug regulations takes the position that "[a]n interested person is affected by, and thus has standing to obtain *judicial* review of final agency action." 21 C.F.R. § 10.45(d)(1)(ii) (1988) (*emphasis added*).

effectiveness information, including adverse health effects of the device, forming the basis for the order.⁶⁵ This provision was also without parallel in the other laws administered by FDA.⁶⁶

One function of this required data summary is to provide a basis for anyone disagreeing with the Agency's decision to mount an administrative challenge. Without the summary, as a practical matter, parties with reason to contest a device's approval—competitors of the sponsor firm, or perhaps medical or consumer groups with questions about the product's safety or effectiveness—would generally lack sufficient detailed knowledge about the premarket approval application to have a chance of successfully reversing or modifying the Agency's initial decision.⁶⁷ The detailed summary of safety and effectiveness data is thus designed, in part, to level the playing field a bit. Additionally, preparation of the formal summary should force the Agency to confront and attempt to resolve both technical and science policy questions⁶⁸ raised in the marketing application, generating a fuller record for subsequent administrative or judicial scrutiny. The requirement of a summary of safety and effectiveness information thus gives practical meaning to the

65. FDCA § 520(h)(1).

66. The agency had adopted by regulation a similar system for new drug approvals, although not compelled to do so by the drug law. 21 C.F.R. § 314.14 (1976).

67. The section 520(h) summary is not the only source of public information on a device's safety and effectiveness. In addition to reviewing medical and scientific literature, one may obtain some types of agency-held information about a device through Freedom of Information Act (FOIA) requests, even before the device is cleared for marketing. *See, e.g.,* Public Citizen Health Research Group v. FDA, 704 F.2d 1280 (D.C. Cir. 1983); 21 C.F.R. §§ 20.101 (administrative enforcement records), 20.113 (voluntary product defect reports), 20.82 (discretionary disclosure by the Commissioner) (1988). However, the length of time and the difficulty involved in obtaining such information through the FOIA generally would preclude its use in a proceeding contesting a product approval, unless FDA exercised its discretionary authority to disclose safety and effectiveness information prior to issuing an approval or denial order. 21 C.F.R. § 814.9(d) (1988).

68. *See generally* Weinberg, *Science and Trans-Science*, 10 MINERVA 209 (1972) (developing concept of "trans-scientific" public policy problems); McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 GEO. L.J. 729 (1979) (same).

One example of how the preparation of a formal summary of safety and effectiveness data for a medical device can advance discussion of public policy issues is the controversy over FDA's licensing in 1979 of three gonorrhea screening kits for women, without releasing such a summary. The Health Research Group, a consumer advocacy organization, successfully petitioned the agency to release the relevant safety and effectiveness data, and used the data as part of its administrative challenge to the Agency's approval decisions on the ground that the tests' high false positive and false negative rates would endanger users' health and waste money. FDA Docket No. 80P-0234/CP; *see Health Group Wants VD Test Kits Withdrawn*, Wash. Post, June 6, 1980, at D1, col. 3. After an administrative hearing, FDA denied the consumer group's petition to withdraw approval of the products, but revised the products' labeling to reflect the group's concerns about providing comprehensible medical information to the public. *See Gonorrhea Antibody Test Kits*, 48 Fed. Reg. 335 (1983).

statutory right to review of Agency action.

Of at least equal importance, the summaries of safety and effectiveness information about approved devices can aid purchasing decisions by hospitals, laboratories, professionals, and individual consumers. FDA-certified comparative safety and effectiveness records are important selling points for marketed products. The summaries can also form a starting point for congressional oversight and media scrutiny of FDA decisions permitting questionable products to go on the market or denying approval to meritorious devices. Hence the congressional charge to FDA to prepare formal safety and effectiveness data summaries serves as a deterrent to ill-considered Agency action.

The legislative history of the Medical Device Amendments makes it evident that Congress placed great emphasis on the importance of the safety and effectiveness summary requirement. The House Committee Report stated:

The Committee recognizes that the best interests of government, industry and the public are served by proper public scrutiny of actions of the Food and Drug Administration. Public scrutiny of the implementation of this legislation would normally be difficult, since some decisions with respect to class III devices will be based upon trade secret information.

For this reason, the Committee has included a provision (new section 520(h) of the Act) which would require the Secretary to promulgate regulations under which a detailed summary of information respecting the safety and effectiveness of a device, which was the basis for *major decisions* made by him with respect to such a device, be released to the public. Such summaries are required to include information respecting any adverse effects of the device on health.

....
In the Committee's view, this provision, coupled with requirements that the proceedings of advisory panels and committees be transcribed and requirements that classification panels and the Secretary set forth reasons for recommendations and decisions, will help assure effective public scrutiny and Congressional oversight.⁶⁹

69. HOUSE REPORT. *supra* note 11, at 51 (emphasis added).

Since the law as enacted was very similar to the House-passed bill, the House Committee Report as a whole should be given considerable weight in interpreting congressional intent. The Conference Report noted that "[b]ecause a more extensive legislative history accompanied the House amendment, the conferees agreed to use the House amendment as the basis for the conference substitute with changes to reflect certain policies embodied in the Senate bill. Thus, except as specifically set forth below [in the Conference Report], the

This history makes clear that the Act's premarket clearance system hinges on faithful implementation of the public accountability principle, and that realization of that principle depends in large part on FDA's carrying out its section 520(h) responsibility to prepare detailed summaries of safety and effectiveness information supporting the Agency's decisions to clear new Class III products for marketing.

In sum, the requirement that the Agency prepare summaries of the bases of its product licensing decisions constitutes a necessary aspect of the system designed by Congress for review of agency actions, an important source of information facilitating the proper functioning of the market, and a systematic, repeated test of agency performance by which FDA can win and maintain, or lose, the public's esteem and trust. It is an essential component of the statutory structure.

In these respects, the philosophy of the Medical Device Amendments of 1976 is of a piece with that of other health, environmental, and open government legislation of the period. These laws, passed by a Democratic Congress during Republican administrations and designed in large part to curb the social hazards of applied technology, provided for decision-making processes subjecting the executive branch to requirements of open proceedings, public participation, and explanation of the reasons underlying agency actions.⁷⁰ Unfortunately, under current FDA

conference substitute conforms to the House amendment." CONFERENCE REPORT, *supra* note 11, at 51. The House Committee Report is of particular significance where, as in the case of section 520(h)(1), the language Congress enacted was identical to that voted out of committee.

Influential criticisms have been raised against the extensive use of legislative history as a source of meaningful information about congressional intent. See, e.g., R. DICKERSON, *THE INTERPRETATION AND APPLICATION OF STATUTES* 137-97 (1975); Starr, *Observations About the Use of Legislative History*, 1987 DUKE L.J. 371, 375-79. In many ways such criticisms are well taken, and this article draws primarily on the language and structure of the statute itself in its analysis of the legality of FDA's regulatory program. The House Committee Report and the Conference Committee Report, however, represent the most focused explanation of the Medical Device Amendments by the legislators and staff most familiar with the law's intricacies. Moreover, FDA interpretations of the law in Federal Register notices repeatedly and prominently feature the language of the two reports as the Agency's primary source of guidance. See, e.g., 51 Fed. Reg. 26,342, 26,352 (1986); 48 Fed. Reg. 40,272, 40,273 (1983); 42 Fed. Reg. 58,874, 58,875 (1977). Consequently, where the statute is ambiguous, reference to the two reports is appropriate. See, e.g., *General Medical Co. v. FDA*, 770 F.2d 214, 220-23 (D.C. Cir. 1985) (quoting HOUSE REPORT); *Contact Lens Mfrs. Ass'n v. FDA*, 766 F.2d 592, 599-601 & nn.7-8 (D.C. Cir. 1985) (quoting HOUSE REPORT), *cert. denied*, 474 U.S. 1062 (1986).

70. See, e.g., National Environmental Policy Act of 1969, 42 U.S.C. §§ 4321-47 (1982); Occupational Safety and Health Act of 1970, 29 U.S.C. §§ 651-78 (1982); Federal Advisory Committee Act of 1972, 5 U.S.C. app. 2 §§ 1-15 (1982); Clean Air Act of 1972, 42 U.S.C. §§ 7401-642 (1982 & Supp. V 1987); Freedom of Information Act Amendments of 1974, 5 U.S.C. § 552 (1982 & Supp. V 1987); Toxic Substances Control Act of 1976, 15 U.S.C. §§ 2601-29 (1982 & Supp. V 1987); Resource Conservation and Recovery Act of 1976, 42 U.S.C. §§ 6901-87 (1982).

practice, the vast majority of new-model Class III devices are marketed without advisory panel participation in marketing decisions, agency justification of those decisions, or provision of safety and effectiveness information to the medical community or the general public.⁷¹

3. *Other Significant Features of the Premarket Approval Process*

Congress devised the premarket approval regimen for devices with general reference to the new drug application process in the drug law. However, Congress recognized that the wide range of devices to which the premarket review process would apply might require different types of premarket studies and postmarketing controls than those to which the Agency was accustomed in its drug regulation activities. For this reason, the drafters of the device law departed from the drug law model by including several provisions that could accommodate a certain flexibility in premarket clearance while providing added postmarketing enforcement authority, as well as ensuring patient protection.

First, Congress employed language different from, and in some respects less strict than, the drug law in setting out the standard of review of effectiveness data to be applied in device marketing decisions.⁷² Second, the device law gives applicants an alternative method of bringing their new Class III devices to market—the product development protocol—not found in the drug law.⁷³ Third, the law allows sponsors of Class III devices various opportunities to avoid premarket testing requirements by petitioning for reclassification to Class I or II.⁷⁴ Fourth, Congress gave the Agency authority broader than that in the drug statute to restrict the sale, distribution, and use of devices after marketing.⁷⁵ Finally, the device law includes explicit protections for human subjects of device investigations that go beyond those in the drug law.⁷⁶

(a) *Standard of review for premarket approval applications*

A firm wishing to market a new drug must demonstrate in its application that the drug is safe and effective.⁷⁷ Effectiveness must be proven by “substantial evidence,” defined as “evidence consisting of adequate

71. See *infra* notes 266–68, 327–33 and accompanying text.

72. See *infra* notes 78–82 and accompanying text.

73. FDCA § 515(f). See *infra* notes 83–85 and accompanying text.

74. See *infra* notes 88–92 and accompanying text.

75. FDCA §§ 515(d)(1)(B)(ii), 520(e). See *infra* notes 94–103 and accompanying text.

76. Compare § 520(g) with § 505(i); see *infra* notes 104–08 and accompanying text. FDA has since incorporated human subject protections in its regulations in an across-the-board fashion. See 21 C.F.R. § 50 (1988).

77. FDCA § 505. The law does not distinguish between drugs and devices with respect to the standard for establishing a product’s safety.

and well-controlled investigations, including clinical investigations, by [qualified] experts."⁷⁸

In contrast, the term "substantial evidence" is not found in the provisions concerning premarket review of devices. Rather, the standard of proof is "reasonable assurance of . . . safety and effectiveness."⁷⁹ Determination of effectiveness in the device law is to be made under either of two standards. The apparently preferred standard requires the applicant to submit "well-controlled investigations, including clinical investigations *where appropriate*, by [qualified] experts."⁸⁰ However, unlike a drug applicant, a device applicant that chooses not to (or cannot) submit well-controlled investigations may still obtain a finding of effectiveness, if the Agency makes a determination that sufficient "valid scientific evidence" exists to permit qualified experts to arrive at such a finding.⁸¹

The contrasting language of the drug and device laws raises two inferences. First, under some circumstances, a device investigation may be deemed "well-controlled" even though it does not include a clinical study (i.e., a study on humans). Second, some sorts of evidence, insufficient to establish the existence of a "well-controlled investigation," may be of sufficient scientific validity to support a finding of device (if not drug) effectiveness.⁸² Congress apparently considered that placing the burden of conducting clinical trials with the full rigor of drug trials on sponsors of new devices would, in some cases, have the effect of retarding innovation, and would thereby defeat one of the major

78. *Id.* § 505(d).

79. *Id.* § 513(a)(1)(C); *see also id.* § 515(d)(2)(A)-(B).

80. *Id.* § 513(a)(3)(A) (emphasis added).

81. *Id.* § 513(a)(3)(B).

82. The legislative history offers the following explanation:

Devices vary widely in type and in mode of operation, as well as in the scope of testing and experience they have received. Thus, the Committee has authorized the Secretary to accept meaningful data developed under procedures less rigorous than well-controlled investigations in instances in which well-documented case histories assure protection of the public health or in instances in which well-controlled investigations would present undue risks to subjects or patients. However, this provision is not intended to authorize approval on the basis of anecdotal medical experience with a device or unsubstantiated opinion as proof of effectiveness.

HOUSE REPORT, *supra* note 11, at 17.

FDA proceeded to define "valid scientific evidence" to include not only well-controlled studies, but also studies that are partially controlled or that lack matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device. "Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness," but such evidence may be considered in identifying devices of questionable safety or effectiveness. 21 C.F.R. § 860.7(c)(2) (1988).

objectives of the law. Therefore, Congress deliberately crafted an alternate standard for device approval, one designed to assure scientifically credible data and patient protection, but at less cost to device manufacturers. The public scrutiny built into the premarket review process was to operate as a check on any abuse of the new standard.

(b) *Product development protocols*

Congress also constructed another route to product licensing for sponsors of new Class III devices: the product development protocol. This seldom-used procedure, which operates as a substitute for the standard premarket approval procedure, merges the investigational and premarket approval stages of product development into one. The procedure involves submitting to FDA a plan for developing safety and effectiveness information on a new device, together with a specification of the results expected to be attained from the investigation. If the Agency, after obtaining an advisory panel's recommendation, approves the protocol, then all that is necessary to obtain a license (the equivalent of a premarket approval) is satisfactory completion of the protocol.⁸³

The purpose of this provision, which has no counterpart in the drug law, was described in the House Committee Report as to assist "the rapid development of innovative devices because [the procedure] should be less expensive than the conventional two-step investigation and premarket approval procedure."⁸⁴ As with premarket approval orders, orders licensing a device on the basis of a completed product development protocol must be accompanied by a detailed public summary of safety and effectiveness information.⁸⁵ Congress viewed the product development protocol as especially likely to assist innovative small device firms.⁸⁶ In fact, however, the procedure has seldom been attempted.⁸⁷ Despite its lack of current practical importance, the product development protocol provision, like the provision easing the standard of proof of effectiveness, does indicate Congress' willingness to smooth the premarket review process for devices, subject always to the test of public accountability.

(c) *Reclassification*

Congress was conscious that the premarket testing process for licensing Class III devices could involve significant costs, that the issuance of private licenses could have the effect of restricting competition, and that premarket testing might no longer be necessary as a once-new device technology reached maturity. The device law therefore provides, in no

83. FDCA § 515(f).

84. HOUSE REPORT, *supra* note 11, at 33.

85. FDCA § 520(h)(1)(B).

86. HOUSE REPORT, *supra* note 11, at 33.

87. See 1988 GAO REPORT, *supra* note 4, at 36 n. 11.

fewer than four separate places, opportunities for firms to request reclassification of their Class III products into a less stringent category.⁸⁸ Reclassification petitions can be submitted for preamendment devices or their postamendment substantial equivalents at any time,⁸⁹ and in particular before FDA can call for premarket approval applications for these devices.⁹⁰ Petitions can also be submitted for devices that are "new" in the statutory sense (i.e., not substantially equivalent to a preamendment device),⁹¹ and for transitional devices that had previously been regulated as drugs.⁹²

FDA must consult with the appropriate advisory panel before rendering a decision on three of the four types of reclassification requests; the fourth type of reclassification is subject to notice-and-comment rulemaking.⁹³ The reclassification provisions thus adhere to the general philosophy of the Amendments that the premarket clearance process not be overly burdensome, but that decisions relating to that process be subject to public scrutiny.

(d) *Restricted devices*

The device law permits FDA to restrict the sale, distribution, or use of a device — either to prescription use, as authorized by the drug law,⁹⁴ or "upon such other conditions as the Secretary may prescribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness."⁹⁵ This power, far broader than any granted the Agency in the drug law, was aimed at authorizing controls over sophisticated or potentially hazardous devices that, in the right hands, would provide public benefits outweighing their risks but that should not be used by those with inadequate training or experience, or in improper health care settings. Some products could be restricted to use in hospital or clinic settings, for example, or to use by trained nurses and technicians rather than lay persons.⁹⁶ Other devices, perhaps those employing particularly sophisticated technology, could be restricted to use by physicians with special training in

88. See generally Kahan, *supra* note 42.

89. FDCA § 513(e).

90. *Id.* § 515(b)(2)(B).

91. *Id.* § 513(f)(2)(A).

92. *Id.* § 520(l)(2). A manufacturer of a Class II product can also seek reclassification if FDA commences a proceeding to develop a performance standard. *Id.* § 514(b).

93. Consultation with an advisory panel is discretionary for section 513(e) petitions for reclassification of a preamendment device or postamendment substantial equivalent. Consultation is required for reclassification pursuant to sections 513(b)(2), 515(b)(2)(B), and 520(l)(2).

94. *Id.* § 503(b).

95. *Id.* § 520(e)(1).

96. See HOUSE REPORT, *supra* note 11, at 24–25.

the application of that technology.⁹⁷

Restrictions on the sale, distribution, or use of a device can be implemented in any of three ways. First, restrictions on a Class III device can be imposed by order, as a condition of premarket approval.⁹⁸ Second, restrictions can be imposed by regulation on Class II or III devices as part of a mandatory performance standard.⁹⁹ Finally, restrictions can be imposed by regulation on devices of any class after notice-and-comment rulemaking.¹⁰⁰ The premarket approval order permits FDA to implement restrictions on a product-by-product basis, while the latter two methods enable FDA to impose across-the-board restrictions for all products within a given type of device.¹⁰¹

These remarkable departures from the drug law were prompted by reports of widespread user errors cited by the Cooper Committee and in hearings on the device amendments, and by FDA's perception of the inadequacy of regulatory controls in the drug law.¹⁰² Inclusion of the restricted device provisions evinced Congress' expectation that, although FDA would facilitate the availability of innovative devices, it would concomitantly act to restrain the uncontrolled marketing of certain complex or potentially hazardous devices in circumstances where, if improperly

97. If the sale, distribution or use of such devices is restricted to physicians whose training or experience satisfies particular criteria, those criteria may not be based solely on physicians' certification or eligibility for certification by a medical specialty board. FDCA § 520(e). See CONFERENCE REPORT, *supra* note 11, at 61-62; 122 CONG. REC. 13,778 (1976) (remarks of Rep. Carter). The Conference Committee rejected language in the House-passed bill that would have prohibited any restrictions based on physicians' training or experience. see H.R. 11,124, 94th Cong., 2d Sess. § 520(e)(1)(B), after considering the strong objections of the Department of Health, Education and Welfare that the House bill "will seriously undermine the Agency's ability to reduce public exposure to medical devices that may be unsafe in the hands of practitioners who lack the training or experience to use them." 122 CONG. REC. 5854 (1976) (HEW analysis). See also S. REP. NO. 33, 94th Cong., 2d Sess. 13, reprinted in 1976 U.S. CODE CONG. & ADMIN. NEWS 1070, 1082 (contemplating restriction of devices to use by "eminently qualified specialists") [hereinafter SENATE REPORT].

98. FDCA § 515(d)(1)(B)(ii). The scope of the restriction is limited to that of a restriction under a section 520(e) regulation.

99. *Id.* § 514(a)(2)(B)(v).

100. *Id.* § 520(e)(1); see *id.* § 513(a)(1)(A)(i), authorizing section 520(e) restrictions under general controls.

101. See Premarket Approval of Medical Devices, 51 Fed. Reg. 26,342, 26,359-60 (1986); *supra* note 36 (explanation of "type of device").

102. See, e.g., COOPER COMMITTEE REPORT, *supra* note 11, at 6; *Medical Device Amendments of 1975: Hearings Before the Subcomm. on Health & the Environment, House Comm. on Interstate & Foreign Commerce, 94th Cong., 1st Sess. 214-15 (1975)* (statement of Asst. Sec'y of Health T. Cooper); personal communication from former FDA Chief Counsel Richard Merrill, Sept. 6, 1988.

used, the products would lack utility or could endanger patients' health.¹⁰³

(e) *Investigational devices*

A final aspect of the legislation bearing on the premarket approval process is the provision governing studies of investigational devices involving human subjects.¹⁰⁴ All proposals for such studies are required to be submitted both to FDA (in at least summary form) and to a local institutional review board (unless no adequate board exists) before the studies may proceed.¹⁰⁵ The purpose of the provision is two-fold: to encourage the discovery and development of useful devices, and to protect patients' safety and rights through informed consent requirements and institutional review board scrutiny of the clinical protocol.¹⁰⁶ The language is far stronger and more comprehensive than that found in the analogous provision of the drug law,¹⁰⁷ although by the time of the device law's enactment, the Agency had promulgated investigational drug regulations containing most of the protections embodied in the device law.¹⁰⁸

D. Controls for Non-Class III Devices

The discussion has concentrated thus far on premarket clearance of Class III devices—those for which the most stringent regulatory controls, akin to those applied to new drugs, are necessary. While these devices (such as cardiac pacemakers, artificial hearts, test kits signalling the likely presence of cancer, intraocular lenses, and soft contact lenses) are perhaps most often in the public eye,¹⁰⁹ Class III devices constitute

103. A further point of regulatory significance concerning restriction of devices is that FDA has jurisdiction over the regulation of the truthfulness of device advertisements only with regard to devices that it has restricted. FDCA § 502(q)-(r). The Federal Trade Commission, in the past few years not the most alert of watchdogs, stands sentinel over the advertising of other devices. This scheme is a carryover from the jurisdictional division in the drug law over advertising, whereby FDA reviews the truth of prescription drug ads while the Federal Trade Commission regulates over-the-counter drug ads. *Id.* § 502(n).

104. *Id.* § 520(g). Such studies are often conducted specifically to support premarket approval applications. However, these studies may also be conducted for devices that do not require premarket approval, or for purposes other than developing data to support commercial distribution.

105. *Id.* § 520(g)(2)(B)(i), (3)(A)-(B).

106. *Id.* § 520(g)(1); HOUSE REPORT, *supra* note 11, at 42-44.

107. Compare FDCA § 520(g) with § 505(i).

108. See 21 C.F.R. § 312 (1976).

109. For a truly reprehensible series of medical device puns, see the first two paragraphs of Judge McGowan's opinion in *General Medical Co. v. FDA*, 770 F.2d 214, 216 (D.C. Cir. 1985) (antiperspirant device).

but a small fraction of the devices regulated by FDA.¹¹⁰ Congress directed the Agency to impose lighter regulatory strictures, not including premarket review, on devices in Classes I and II.

1. General Controls

Class I devices are subject only to the general controls applicable to all devices.¹¹¹ In addition to the longstanding prohibitions against adulteration and misbranding,¹¹² these controls include registration of device manufacturers;¹¹³ notification to FDA of intent to market;¹¹⁴ good manufacturing practices;¹¹⁵ recordkeeping;¹¹⁶ and reporting.¹¹⁷ The Agency may by special action implement other general controls—restrictions on sale, distribution or use;¹¹⁸ public notification of risks;¹¹⁹ requirements for repair, replacement or refund;¹²⁰ and banning of hazardous or deceptive devices¹²¹—though these additional controls likely would seldom be required for Class I products. Congress further authorized FDA to exempt Class I devices from registration, good manufacturing practice, recordkeeping and reporting requirements unnecessary for protection of public health.¹²²

Among the most important of the general controls, as a practical matter, are those relating to good manufacturing practices (“GMP’s”). This is so because FDA inspectors are trained and directed to look for violations of GMP regulations or orders, and detection of such violations renders a device “adulterated” and therefore subject to enforcement action.¹²³ Despite the opposition of the Department of Health, Education and Welfare,¹²⁴ Congress built the concept of public accountability into the GMP provisions, establishing a special advisory committee composed primarily of representatives of industry, the health professions,

110. By the author’s count, only about nine percent of all types of device have been classified in Class III. See *infra* note 238.

111. FDCA § 513(a)(1).

112. *Id.* §§ 501–02.

113. *Id.* § 510(k).

114. *Id.*

115. *Id.* § 520(f).

116. *Id.*

117. *Id.* § 519.

118. *Id.* § 520(e).

119. *Id.* § 518(a).

120. *Id.* § 518(b)–(c).

121. *Id.* § 516.

122. See HOUSE REPORT, *supra* note 11, at 35, and provisions of the Act cited therein.

123. FDCA §§ 501(h), 301–04.

124. See 122 CONG. REC. 5854 (1976) (letter from HEW Undersec’y Lynch).

and the general public.¹²⁵ Congress required FDA to consult the advisory committee before promulgating regulations implementing the GMP provisions, and authorized such consultations before the Agency grants petitions for exemptions or variances from GMP requirements.¹²⁶

A second type of general control of critical practical importance is the law's authorization of recordkeeping and reporting rules for manufacturers, importers, and distributors.¹²⁷ The provision is designed to enable FDA to keep track of device-related deaths, injuries and adverse reactions, and product defects and recalls. The legislative history also suggests the appropriateness of postmarketing surveillance of Class III devices.¹²⁸

2. Performance Standards

Class II devices must adhere to performance standards when promulgated.¹²⁹ The law is unclear as to whether FDA is obligated to issue standards for all Class II devices. The provision defining Class II products seems to indicate that the Agency has no discretion in the matter,¹³⁰ but the section setting out the standards promulgation process is worded more flexibly.¹³¹ The ambiguity has little practical significance, however, since the statutory process for developing performance standards is so convoluted that few standards will ever be completed.¹³²

125. FDCA § 520(f)(3). See also HOUSE REPORT, *supra* note 11, at 25; SENATE REPORT, *supra* note 97, at 17.

126. FDCA § 520(f)(1)-(2). See *United States v. Bioclinical Systems*, 666 F. Supp. 82 (D. Md. 1987) (FDA failure to follow public review process for GMP).

127. FDCA § 519(a).

128. HOUSE REPORT, *supra* note 11, at 23. Unduly burdensome requirements are prohibited, and some parties (e.g., licensed practitioners, researchers, and, for some purposes, manufacturers of Class I devices) are exempted. FDCA § 519(a)(5)-(b).

129. FDCA § 501(e).

130. A Class II device is defined as one "which cannot be classified as a class I device because the [general] controls . . . by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, for which there is sufficient information to establish a performance standard to provide such assurance, and for which it is therefore *necessary* to establish for the device a performance standard under section 514 to provide reasonable assurance of its safety and effectiveness." *Id.* § 513(a)(1)(B) (emphasis added).

FDA has adopted the view that Class II designation requires the development of a mandatory standard. See 50 Fed. Reg. 43,060, 43,060 (1985).

131. Section 514 begins: "The Secretary *may* by regulation . . . establish a performance standard for a class II device." FDCA § 514(a)(1) (emphasis added).

132. The House Committee Report, giving somewhat tepid support to the view that the Agency is required to issue standards, recognized the likelihood of long delays. It states:

Devices classified into class II eventually will be required to conform to performance standards. . . . [T]he Committee recognizes that a considerable period of

The debacle of the peanut butter standard is famed as the quintessential regulatory nightmare, in which FDA was ensnared in procedural entanglements for twelve years before its regulation on the minimum peanut content of peanut butter finally emerged from the administrative and judicial process.¹³³ Drafters of the Medical Device Amendments may have taken perverse pleasure in contriving a procedural maze that, if it is ever used, will make the peanut butter proceeding look straightforward by comparison.

As illustrated in the accompanying diagram, before a medical device standard can go into effect, FDA must go through the following process. (1) The Agency must provide an opportunity for interested parties to request reclassification of the device in question, and upon receiving such a request and (2) consulting with an advisory panel, FDA must either (3A) initiate a reclassification proceeding or (3B) deny the request.¹³⁴ (4) If the device is not reclassified, FDA must invite submissions of existing standards or of offers to develop a standard.¹³⁵ (5A) FDA may accept an existing standard as a proposed mandatory standard;¹³⁶ or (5B) accept an offer to develop a standard,¹³⁷ after issuing regulations governing such offers.¹³⁸ (6) If the Agency decides not to accept an existing standard or an offer to develop a standard, or accepts one but later finds it unsatisfactory, it must publish a notice of its reasons.¹³⁹ (7) If it does so, FDA may develop a standard itself.¹⁴⁰ (8) Public participation is required in the development of standards by offerors¹⁴¹ or by FDA.¹⁴² (9) The Agency then publishes the standard, however developed, as a proposed regulation.¹⁴³ (10) The Agency may then refer the proposed standard to an expert advisory committee, with

time may elapse between classification of a device into class II and development of a performance standard for it.

HOUSE REPORT, *supra* note 11, at 26-27.

133. *See, e.g.*, 15 WEEKLY COMP. OF PRES. DOC. 482, 484 (March 25, 1979) (remarks of President Carter); J. GOULDEN, *THE SUPERLAWYERS* 185-89 (1972); Note, *FDA Rule-Making Hearings: A Way out of the Peanut Butter Quagmire*, 40 GEO. WASH. L. REV. 726 (1972).

134. FDCA § 514(b).

135. *Id.* § 514(c)(1)-(2).

136. *Id.* § 514(d)(1).

137. *Id.* § 514(e)(1).

138. *Id.* § 514(c)(3), (e)(4).

139. *Id.* § 514(d)(2), (e)(5), (f)(3).

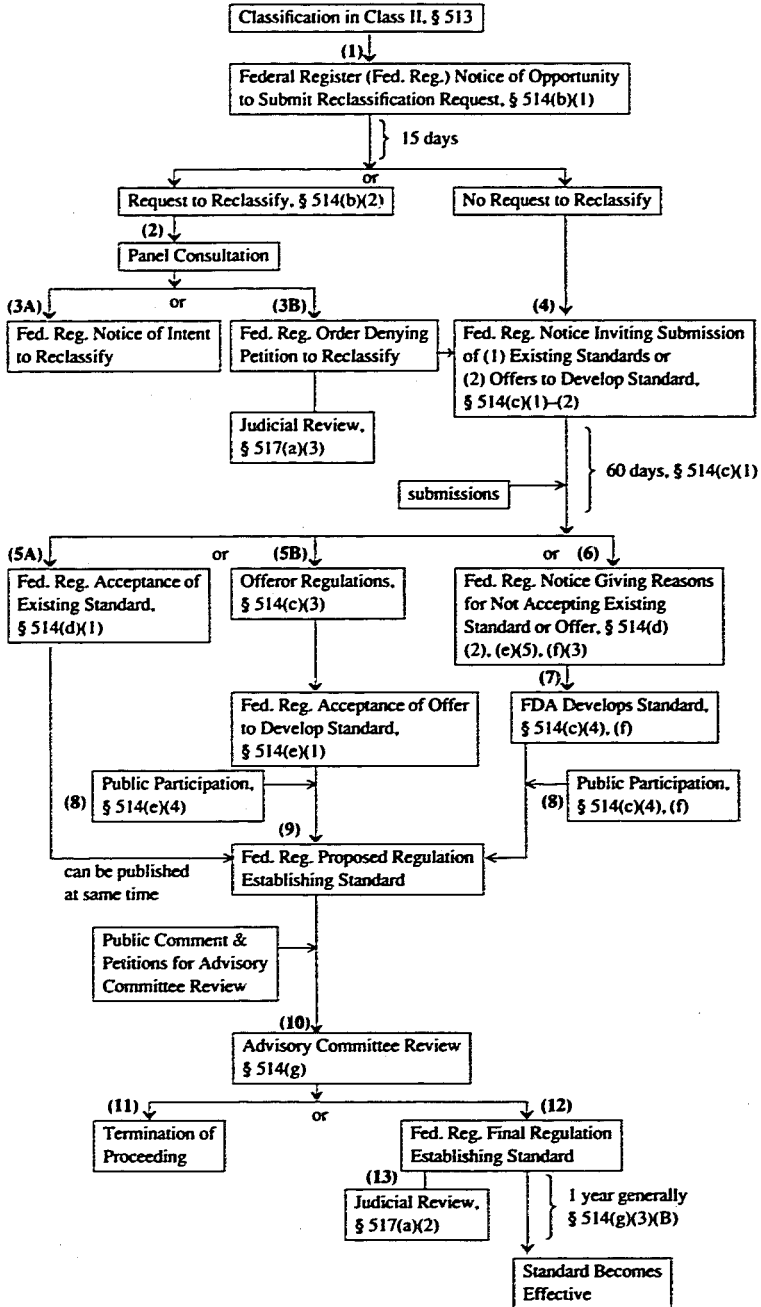
140. *Id.* § 514(f).

141. *Id.* § 514(e)(4)(B).

142. *Id.* § 514(c)(4), (f).

143. *Id.* § 514(g)(1).

STANDARD-SETTING PROCEDURES FOR CLASS II DEVICES



Adapted from Campbell, The 1976 Medical Device Amendments and the 510(k) Process (unpublished, 1983).

nonvoting consumer and industry representatives.¹⁴⁴ (11) At any time during the process, the Agency may terminate the proceeding.¹⁴⁵ (12) After receiving public comments and the advisory committee's report, if any, the Agency issues a final standard.¹⁴⁶ (13) The standard is then subject to judicial review.¹⁴⁷

By constructing this regulatory labyrinth and filling it with procedural snares, Congress ensured that only the bravest or most foolhardy of regulators would ever venture therein, and then only at times of compelling necessity. In fact, in twelve years, the Agency has scarcely passed the outer portal of the maze.¹⁴⁸ The practical effect of enacting these provisions, as Congress apparently foresaw,¹⁴⁹ would be that most Class II devices would be subject only to general controls for a protracted period. During that interval, Class II would be a regulatory illusion. Consequently, the critical agency decision with respect to each device has nothing to do with performance standards but focuses instead on whether the device should be subject to the premarket clearance process mandated for Class III products.¹⁵⁰

E. Premarket Notification and "Substantial Equivalence"

For each new-model device that a manufacturer wishes to bring to market, other than one that as a "transitional" device (i.e., one formerly regulated as a drug) is automatically and immediately subject to premarket approval requirements,¹⁵¹ the critical agency decision is the determination of whether the device is substantially equivalent to a preenactment device.¹⁵² FDA makes that determination in response to information submitted in the premarket notification required by section 510(k).¹⁵³ If the product is found substantially equivalent, even to a

144. *Id.* § 514(g)(5).

145. *Id.* § 514(g)(1)(A)(ii), (3)(A)(ii).

146. *Id.* § 514(g)(3).

147. *Id.* § 517(a)(2).

148. *See infra* notes 238-51 and accompanying text.

149. *See supra* note 132.

150. *See HOUSE REPORT, supra* note 11, at 35.

151. FDCA § 520(1).

152. *Id.* § 513(f)(1).

153. Section 510(k) requires each person desiring to market a medical device to report to the Secretary, at least 90 days before introducing the device for commercial distribution, "in such form and manner as the Secretary shall by regulation prescribe." (1) the class, if any, in which the device is classified under section 513 and (2) the action taken to comply with the requirements of section 514 or 515 (performance standards or premarket approval), if any, applicable to the device. FDA's regulations for section 510(k) submissions, 21 C.F.R. § 807.81-97 (1988), are discussed *infra* at notes 284-85 and accompanying text.

legally unproven preenactment Class III device.¹⁵⁴ FDA cannot later require the product to undergo the premarket approval process until such time as the Agency promulgates a regulation under section 515(b) requiring premarket approval for the device or for all products within its type of device.¹⁵⁵ A determination of substantial equivalence, then, though it does not connote FDA certification of the product's safety and effectiveness,¹⁵⁶ constitutes the Agency's provisional green light for marketing.

The overwhelming majority of new-model devices comes to market by this premarket notification route,¹⁵⁷ which one leading writer has termed "a relatively speedy and efficient procedure for premarket review and quasi-approval."¹⁵⁸ The process has become so routine that a new transitive verb has emerged in medical device regulatory parlance: "to five-ten-K" a device, meaning to obtain a substantial equivalence determination for a new-model product upon submission of a section 510(k) premarket notification. In view of its current importance, close attention to the role Congress envisioned for the premarket notification process is in order.

Section 510(k) simply requires firms to notify FDA at least ninety days before introducing a new-model device into commerce. The notification is to contain the class (if any) into which the device has been classified and the action taken in compliance with any applicable performance standards or premarket approval requirements.¹⁵⁹ Legislative history on the provision is sparse, but what little there is emphasizes an intent to prevent circumvention of the premarket approval process.¹⁶⁰

154. "Legally unproven" in this context signifies that the predicate preamendment device lacks a finding of safety and effectiveness through an approved premarket approval application.

155. FDCA §§ 501(f)(1)-(2), 513(f)(1), 515(a)-(b) (by implication). Though the law has no explicit language to this effect, the provisions listed operate together to make the conclusion drawn in the text inescapable. If FDA has not issued a section 515(b) regulation for the substantially equivalent device, the only other statutory basis for requiring premarket approval would be if the device were "a class III device because of section 513(f)." *Id.* § 515(a)(2); see *id.* § 501(f). But under section 513(f)(1)(A), the device's status as substantially equivalent exempts it from Class III.

156. 21 C.F.R. § 807.97 (1988).

157. See 1986 GAO REPORT, *supra* note 4, at 25; Kahan, *Premarket Approval Versus Premarket Notification: Different Routes to the Same Market*, 39 FOOD DRUG COSM. L.J. 510, 510 (1984); notes 265-68 *infra* and accompanying text.

158. Cooper, *supra* note 42, at 193.

159. See *supra* note 153.

160. The House Report explains:

The proposed bill contains provisions designed to insure that manufacturers do not intentionally or unintentionally circumvent the automatic classification of "new" devices. These provisions, included in amendments to section 510 of the Act, would require all persons to advise the Secretary ninety days before they intend to begin

The statute does not explicitly require FDA to make any determination about substantial equivalence in response to a premarket notification, nor indeed to take any action whatever. Presumably, FDA could adopt a policy of waiting until new-model products are introduced into commerce. The Agency could then commence selected enforcement actions on the ground that some products are not substantially equivalent to preamendment devices, and under sections 513(f) and 515(a) are therefore adulterated Class III devices because they lack the required premarket approvals.¹⁶¹ But to routinely rely on enforcement actions in federal courts to remove nonequivalent devices from the market after their introduction into commerce would be cumbersome, as well as contrary to the Medical Device Amendments' philosophy of prescreening Class III devices.

Consequently, the Agency has chosen to exercise its rule-making authority under sections 510(k) and 701(a) to require that firms intending to market new-model products provide, in their premarket notifications, data demonstrating the basis for the claimed equivalence.¹⁶² The Agency has put the industry on notice that failure to file an adequate premarket notification renders a firm's product subject to regulatory action if marketed.¹⁶³ If a firm introduces such a product into commerce without demonstrating equivalence to the Agency's satisfaction, FDA's regulatory arsenal contains not only the adulteration sanction noted above,¹⁶⁴ but also the standard misbranding sanctions¹⁶⁵ and the statutory prohibitions against failure to provide information required by section 510(k).¹⁶⁶

In view of the importance of the Agency's substantial equivalence determinations, it is surprising that the law itself provides no standards by which the determinations are to be made.¹⁶⁷ For aid in divining the

marketing a device as to whether the device has been classified under section 513. This provision will enable the Secretary to assure that "new" devices are not marketed until they comply with premarket approval requirements or are reclassified into class I or II.

HOUSE REPORT, *supra* note 11, at 37. The quotation marks around the word "new" do indicate recognition that new-model devices that are not "new" in the statutory sense — i.e., those substantially equivalent to preenactment devices — need not immediately go through premarket approval.

161. FDCA § 501(f)(1)(B).

162. 21 C.F.R. § 807.81-97 (1988).

163. See Establishment Registration and Premarket Notification Procedures, 42 Fed. Reg. 42,520, 42,524 (1977).

164. See *supra* note 161 and accompanying text.

165. E.g., FDCA § 502(f).

166. *Id.* §§ 301(p), 502(o).

167. The former FDA Chief Counsel, who was responsible for implementing sections 510(k) and 513(f), observed that "[s]ubstantial equivalence — like truth, beauty, love, and justice — is greatly desired, but also ultimately mysterious. Both the statute and FDA's regulations fail to define it." Cooper, *supra* note 42, at 194.

proper application of the substantial equivalence concept, one must look to the law's purposes as expressed in legislative history and to the structure of the statute.¹⁶⁸

The House Committee Report, in a roundabout way, explains the phrase's meaning as follows:

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 purposes as marketed products. The Committee believes that the term should be construed narrowly where necessary to assure the safety and effectiveness of a 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.¹⁶⁹

The last two sentences are the operative ones. The standard is whether the new-model product is shown to be at least as safe and effective as the predicate preamendment device. If the new-model product varies from a preenactment product in a way that could materially affect safety or effectiveness—presumably for the worse—then the product must be found not substantially equivalent and must go through premarket approval or reclassification. By necessary implication, for FDA to arrive at a substantial equivalence determination, the Agency must obtain sufficient information about both the new-model product and the old to enable it to perform the necessary comparative analysis in a responsible way. If the Agency lacks the requisite information, a finding of non-equivalence is required.¹⁷⁰

168. See, e.g., *INS v. Cardoza-Fonseca*, 107 S.Ct. 1207, 1220-22 (1987) (examining statute and legislative history to review agency interpretation of law).

169. HOUSE REPORT, *supra* note 11, at 36-37.

170. The Senate Committee Report also casts light on the intended operation of the premarket notification and substantial equivalence provisions. Regarding the former, the Report states:

The Committee believes that a manufacturer who thinks he has developed a

This focus on comparative safety and effectiveness seems reasonably consistent with the fundamental structure of the statute, as long as the temporary character of the substantial equivalence determination is kept firmly in mind. The primary purpose of the legislation is "to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety and effectiveness of medical devices."¹⁷¹ Ascertaining that newly marketed products are at least no less safe or effective than those sold before the Act was passed places the Agency and the public in a holding pattern of sorts, until the provision requiring premarket approval of all Class III devices¹⁷² "to provide a reasonable assurance of [their] safety and effectiveness"¹⁷³ can be fully implemented. As a stop-gap measure, FDA's employment of the premarket notification requirement as a screening process for new-model devices appears justified.

The substantial equivalence determinations in the premarket

significantly new or modified medical device should have the opportunity to petition for a classification of that new device. Until such time as that new product is classified the manufacturer may not market the product. . . . This section (section 510(k) in the law as enacted) is simply intended to provide a mechanism whereby devices which are new or which significantly differ from those devices previously classified, can be brought to the attention of the Secretary for purposes of classification prior to marketing.

SENATE REPORT, *supra* note 97, at 11.

Explaining which devices would require full-scale scientific review prior to marketing and which could receive scientific review only "when this appears necessary in order to protect the public health," the Senate Committee quoted approvingly the cardiovascular devices advisory panel's distinction between critical devices "in a stage of rapid development" and devices whose "widespread clinical use may generally be considered safe and effective." Pacemakers and artificial heart valves, in the Committee's view, fell in the former category, so that premarket scientific review would be mandated for new-model devices of these types; monitoring devices used in intensive care units and other cardiac diagnostic devices currently in use fell in the category for which immediate scientific review would not be required. *Id.* at 15.

The effect of the Senate Committee's distinction between these two categories of devices corresponds to the law's ultimate categorization of new-model devices as either not substantially equivalent (and therefore immediately subject to premarket approval requirements) or substantially equivalent (and therefore permitted to be marketed until FDA issues a section 515(b) call for premarket approval applications). Therefore it is proper to look to this part of the Senate Committee Report for assistance in ascertaining the meaning of the premarket notification and substantial equivalence provisions of the law.

The Senate Committee's focus on the "need [for] premarket clearance in order to insure [the] safety and efficacy" of types of device undergoing rapid development is consistent with an interpretation of substantial equivalence as requiring a demonstration that product changes do not adversely affect safety and effectiveness when the new-model product is compared with the old. Following this reasoning, failure to supply FDA with information sufficient for the Agency to perform a safety and effectiveness comparison between the two products should trigger the requirement of premarket approval.

171. CONFERENCE REPORT, *supra* note 11, at 1, 51.

172. FDCA § 515(b)(1).

173. *Id.* § 513(a)(1)(C).

notification process serve a second, though incidental, function: affording marketing equity between sellers of preamendment products and their would-be postamendment competitors. Firms that had established their market position before enactment could unduly entrench themselves against potential competition if FDA subjected subsequent sponsors of "me-too" devices to significantly greater regulatory burdens than those imposed on sellers of preenactment products. To the extent that the promotion of competition is accepted as a goal of the medical device law,¹⁷⁴ a temporary facilitation of market entry by lowering premarket clearance standards may be a reasonable policy.

The rationale for this policy diminishes over time, however. As new firms enter the market, become established, and strengthen their research and product marketing capabilities, special measures to promote competition should no longer be necessary. Sponsors of new-model devices should have less need of policies promoting marketing equity with preamendment devices because cumulative product variations increasingly remove new-model devices from direct competition with their preamendment predecessors.

Congress gave its attention to the problem of barriers to market entry by decreasing the burden of proof of device effectiveness as compared with the drug law, by establishing the product development protocol as a shortcut to a marketing license, and by providing for reclassification to a regulatory status not requiring premarket approval.¹⁷⁵ The Agency's venturing beyond the congressional mandate, by adopting a long-term substantial-equivalence-based premarket review policy in order to further lower barriers to entry, can no longer be justified on the ground of encouraging competition. The congressional purpose of establishing regulatory standards providing reasonable assurance of safety and effectiveness for all medical devices eventually must be given primacy.

Excessively prolonging the practice of making substantial equivalence findings the primary gateway to the market would undermine the congressional mandate of the Medical Device Amendments in several ways. Most fundamentally, it would untenably postpone the law's requirement that all Class III devices go through the process

174. Neither the statute nor its legislative history mentions the promotion of competition as a statutory objective, commentators' intimations to the contrary notwithstanding. See, e.g., Kahan, *supra* note 157, at 514-15. Nevertheless, it is difficult to explain the substantial equivalence provisions in any other fashion. FDA has interpreted these provisions of the law as being responsive to the goal of competitive equity. See 1982 *FDA Oversight Hearing*, *supra* note 3, at 9 (statement of FDA Commissioner Hayes); FDA Center for Devices and Radiological Health, *Guidance on CDRH's Premarket Notification Review Program 1* (June 30, 1986). The Office of Technology Assessment, a research arm of Congress, has come to a similar conclusion. See *OTA REPORT*, *supra* note 4, at 104.

175. See *supra* notes 72-73, 78-92 and accompanying text.

required to provide a reasonable assurance of safety and effectiveness. A "no worse than 1976" marketing threshold ultimately must be deemed unacceptable: the safety and effectiveness of many preamendment products have never been demonstrated by valid scientific studies, and new-model products that are substantially equivalent to dross are likely to be dross themselves.¹⁷⁶

Moreover, the substantial equivalence review contains procedural infirmities that render it an unsatisfactory surrogate for the premarket approval system prescribed by Congress. First, substantial equivalence review is conducted entirely as an internal agency process, without public participation. FDA does not convene advisory committees to discuss substantial equivalence determinations: there is no public record of any debate over the matter. Second, unlike premarket approvals or denials, substantial equivalence determinations are not accompanied by summaries of safety and effectiveness data.¹⁷⁷ No FDA-approved information about the product's performance typically is released, so would-be buyers may have little reliable basis for their purchasing decisions. Since the Agency provides no reasons for its determinations, neither Congress nor the public has a means of assessing the propriety of the Agency's actions.

Finally, there is no practical method for a member of the public or a competitor to mount an administrative or judicial challenge to a substantial equivalence determination, despite the fact that such a determination constitutes *de facto* permission for marketing.¹⁷⁸ Significantly, Congress provided for judicial review of "actions by the Secretary . . . that have immediate and substantial impact"¹⁷⁹: classification decisions; product licensing decisions; section 515(b) regulations requiring submission of premarket approval applications; performance standard regulations; banned device regulations; investigational device exemption denials; and even good manufacturing practice variance decisions.¹⁸⁰ Substantial equivalence determinations are *not* on this extensive list of reviewable major Agency actions, indicating that Congress intended such determinations to have at most a temporary and insubstantial place in the Act's

176. See generally *Failed Pacemaker Leads*, *supra* note 3, at 139 (exchange between then-Rep. Gore and CDRH Director Villforth).

177. FDCA § 520(h)(1): FDA'S NEGLECTED CHILD, *supra* note 1, at 36 n.130.

178. In contrast, a firm does have opportunities to seek redress for a finding that its product is *not* substantially equivalent. The firm can petition for reclassification to Class I or II under section 513(f). Or, more commonly, it can market the product notwithstanding the FDA finding, wait for enforcement action, and, if such an action materializes (as it rarely does in such circumstances), contest the Agency's action in federal court. However, the Agency's position is typically upheld. See *infra* note 290.

179. HOUSE REPORT, *supra* note 11, at 53.

180. FDCA § 517(a).

overall regulatory scheme. The legislative history stresses the importance of the Agency's "assur[ing] development of a complete record for judicial review" of its significant actions.¹⁸¹ But the substantial equivalence review process is a black box, entirely shielded from the public scrutiny that Congress deemed essential to the premarket clearance process.

F. Timing of the Implementation of Premarket Approval Requirements

The claim advanced above, that excessively prolonging the substantial equivalence review system as the main route to the market for new-model devices would be contrary to law, requires some attempt at specifying how long is too long. Although Congress could have been clearer on the issue, the Act and its legislative history provide some guidance.

It is reasonable to ascribe to Congress an understanding of FDA's need for adequate time to accomplish its workload. When Congress passed the Medical Device Amendments, the Agency was in the midst of its Drug Efficacy Study Implementation process, a review of the effectiveness of all prescription drugs mandated fourteen years earlier by the Kefauver-Harris Amendments to the drug law.¹⁸² FDA was under a court order to complete the process,¹⁸³ and showed few signs of a present ability to do so. At the same time, FDA was also undertaking a massive and slow-moving review of the effectiveness of over-the-counter drugs.¹⁸⁴ Therefore, at the time the Amendments were passed, the Agency was no more likely to be able rapidly to carry out its congressionally mandated review of marketed medical devices than it was to fulfill its responsibilities promptly with regard to drugs.

Cognizant of the scale of the tasks assigned and of FDA's deliberate pace, Congress spaced out the agency's premarket approval duties in the device law. The statute set out two immediate priorities for premarket approvals and allowed FDA some latitude in reviewing other products for which premarket approval was required.

The first immediate priority was for transitional devices, those devices for which the Agency already had made a special determination of potential risk or lack of utility.¹⁸⁵ The second priority was for devices

181. HOUSE REPORT, *supra* note 11, at 55.

182. Pub. L. No. 87-781, 76 Stat. 780 (1962).

183. *Am. Public Health Ass'n v. Veneman*, 349 F. Supp. 1311 (D.D.C. 1972).

184. *See* 37 Fed. Reg. 9464 (1972) (OTC classification procedures); R. MERRILL & P. HUTT, *FOOD AND DRUG LAW: CASES AND MATERIALS* 450 n.8 (1980) (list of OTC proceedings).

185. FDCA § 520(1). No exception was made for new-model products substantially equivalent to those already marketed.

that were "new" in the statutory sense, i.e., not substantially equivalent to preenactment devices. These "new" devices, as well as transitional products that had not yet received marketing approval through new drug applications, were all required to go through the premarket approval process or to seek reclassification before marketing.¹⁸⁶

Preenactment devices and their substantial equivalents, by contrast, were given grace periods before imposition of premarket approval requirements. The grace periods have two parts. The first part is the interval before final classification of each type of device into Class III. In anticipation of the 1976 legislation, FDA convened advisory panels to recommend preliminary classifications of existing devices.¹⁸⁷ However, Congress provided that the panels were to review those recommendations in light of the new statutory standards and submit, within a year, new classification recommendations.¹⁸⁸ FDA would then propose and, after reviewing comments, promulgate final classification regulations.¹⁸⁹ The entire process was to put manufacturers of Class III devices on notice that premarket approval applications would likely be required.

The second part of the grace period occurs after final classification. FDA is required to issue a regulation under section 515(b) calling for premarket approval applications for each Class III device.¹⁹⁰ However, the device is not considered adulterated for a period of (1) thirty months after final classification of the device into Class III or (2) ninety days after the issuance of the section 515(b) regulation, whichever is later.¹⁹¹ Thus, Congress contemplated that while FDA was preparing to implement the new law fully, the Agency could postpone reviewing premarket approval applications for preenactment devices and their substantial equivalents for at least two years, more or less, during the classification process, and for an additional two and one-half to three years after final classification.

The law makes further specific provision for easing FDA's premarket approval workload. First, to permit the Agency to allocate its resources efficiently, Congress authorized the Agency to establish priorities to be used in applying premarket approval requirements to preenactment Class III devices.¹⁹² Second, so that FDA would not be saddled with responsibility for reviewing premarket approval applications for devices that should no longer be placed in Class III because their technology has

186. FDCA §§ 513(f), 515(a)(2).

187. HOUSE REPORT, *supra* note 11, at 39.

188. FDCA § 513(c)(2)(A),(3).

189. *Id.* § 513(d)(1).

190. *Id.* § 515(b)(1).

191. *Id.* § 501(f)(2)(B).

192. *Id.* § 513(d)(3).

matured or because their use has become standardized, the law affords manufacturers of Class III devices the automatic opportunity to petition for reclassification when a section 515(b) regulation calling for pre-market approval applications is promulgated.¹⁹³

What can one infer from this structure about the speed with which Congress intended FDA to review the safety and effectiveness of pre-amendment Class III devices and their *postamendment* substantial equivalents? One possible congressional directive is notable for its absence: no absolute deadline was set for completion of the review process. However, there are many indications that the process is to be carried out with dispatch.

First, the statute itself suggests that the review process should begin quickly. The fact that the grace period for each Class III device ends either thirty months after final classification or ninety days after issuance of a section 515(b) regulation calling for premarket approval applications, whichever is later,¹⁹⁴ necessarily indicates Congress' expectation that at least some, if not all, section 515(b) regulations would be promulgated soon after final classification. Had Congress intended that no such calls for safety and effectiveness data be issued for a two and one-half year period after classification, it could easily have said so.

Second, the legislative history indicates that the process of establishing Class III devices' safety and effectiveness should be conducted promptly. Delaying the requirement for submission of premarket approval applications is permitted, but only "for a statutory period"¹⁹⁵—a phrase that connotes a definite interval, apparently the thirty-month/ninety-day moratorium on enforcement of the requirement. The House Committee Report states:

The Committee believes that the thirty month "grace period" afforded after classification of a device into class III before a device *must obtain premarket approval* is sufficient time for manufacturers and importers to develop the data and conduct the investigations necessary to support an application for pre-market approval.¹⁹⁶

Moreover, once ninety days has expired following promulgation of a section 515(b) regulation, no extensions of the deadline for premarket approval submission are permitted; a device lacking an approved appli-

193. *Id.* § 515(b)(2)(A)(iv),(B).

194. *Id.* § 501(f)(2)(B).

195. HOUSE REPORT, *supra* note 11, at 31.

196. *Id.* at 42 (emphasis added).

cation "would be required to be removed from the market."¹⁹⁷

Third, the House subcommittee responsible for oversight of FDA's implementation of the medical device law has taken the position 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."¹⁹⁸

If these indications of congressional intent are not entirely conclusive, one point is clear: the law contains no suggestion that the requirement for premarket approval submissions may be postponed indefinitely. The law provides that the Agency "shall . . . require" each marketed Class III device to receive premarket approval.¹⁹⁹ The House Committee Report reinforces this directive, stating that "[d]evices classified into class III will be required to undergo premarket approval."²⁰⁰ The law's authorization for the Agency to establish priorities in applying this requirement to Class III devices²⁰¹ in no way undercuts Congress' basic command. If premarket approval is unnecessary for any Class III device, the law provides a single and sufficient method of avoiding the requirement: reclassification.

This conclusion is particularly compelling given the alternative: that Class III devices continue indefinitely to receive de facto marketing permission through a substantial equivalence review that bypasses the structure of public accountability painstakingly designed by Congress. An endless, olamic deferral of the Agency's regulatory duty would subvert the purpose of the statute.

III. MEDICAL DEVICE REGULATION: WHAT THE PUBLIC GOT

In the years following enactment of the Medical Device Amendments, FDA acted promptly to implement some aspects of the law, moved slowly with respect to others, and left still other provisions

197. *Id.*

198. FDA'S NEGLECTED CHILD, *supra* note 1, at 20. The postenactment conclusion of a congressional subcommittee concerning Congress' intent in enacting a statute, however, should be given at most only limited weight. See R. DICKERSON, THE INTERPRETATION AND APPLICATION OF STATUTES 179 (1975).

Dr. John Villforth, director of FDA's Center for Devices and Radiological Health, later testified that he agreed with the oversight subcommittee's position. *Failed Pacemaker Leads*, *supra* note 3, at 168. However, the Agency as a whole does not subscribe to this position. See *infra* note 261 (FDA denial of Health Research Group petition to require PMA's for preamendment Class III devices).

199. FDCA § 515(b)(1).

200. HOUSE REPORT, *supra* note 11, at 30.

201. FDCA § 513(d)(3).

unimplemented. Several branches of Congress have criticized agency inaction,²⁰² and FDA has responded with efforts to speed implementation of the law and to strengthen the scientific review process. A review of significant features of the Agency's record will provide insight into where the Agency is succeeding, where its conduct is falling short of legal requirements, and where the law needs to be changed. After a brief overview of FDA's implementation of the regulatory controls applicable to non-Class III devices—general controls and performance standards—the discussion will center on the critical issue of the Agency's procedures for scrutinizing devices requiring premarket clearance.

A. Implementation of Non-Class III Controls

1. General Controls

FDA's good manufacturing practices regulation, perhaps the most important of the general controls,²⁰³ went into effect in mid-1978.²⁰⁴ The regulation set out requirements for quality assurance programs, such as controls over components, production, packaging, labeling, and inspection procedures.²⁰⁵ Focusing special attention on "critical devices," such as surgical implants and life-supporting or life-sustaining devices whose failure could result in significant injury,²⁰⁶ the regulation requires firms to keep records of complaints, to conduct and document investigations of the complaints, and to provide FDA inspectors access to this information.²⁰⁷ FDA inspections of manufacturers of Class II or III devices occur every two years.²⁰⁸

The Agency also set up a voluntary reporting system, the Device Experience Network, to try to keep track of medical device problems. But as congressional investigators determined and as the Agency itself ultimately acknowledged, the complaint files and the voluntary reports have proved inadequate to apprise the Agency sufficiently of deaths, injuries, and defects associated with marketed devices.

Inspection of complaint files has proved insufficient for several rea-

202. See *supra* notes 3 & 4.

203. See 1982 FDA Oversight Hearing, *supra* note 3, at 6 (statement of FDA Commissioner Hayes).

204. 21 C.F.R. § 820, promulgated in 43 Fed. Reg. 31,508 (1978).

205. *Id.*

206. 21 C.F.R. § 820.3(f) (1988).

207. 21 C.F.R. § 820.180-.198 (1988).

208. FDCA § 510(h). See 1986 GAO REPORT, *supra* note 4, at 33.

sons. First, it is labor-intensive and inefficient.²⁰⁹ Second, biennial inspections inevitably fail to discover many problems in a timely fashion.²¹⁰ Third, many manufacturers have been interpreting the good manufacturing practices recordkeeping regulation very narrowly,²¹¹ perhaps motivated by fear that files will be subject to discovery by plaintiffs' attorneys in product liability cases. Consequently, manufacturers' complaint files often fail to include reports received about product defects and patient injuries.²¹² Of equal concern, manufacturers simply do not learn about a great many device problems from product users.²¹³

The voluntary Device Experience Network has also proved inadequate. Manufacturers have been reluctant to make voluntary reports because of the accessibility of those reports under the Freedom of Information Act.²¹⁴ In some cases, manufacturers have reported to FDA only after a recall or other remedial action is completed.²¹⁵ Hospitals have reported only infrequently to FDA; a 1986 General Accounting Office ("GAO") report found that fewer than one percent of identified device-related problems occurring in hospitals were reported directly to the Agency.²¹⁶ In addition, many physicians and other health professionals are unaware of the voluntary reporting system.²¹⁷ Because of this pervasive underreporting, the GAO concluded that FDA cannot rely on its voluntary reporting network to provide early warnings of problems, to

209. 1986 GAO REPORT, *supra* note 4, at 33-34.

210. OTA REPORT, *supra* note 4, at 115.

211. One FDA compliance officer lamented firms' "interesting definitions of complaints: i.e., 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.'" Memo from FDA Associate Director for Compliance Holt, Feb. 16, 1982, p. 5, reprinted in *1982 FDA Oversight Hearing*, *supra* note 3, at 207.

According to an FDA survey of manufacturers' complaint files, 60% of the firms canvassed were rated as having either poor or unusable complaint files. *Id.* See also 1986 GAO REPORT, *supra* note 4, at 33.

212. As a recent General Accounting Office (GAO) study found, only 41% of hospital reports to manufacturers of device-related problems wound up in manufacturers' complaint files when the reports involved actual injury to a patient. When the problem involved potential rather than actual injury, only 11% of the reports found their way into the complaint files. 1986 GAO REPORT, *supra* note 4, at 60.

213. The GAO study found that fewer than half of device-related problems identified in its hospital survey were transmitted by hospitals to manufacturers. *Id.* at 41. Hospitals were least likely to inform manufacturers about problems with devices not under warranty, *id.* at 45, since no financial incentive for reporting existed.

214. 5 U.S.C. § 552; 21 C.F.R. §§ 20.111, 20.113 (1988). The GAO survey found that manufacturers reported problems to FDA in just 11% of cases in which injury occurred. 1986 GAO REPORT, *supra* note 4, at 59.

215. OTA REPORT, *supra* note 4, at 115.

216. 1986 GAO REPORT, *supra* note 4, at 41; *1987 Medical Device Hearings*, *supra* note 3, at 367 (statement of Eleanor Chelimsky of GAO).

217. 1983 GAO REPORT, *supra* note 4, at 14.

estimate their extent, to spot trends, or to assess patterns or causes of hazards.²¹⁸

FDA, aware of many of these problems, proposed a mandatory reporting system of broad scope in the closing months of the Carter Administration in 1980.²¹⁹ After objections to paperwork burdens by industry and by the Reagan Administration's Office of Management and Budget, however, FDA announced it was holding the proposal in abeyance.²²⁰ This announcement provoked substantial congressional criticism.²²¹

In response, FDA promulgated a mandatory device reporting rule²²² more limited in scope than the 1980 proposal. The regulation went into effect in December 1984. Since then, the number of reports of adverse device experiences coming to FDA has increased dramatically.²²³ However, the mandatory reporting rule will not solve all the problems identified in the 1986 GAO report.²²⁴ The regulation does not implement FDA's statutory authority to require reporting from independent distributors.²²⁵ And even if the reporting regulation were expanded to apply to independent distributors, a further limitation would remain: the law currently does not authorize FDA to require reports from hospitals, clinics, physicians' offices, or laboratories, where most device problems are experienced.²²⁶ The lack of a hospital reporting requirement is

218. 1986 GAO REPORT, *supra* note 4, at 35; 1987 Medical Device Hearings, *supra* note 4, at 379 (statement of Eleanor Chelimsky, Director of the Program Evaluation and Methodology Division of GAO: "ad hoc quality" of FDA's system means that the communications network could break down "at about 15 different points").

219. 45 Fed. Reg. 76,183 (1980).

220. 46 Fed. Reg. 57,568 (1981); FDA'S NEGLECTED CHILD, *supra* note 1, at 23; 1983 GAO REPORT, *supra* note 4, at 15.

221. FDA'S NEGLECTED CHILD, *supra* note 1, at 11, 21-27 (FDA "totally at sea" regarding extent of device problems); *see also* 1983 GAO REPORT, *supra* note 4, at 9-18 (voluntary reporting system has "major deficiencies").

222. 21 C.F.R. § 803 (1988).

223. The head of the device surveillance program recently estimated that 18,000 reports came in during the first year in which the mandatory reporting rule was in effect, as compared with some 20,000 during the nine years of the voluntary system. Speech by Chester Reynolds to the Food and Drug Law Institute (June 25, 1987). A congressional staff report estimated that almost six times as many reports came in to FDA under the mandatory system as under the voluntary system. 1987 Medical Device Hearings, *supra* note 3, at 340, 347.

224. 1987 Medical Device Hearings, *supra* note 3, at 379 (statement of Eleanor Chelimsky, Director of GAO's Program Evaluation and Methodology Division).

225. *See* 1986 GAO REPORT, *supra* note 4, at 41 n. 2. In the GAO survey, about 12% of the reports on device problems that hospitals sent to outside entities went to independent distributors. *Id.* Requiring independent distributors to report in turn to FDA would therefore create a substantial additional source of information for the Agency.

226. *See* FDCA § 519. FDA itself has recognized that it lacks information about adverse experiences with devices such as orthopedic implants used by persons not required to report such experiences. Orthopedic Devices: General Provisions and Classifications of

particularly disturbing since many of the newest and consequently least familiar devices, as well as the riskiest devices, are commonly used in hospitals.²²⁷

One general control on which FDA has placed considerable emphasis as a tool for regulating devices of questionable safety or effectiveness is its authority over misleading labeling.²²⁸ Through guidance to device manufacturers and importers about adequate labeling, FDA is often able to win adherence to informal FDA standards concerning not only truthfulness of claims but also product quality.²²⁹ Firms failing to follow the Agency's guidance risk product seizures and other enforcement actions.²³⁰ This often-used method for enforcing compliance with agency policy has not been formalized through notice-and-comment procedures.

FDA has fared poorly, however, in implementing other general controls by regulation. A hasty attempt to issue a restricted device regulation of general applicability to prescription devices, without affording the public an opportunity for comment,²³¹ was rejected by the courts on procedural grounds.²³² The Agency tried again, proposing a restricted devices regulation at the end of the Carter Administration,²³³ but withdrew the proposal a year later.²³⁴ The Agency has yet to put in force its section 520(e) restricted device authority.²³⁵

77 Devices, 52 Fed. Reg. 33,686, 33,690 (1987).

227. Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 FOOD DRUG COSM. L.J. 511, 518-19 (1988).

228. See FDCA §§ 201(n), 502(a), (f).

229. For example, FDA takes regulatory action against manufacturers and importers of condoms when the leakage rate for a lot is greater than 0.4%. If the condoms are labeled as preventing disease, FDA charges that the claim is "false and misleading, because the article contains holes." FDA Compliance Guide No. 7124.21 (Dec. 30, 1987), *reprinted in* 2 Med. Devices Rep. (CCH) ¶ 18,007.

230. For example, FDA has ordered manufacturers of drug abuse screening test kits to include on their labels information indicating that results from use of the kits are "preliminary," that positive results should be confirmed by "an independent and more specific method," and that "reliance on positive findings . . . for employment purposes or any other purpose is not advised without confirmatory testing." Letter from FDA CDRH Office of Device Evaluation Director K. Mohan (Jan. 27, 1987) (on file with author). Failure to include the required labeling would render the product misbranded.

231. 41 Fed. Reg. 22,620 (1976).

232. *Becton, Dickinson & Co. v. FDA*, 589 F.2d 1175 (2d Cir. 1978); *In re Establishment Inspection Portex, Inc.*, 595 F.2d 84 (1st Cir. 1979).

233. 45 Fed. Reg. 65,619 (1980).

234. 46 Fed. Reg. 57,568 (1981).

235. In the nearly thirteen years since the Medical Device Amendments were enacted, the only restrictions FDA has apparently employed have been those restricting devices to prescription use. See, e.g., 21 C.F.R. § 801.109 (1988) (prescription devices in general); *id.* § 801.421 (hearing aids); *id.* § 801.427 (IUD's); FDA Compliance Policy Guide No. 7124.09 (1987), *summarized in* 1 Med. Devices Rep. (CCH) ¶ 3063.55 (diaphragms).

Near the end of the Carter Administration, the Agency proposed a controversial regula-

Nor has the Agency made use of its authority to require firms to repair, replace, or to give refunds and expense reimbursements for devices presenting an unreasonable risk of substantial harm.²³⁶ It has taken action to ban a device only once.²³⁷

2. Performance Standards

FDA's attempts to implement performance standards over Class II devices have fared even worse. Responding to advisory panel recommendations during the device classification process, FDA issued regulations classifying more than half of all device types— well over 800 in all— in Class II.²³⁸ But the procedural intricacy of the standards development process²³⁹ makes impractical the development of standards for even a small fraction of these products.²⁴⁰ By overloading Class II, as a House oversight subcommittee aptly observed, the Agency was creating a monster that it had no hope of controlling— “a regulatory Frankenstein.”²⁴¹

FDA initially sought a way out of its dilemma by avoiding issuance of mandatory performance standards altogether. It adopted a policy of endorsing voluntary standards written by private technical organizations.²⁴² Upon objection by industry and consumer groups alike, and upon advice from its own legal staff, the Agency withdrew the policy.²⁴³

tion to restrict alpha-fetoprotein reagents for detection of neural tube birth defects. 45 Fed. Reg. 74,158 (1980). That proposal, like the general restricted devices proposal, was withdrawn by the Reagan Administration. 48 Fed. Reg. 27,780 (1983).

236. FDCA § 518(b). Members of a House oversight committee took the agency to task for its failure to employ its section 518(b) authority in handling the case of widespread failures of Medtronic model 6972 cardiac pacemaker leads. See *Failed Pacemaker Leads*, *supra* note 3, at 147–51 (statements by Rep. Wyden and then-Rep. Gore). See also Adler, *supra* note 227, at 528–29 & n. 112.

237. 21 C.F.R. § 895.101 (1988) (prosthetic hair fibers).

238. By the author's approximate count, of the first 1588 types of device finally classified, 840 (53%) had been placed into Class II; 146 (9%) were in Class III; and 602 (38%) were in Class I. See I Med. Devices Rep. (CCH) ¶¶ 4612–42 (summarizing classification results by panel). A GAO survey of “either final or proposed regulations” for 1725 device types is consistent with these figures. 1988 GAO REPORT, *supra* note 4, at 29 (Class III: 8%; Class II: about 54%; Class I: about 35%). A congressional subcommittee, however, has estimated the number of Class II types of device to be as high as 1100. 1987 Medical Device Hearings, *supra* note 3, at 340.

239. See *supra* notes 129–50 and accompanying text.

240. GAO reported an estimate that developing standards for all Class II products would take 120 years. 1983 GAO REPORT, *supra* note 4, at 43–44.

241. FDA'S NEGLECTED CHILD, *supra* note 1, at 17.

242. 45 Fed. Reg. 7490 (1980).

243. 50 Fed. Reg. 43,060 (1985). The Agency still uses voluntary standards for various purposes, however. These purposes include setting priorities for initiating mandatory performance standards proceedings. see *id.* at 43,081; providing “guidance” to manufacturers. see FDA CDRH Division of Small Mfrs. Assistance, Pertinent Voluntary Standards and Problem Definition Studies for Certain Preamendment Class III Medical Devices, *reprinted*

FDA took the first step toward initiating mandatory standards proceedings for eleven devices,²⁴⁴ but has contracted to begin the standards-writing process for only one of them.²⁴⁵

It is clear that the performance standards provisions of the law are a virtual nullity.²⁴⁶ Class II devices are regulated in essentially the same fashion as if they were in Class I, except that their manufacturers receive FDA inspections for compliance with good manufacturing practices.²⁴⁷ But quality control measures in the manufacturing process will not remedy deficiencies of conception or design.²⁴⁸ Experience with potentially hazardous life-supporting Class II products such as the esophageal obturator airway, a critical care device widely used for ventilation in emergency resuscitation but alleged to be "inadequate to support life in the majority of patients,"²⁴⁹ confirms that general controls are inadequate for at least some products in the standards category.²⁵⁰

It remains to be seen if the mandatory device experience reporting rule will enable FDA to conduct postmarket surveillance efficiently enough to minimize the costs of unsafe or ineffective Class II devices. In any case, excessive reliance on after-the-fact remedial actions rather than preventive standard-setting measures for Class II devices is an approach certain to put many patients at risk. A radical revision of the standards provisions—simplifying their labyrinthine procedures and focusing the Agency's attention on a smaller set of products raising

in 2 Med. Devices Rep. (CCH) § 17,992; and determining compliance policies for taking enforcement actions. See, e.g., FDA Compliance Policy Guide No. 7124.21 (Dec. 30, 1987), reprinted in 2 Med. Devices Rep. (CCH) § 18,007 (conform defect criteria altered in response to American Society for Testing Materials voluntary standard).

244. See 48 Fed. Reg. 27,723 (1983); 48 Fed. Reg. 31,387-97 (1983).

245. 53 Fed. Reg. 13,296 (1988) (neonatal apnea monitor). FDA has also withdrawn from proceeding with other mandatory standards previously considered. See, e.g., 52 Fed. Reg. 38,276 (1987) (electromedical devices).

246. Senator Gaylord Nelson foresaw the probable futility of standards-based device regulation as early as the 1973 congressional debate over the proposed medical device law. Nelson held that attempts to regulate devices by standards would be pointless because changes in the products would occur before standards could be written to regulate them. *Medical Device Amendments of 1973: Hearings on S. 2368 Before the Subcomm. on Health, Senate Comm. on Labor & Public Welfare*, 93d Cong., 1st Sess. 5-9 (1973).

247. FDA has also informally adopted "guidance documents," circulated to the industry, containing recommended design or performance criteria for a number of Class II devices. These guidance documents, though of uncertain enforceability, may carry out some of the functions Congress contemplated for mandatory performance standards. See 1988 GAO REPORT, *supra* note 4, at 34.

248. See FDA'S NEGLECTED CHILD, *supra* note 1, at 15.

249. Jordan & Smith, *FDA's Approval of the Esophageal Obturator Airway: A Case Study with Implications for Regulation of Critical Care Devices*, 40 FOOD DRUG COSM. L.J. 456, 456 & n. 5 (1985) (citing studies).

250. See also 1987 Medical Device Hearings, *supra* note 3, at 350-51, 358 (anecdotal evidence of problems with malfunctioning incubators and ventilators).

important safety or effectiveness concerns — seems essential.²⁵¹

B. Implementation of Premarket Clearance Procedures

The primary focus of this Article is on the adequacy and legality of FDA's discharge of its responsibility for regulatory oversight of devices requiring premarket clearance. Agency policy and activity will be reviewed under four headings: (1) handling of "old" Class III devices, those on the market prior to enactment of the device amendments; (2) substantial equivalence determinations; (3) the premarket approval process; and (4) reclassification decisions.

1. Handling of Preamendment Class III Devices

Completion of the device classification process was the essential first step in gaining control over the unregulated preamendment market for risky devices of unproven safety or effectiveness. Designation of such preamendment products (and, by statutory dynamic, of their post-amendment substantial equivalents) as Class III devices began the process which Congress envisioned would culminate in submission to the Agency of convincing scientific evidence of safety and effectiveness or, alternatively, in removal of the products from commerce.

Congress allotted one year for FDA's previously constituted advisory panels to review their preliminary deliberations and to submit recommendations about classification of all preamendment device types.²⁵² Presumably, the Agency was to act on those recommendations with due dispatch.²⁵³ However, FDA "lost control of the medical device classification process."²⁵⁴ The Agency took more than three years to publish a final classification rule for the first of the nineteen subgroupings of devices.²⁵⁵ Other classification rules followed haltingly; the final device subgroup was not classified until mid-1988, twelve years after the law was enacted.²⁵⁶

As a House oversight committee observed, the classification delays

251. The suggestion is not original. See FDA'S NEGLECTED CHILD, *supra* note 1, at 17-18 (Class IIA); 1983 GAO REPORT, *supra* note 4, at 110; FDA CDRH, EXECUTIVE SUMMARY OF THE CRITICISMS TASK FORCES' REPORTS 10-11 (1985); H.R. 2771, 99th Cong., 2d Sess. (1986) (providing for fast-track reclassification of transitional devices); S. 1808, *supra* note 9 (same); S. 1928, *supra* note 9 (same); H.R. 4640, *supra* note 9, at 5, 6 (comprehensive simplification of standards procedures).

252. FDCA § 513(c)(3). See HOUSE REPORT, *supra* note 11, at 39-40.

253. FDA'S NEGLECTED CHILD, *supra* note 1, at 6.

254. *Id.* at 4.

255. 44 Fed. Reg. 51,730 (1979) (neurological devices).

256. 53 Fed. Reg. 23,856 (1988) (general and plastic surgery devices).

had "far-reaching consequences."²⁵⁷ A preamendment device or substantial equivalent cannot be considered adulterated due to the manufacturer's failure to file an approved premarket approval application until two and one-half years from the time the device type is finally classified into Class III, or until ninety days from issuance of a section 515(b) regulation calling for a premarket approval application, whichever is later.²⁵⁸ Thus, even if FDA had issued section 515(b) calls for premarket approval applications as soon as possible after final classification, large numbers of preamendment Class III devices and their postamendment equivalents would remain on the market without proof of safety or effectiveness for many years after the device law was passed.

Multiplying the product-years of regulatory delay in assessment of existing device technology, FDA has adhered to a policy of calling for premarket approval applications for only a small fraction of all the device types finally classified into Class III. As of this writing, FDA has promulgated section 515(b) regulations for only six devices, out of the approximately 150 Class III products.²⁵⁹ One estimate put completion of the process "well into the next century."²⁶⁰ The Agency has received criticism from Congress and consumer groups for its deliberate pace in calling for safety and effectiveness data for these existing technologies.²⁶¹ But FDA has taken the view that the imprecise statutory

257. FDA'S NEGLECTED CHILD, *supra* note 1, at 7.

258. FDCA § 501(f)(2)(B).

259. 21 C.F.R. § 870.3925 (replacement heart valve); *id.* § 882.5820 (implanted cerebellar stimulator); *id.* § 882.5830 (implanted diaphragmatic/phrenic nerve stimulator); *id.* § 884.1600 (fetoscope); *id.* § 884.5360 (IUD); *id.* § 884.5380 (contraceptive tubal occlusion device).

FDA has proposed section 515(b) regulations for a few other Class III devices. *See, e.g.*, 53 Fed. Reg. 5108 (1988) (proposed 21 C.F.R. § 864.9245) (automated blood cell separator); 51 Fed. Reg. 1910 (1986) (proposed 21 C.F.R. § 880.5130) (infant radiant warmers). *See also* 48 Fed. Reg. 40,272, 40,273 (1983) (list of 13 high-priority devices for section 515(b) regulations, inclusive of those noted above).

260. Kessler, Pape & Sundwall, *supra* note 28, at 359.

261. The Health Research Group, a branch of the Ralph Nader-founded Public Citizen organization, first petitioned FDA to issue section 515(b) regulations shortly after the two and one-half year period after final classification of neurological devices had elapsed. FDA Docket No. 82P-0151/CP (May 5, 1982). A House oversight subcommittee, viewing the statutorily specified period as an "outside time limit" for the submission of safety and effectiveness data, found the Health Research Group petition "appropriate." FDA'S NEGLECTED CHILD, *supra* note 1, at 20-21. The consumer group later filed a similar petition calling on FDA to issue section 515(b) regulations for obstetric/gynecological devices. FDA Docket No. 83P-0066/CP (filed March 4, 1983) [1976-1985 Petitions Transfer Binder] Med. Devices Rep. (CCH) ¶ 13,819. However, FDA denied both petitions on the ground that the statutory period simply sets the earliest time at which FDA can proceed against a product to which a section 515(b) regulation, issued at FDA's discretion, applies.

language allows,²⁶² and the agency's limited resources require,²⁶³ calling for data on preamendment Class III devices on a highly selective basis.²⁶⁴

2. Substantial Equivalence Determinations

The vast majority of new-model devices are cleared for marketing through the section 510(k) premarket notification process, in which FDA determines whether the device is "substantially equivalent" to a predicate device on the market before the 1976 enactment of the Medical Device Amendments.²⁶⁵ Of the approximately five thousand 510(k) determinations FDA makes each year, the Agency typically finds only two to three percent of the products "not substantially equivalent."²⁶⁶ Another ten to fifteen percent of the 510(k) submissions are withdrawn, deleted, or otherwise escape agency determinations.²⁶⁷

Even Class III products are handled primarily in this fashion. From 1977 through 1986, FDA cleared about six new-model Class III devices for marketing through section 510(k) "substantial equivalence" determinations for each such device found "safe and effective" through the premarket approval process.²⁶⁸ Thus, the great majority of Class III devices

262. See *Young v. Community Nutrition Inst.*, 106 S. Ct. 2360 (1986).

263. "FDA could not call for PMAs [Premarket Approval Applications] for all eligible preamendment class III devices without devastating the Agency's resources for device activities." FDA CDRH, EXECUTIVE SUMMARY OF THE CRITICISMS TASK FORCES' REPORTS 6 (1985).

264. See, e.g., FDA CDRH, REPORT OF THE PRE-AMENDMENTS PMA CRITICISM TASK FORCE, *supra* note 7.

265. From Fiscal Year (FY) 1980 through FY 1987, for example, FDA reviewed more than 32,000 section 510(k) submissions, compared with about 350 original premarket approval applications. FDA CDRH OFFICE OF DEVICE EVALUATION, MIDYEAR REPORT, FISCAL YEAR 1988, at 18 (hereinafter MIDYEAR REPORT, FY 1988).

266. 1988 GAO REPORT, *supra* note 4, at 22-23; MIDYEAR REPORT, FY 1988, *supra* note 265, at 17; 1987 Medical Device Hearings, *supra* note 3, at 340-41; Blozan & Tucker, *Premarket Notifications: The First 24,000*, 8 MED. DEVICE & DIAGNOSTIC INDUS. 59, 65 (1986); see FDA'S NEGLECTED CHILD, *supra* note 1, at 34 (one to two percent).

267. 1988 GAO REPORT, *supra* note 4, at 23, 74; MIDYEAR REPORT, FY 1988, *supra* note 265, at 17; FDA CDRH, REPORT OF THE PREMARKET NOTIFICATION TASK FORCE 15-16 (1985); Blozan & Tucker, *supra* note 266, at 65. Thus, of all section 510(k) submissions received, FDA finds roughly 85% substantially equivalent. 1988 GAO REPORT, *supra* note 4, at 23.

268. See 1987 Medical Device Hearings, *supra* note 3, at 343 (chart showing that from FY 1977 through FY 1986, 1842 Class III devices were cleared through the premarket notification process versus 316 cleared through premarket approvals, a 5.8 to 1 ratio). See also FDA CDRH, REPORT OF THE PMA CRITICISMS TASK FORCE 35 (1985) (estimate of similar ratio).

The ratio is even higher if one excludes from the comparison the "transitional devices" previously regulated as drugs. These products are statutorily required to go through premarket approval and cannot be cleared for marketing through a substantial equivalence

sold currently lack, and will likely continue for the foreseeable future to lack, any FDA determination of a reasonable assurance of safety and effectiveness.

It is usually in the interest of most would-be marketers of new-model medical devices to bring their products to market through a section 510(k) premarket notification (known as a "510(k)") rather than through a premarket approval application ("PMA").²⁶⁹ Compared with a PMA, the 510(k) process is quicker, cheaper, and more likely to be successful.²⁷⁰ In most cases, the 510(k) submission need not contain clinical data demonstrating safety and effectiveness, although FDA has begun asking for clinical data in 510(k)'s in some circumstances. The median length of a 510(k) has been less than ten pages, compared with about 1000 pages for a typical premarket approval application.²⁷¹ Costs of preparing submissions vary widely across device types, but one research team found a range from \$50 to \$2000 for 510(k)'s without clinical data, compared to \$111,000 to \$828,000 for premarket approval applications.²⁷² The average review time for 510(k)'s in the first half of fiscal year ("FY") 1988 was sixty-six days, as opposed to 264 days for PMA's.²⁷³ As noted above, the Agency found products "not substantially equivalent" in only two to three percent of all determinations on 510(k) submissions, and less than ten percent of the rest were withdrawn by manufacturers.²⁷⁴ By contrast, about twenty-five to thirty percent of all PMA's submitted to FDA are withdrawn by their sponsors in the face of FDA or advisory panel disapprobation.²⁷⁵ Thus, as one leading industry attorney advised, "If an arguable basis exists for making a

determination. See *supra* note 41 and accompanying text. About three-fifths of the devices on the premarket approval track fall into this transitional category. FDA CDRH, EXECUTIVE SUMMARY OF THE CRITICISMS TASK FORCES' REPORTS 10 (1985). If the comparison excludes these transitional devices, and focuses only on new-model Class III devices as to which FDA has discretion whether to require a PMA application, the comparison yields a ratio of about fifteen to one.

269. Cooper, *supra* note 48, at 192 n.5 and accompanying text.

270. Kahan, *supra* note 157, at 514-18.

271. Blozan & Tucker, *supra* note 266, at 66; Tucker & Blozan, *PMA Applications for Post-Amendment Devices: A Look at the Current Process*, 7 MED. DEVICE & DIAGNOSTIC INDUS. 87, 88 (1985). These studies covered submissions from 1976 to 1983.

272. Blozan & Tucker, *supra* note 266, at 67; Tucker & Blozan, *supra* note 247, at 93. See also Contact Lens Mfrs. Ass'n v. FDA, 766 F.2d 592, 596 (D.C. Cir. 1985) (industry estimate of PMA costs at \$750,000 to \$1 million).

273. MIDYEAR REPORT, FY 1988, *supra* note 265, at 2, 7.

274. See *supra* notes 266-67 and accompanying text; 1988 GAO REPORT, *supra* note 4, at 74 (10% deleted by FDA or withdrawn by sponsors).

275. Personal communication from Charles Kyper, Director, FDA CDRH Premarket Approval Staff (August 11, 1988).

claim of substantial equivalence, a company would be remiss in not trying the 510(k) route."²⁷⁶

It is in the interest of FDA as well to use the 510(k) process extensively, at least from the standpoint of administrative convenience. Section 510(k) submissions can be processed using far fewer agency person-hours than are required for PMA applications;²⁷⁷ the submissions require no consultation with an advisory panel; the Agency need not oversee the preparation of an accurate summary of the device's safety and effectiveness characteristics;²⁷⁸ and the Agency's determinations about substantial equivalence are virtually never the subject of requests for administrative or judicial review.²⁷⁹

Given the critical function of the premarket notification process in FDA practice, the Agency's standards for "substantial equivalence" determinations are of high importance. As noted above, Congress did not define the concept in the law.²⁸⁰ The legislative history, though, is reasonably clear that a new-model device is to be deemed "substantially equivalent" to a similar product marketed before enactment only if the new-model device does not vary from the predicate product in a way that could have an adverse material effect on safety and effectiveness.²⁸¹ The congressional purpose was to ensure that newly marketed devices be at least as safe and effective as preenactment devices during the temporary period, pending full implementation of the premarket approval process.²⁸²

FDA responded by providing, for almost a decade, virtually no guidance about its interpretation of the meaning of "substantial equivalence." As the Agency itself conceded in 1985, no written guide-

276. Kahan, *supra* note 157, at 523.

Despite the advantages of bringing a product on the market through the 510(k) process, in some cases the protection against competition afforded by an approved PMA will lead the sponsor of a new-model Class III product to seek premarket approval rather than a substantial equivalence determination. If FDA rules that a particular kind of device requires a PMA, would-be competitors would then have to go through the expensive, time-consuming PMA process themselves, giving the holders of approved PMA's a kind of "regulatory patent." See *id.* at 519; Contact Lens Mfrs. Ass'n v. FDA, 766 F.2d 592 (D.C. Cir. 1985) (upholding FDA determination that certain contact lenses require PMA's).

277. James Benson, Deputy Director of FDA's Center for Devices and Radiological Health, estimated that, on average, 1200 person-hours are required to process a PMA, but only 20 person-hours are needed for a 510(k). 1987 *Medical Device Hearings*, *supra* note 3, at 384.

278. See *supra* note 177 and accompanying text.

279. See *infra* note 290.

280. See Cooper, *supra* note 167 and accompanying text.

281. See *supra* notes 169-70 and accompanying text.

282. See *supra* notes 169-73 and accompanying text.

lines existed to assist it in reviewing 510(k) submissions.²⁸³ All that the implementing regulation provided was that firms need not submit a pre-market notification for a modified product unless the modification "could significantly affect the safety or effectiveness of the device" or unless it represented "a major change or modification in the intended use of the device."²⁸⁴ Whether the contemplated modification would have a "significant" effect on safety or effectiveness or would represent a "major" change in the intended use of the device was a determination that "the manufacturer [was] . . . best qualified" to make,²⁸⁵ although the Agency could review the firm's conclusion.

The consequence of FDA's longstanding absence of guidelines was that substantial equivalence determinations were inevitably made in ad hoc fashion.²⁸⁶ As an internal agency critique concluded, review personnel "could not . . . describe a general rule that establishes what ty[p]es of concerns make a device NSE (not substantially equivalent) and exclude that device from evaluation under a 510(k)."²⁸⁷ Policies for collecting performance testing information in 510(k) submissions "were not in writing, and may not always be followed by individual reviewers."²⁸⁸ The results have allegedly been inconsistent decisions in similar cases.²⁸⁹ Review of such decisions is difficult to obtain,²⁹⁰ particularly since the

283. FDA CDRH, EXECUTIVE SUMMARY OF THE CRITICISMS TASK FORCES' REPORTS 8 (1985).

284. 21 C.F.R. § 807.81(a)(3)(i)-(ii) (1988). The same standard applied to the determination whether an entirely new product would be considered substantially equivalent to another firm's preenactment product. See 42 Fed. Reg. 42,522 (1977) (para. 17).

285. Establishment Registration and Pre-market Notification Procedures, 42 Fed. Reg. 42,520, 42,522-23 (1977); FDA CDRH, PREMARKET NOTIFICATION: 510(K) REGULATORY REQUIREMENTS FOR MEDICAL DEVICES, p. IV-3 (1983). The standard that a change in a product must "significantly" affect safety or effectiveness or represent a "major" change in intended use before a premarket notification is required was adopted by FDA in response to industry comments on its proposed regulation. Compare proposed 21 C.F.R. § 807.81(a)(3), 41 Fed. Reg. 37,464 (1976), with the final regulation and its preamble, 42 Fed. Reg. 42,520, 42,522-23, 42,528 (1977). Neither section 510(k) of the Act nor the parts of the House report explaining that section contain qualifying language of the sort promulgated by the Agency in section 807.81(a)(3). Still, FDA's regulation in this respect appears within the ambit of the Agency's interpretive power. See *American Textile Mfrs. Inst. v. Donovan*, 452 U.S. 490 (1981).

286. Rep. John Dingell, chairman of the House Committee on Energy and Commerce, noted the ad hoc nature of FDA's substantial equivalence determination in the course of hearings on Medtronic's defective polyurethane cardiac pacemaker leads. *Failed Pacemaker Leads*, *supra* note 3, at 155, 157.

287. FDA CDRH, REPORT OF THE PREMARKET NOTIFICATION CRITICISM TASK FORCE 7 (1985).

288. *Id.* at 10.

289. Kahan, *supra* note 157, at 521 n. 55; Kessler, Pape & Sundwall, *supra* note 28, at 360.

290. Challenges to FDA substantial equivalence determinations are rare. Many companies, fearing a determination of nonequivalence, simply market the device in question without submitting a 510(k) premarket notification, either believing the device to be exempt

reasons for the Agency's determinations are not revealed to the public.²⁹¹ The arbitrariness of the process led one writer to suggest that the Agency's standards for determining substantial equivalence are so flexible as to be unconstitutionally vague.²⁹² The D.C. Circuit also expressed in dicta its "discomfort" with the FDA's interpretation of substantial equivalence.²⁹³

The absence of a clear rule on substantial equivalence led to enforcement difficulties. Since FDA had no compliance program to determine if 510(k)'s were being submitted when required, the Agency could not easily determine which firms were flouting statutory requirements of pre-market notification.²⁹⁴ However, Agency personnel were convinced that noncompliance was widespread, in part due to the indefiniteness of the Agency's 510(k) submission requirements.²⁹⁵ In fact, some companies apparently failed to notify FDA of product changes in order to avoid drawing the Agency's (and, potentially, plaintiffs' attorneys') attention

from the notification requirement or hoping that the Agency will ignore or fail to learn of the introduction of the device into commerce. In a typical scenario, FDA takes enforcement action against the device, contending that it lacks the required approved PMA application or investigational device exemption and is therefore adulterated. The court upholds the FDA action, holding, *inter alia*, that the company failed to submit the required premarket notification and to obtain a substantial equivalence determination. *E.g.*, United States v. "Stryker Shoulder 130-10 Dacron Ligament Prosthesis." [1982-1985 Developments Transfer Binder] Med. Devices Rep. (CCH) § 15.077 (W.D. Mich. Apr. 2, 1985); United States v. Ovutron, [1977-1982 Developments Transfer Binder] Med. Devices Rep. (CCH) § 15.042 (D. Ariz. Feb. 25, 1982).

In at least one case, a firm did challenge an FDA determination of nonequivalence. General Medical Co. v. FDA, No. 83-3314 (D.D.C. filed Nov. 7, 1983). The Agency reversed its position in part and acknowledged in a stipulation dismissing the case that the product in question (an antiperspirant device), if prescribed by a physician, was substantially equivalent to a preamendment device. General Medical Co. v. FDA, 770 F.2d 214, 216-17 (D.C. Cir. 1985). To the author's knowledge, no other FDA determination of nonequivalence has been successfully challenged in court. The incentive not to challenge such determinations is strong because firms fear FDA's ability to retaliate by making life difficult for the regulatee in a multiplicity of ways. Personal communication from Jonathan Kahan, Esq. (Aug. 4, 1988).

Agency determinations that a product is substantially equivalent are even less likely to be contested successfully, since potential plaintiffs (e.g., competitors, medical or consumer organizations) would have little if any information for the mounting of a legal challenge.

291. See *supra* text accompanying note 177; FDA'S NEGLECTED CHILD, *supra* note 1, at 36 n. 130.

292. Kaplan, *Through the Maze of 510(k)s*, 39 FOOD DRUG COSM. L.J. 160, 163 (1984).

293. General Medical Co. v. FDA, 770 F.2d 214, 217 n.1 (D.C. Cir. 1985).

294. FDA CDRH, PREMARKET NOTIFICATION CRITICISM TASK FORCE REPORT 22 (1985).

295. *Id.* at 19.

to the defects in marketed products that the changes were designed to overcome.²⁹⁶

Further easing the regulatory impact of its premarket clearance process on device firms, FDA adopted a policy of making substantial equivalence determinations for products equivalent to *postamendment* devices that had previously been found equivalent to *preamendment* devices. This approach, which came to be known as "piggybacking" or "equivalence creep,"²⁹⁷ permitted a new-model product to be cleared for marketing without going through the premarket approval process, as long as its sponsor could trace its ancestry to a device on the market before 1976 and as long as the equivalency chain was not interrupted by what agency officials termed "unanswered questions" of safety and effectiveness.²⁹⁸ FDA would sometimes clear a product for marketing whose sponsor had traced different aspects of the product to different predicate devices;²⁹⁹ consequently, the product bore only a distant resemblance to the preenactment devices to which it was supposedly substantially equivalent.³⁰⁰

Moreover, the Agency's determinations about substantial equivalence have been vulnerable to substantive shortcomings in the quality of scientific review. The potential for these shortcomings is attributable less to agency staff than to the review process itself. Manufacturers may market their new-model products ninety days after submitting a premarket notification.³⁰¹ But the information on performance comparisons they submit to show equivalence to previously marketed products may be insufficient, in kind or quality, to permit valid scientific conclusions to be drawn. Rushed by the statutory deadline and rated on efficiency for job advancement purposes, agency staffers inevitably will be pressed in many cases either not to closely scrutinize data in the premarket

296. See, e.g., *Failed Pacemaker Leads*, *supra* note 3, at 9, 19, 144, 223, 260-61 (testimony of FDA CDRH Director Villforth on Medtronic polyurethane pacemaker leads; statements by then-Rep. Gore and Rep. Sikorski).

297. See Campbell, *The 1976 Medical Device Amendments and the 510(k) Process* 39-42 (1983) (unpublished paper presented to the Food & Drug Law Institute) (on file with author); 1983 GAO REPORT, *supra* note 4, at 58; OTA REPORT, *supra* note 4, at 130.

298. Address by Robert Sheridan, FDA Acting Associate Director for Device Evaluation, the Food and Drug Law Institute's Medical Device Update (June 21, 1982), *quoted in* Campbell, *supra* note 297; see FDA CDRH, *PREMARKET NOTIFICATION: 510(K) REGULATORY REQUIREMENTS FOR MEDICAL DEVICES 2* (1986).

299. For example, Hybritech's 510(k) notification for an early monoclonal antibody-based *in vitro* diagnostic product compared various features of its device to those of several other devices, including products used for other indications. Campbell, *supra* note 297, at n. 287 (quoting MDDI Reports 1-2 (Jan. 25, 1982) ("The Gray Sheet")).

300. Former FDA Chief Counsel Richard Cooper analogized the piggybacking process to the children's game "Whispering down the Lane," in which the original message is incrementally distorted from one participant to the next. Cooper, *supra* note 42, at 192 n. 4.

301. FDCA § 510(k).

notification submissions or not to require submission of further data when necessary to make a responsible determination about the product's safety and effectiveness. Moreover, as a recent GAO study found, agency reviewers of premarket notification submissions have difficulty obtaining information on problems reported to FDA about similar devices already in use.³⁰²

The Agency's policy on substantial equivalence aroused the concern of consumer groups,³⁰³ research arms of Congress,³⁰⁴ and, most importantly, congressional committees with jurisdiction over the medical device program.³⁰⁵ Several examples of apparent policy failures came to the congressional committees' attention: defective cardiac pacemaker leads;³⁰⁶ the Travenol volumetric pump cassette, which received an FDA substantial equivalence determination despite the submission of a faked photograph of a nonexistent prototype;³⁰⁷ cardiac pacemakers; prosthetic knee implants; springs for spinal fixation; and mechanical ventilators.³⁰⁸

Congressional criticism of FDA's reliance on substantial equivalence determinations as the Agency's primary premarket clearance mechanism was scathing. A 1983 report from the House oversight subcommittee with jurisdiction over medical device regulation concluded: "A 510(k) finding of substantial equivalence is not an acceptable substitute for the regulatory system at the heart of the device amendments. . . . A finding of substantial equivalence to an already marketed device is not an assurance of safety and efficacy."³⁰⁹ The subcommittee found that "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."³¹⁰

302. 1988 GAO REPORT, *supra* note 4, at 40.

303. Public Citizen Health Research Group was an early critic of FDA's substantial equivalence policy. See, e.g., Statement of the Health Research Group representative before the FDA Obstetrical & Gynecological Devices Advisory Panel (public hearing on tampons and toxic shock syndrome) (Oct. 10, 1980).

304. 1983 GAO REPORT, *supra* note 4, at 52-64; OTA REPORT, *supra* note 4, at 128-31.

305. See, e.g., 1984 Medical Device Hearings, *supra* note 3, at 273, 275, 279, 289-93 (GAO conclusion that "the whole substantial equivalence process really is ineffective"); *id.* at 295-96, 304, 340 (statements of FDA Acting Commissioner Novitch), 362, 367-68 (statement of Allen Greenberg, Health Research Group); *Failed Pacemaker Leads*, *supra* note 3; 1987 Medical Device Hearings, *supra* note 3, at 332-47.

306. See *Failed Pacemaker Leads*, *supra* note 3.

307. FDA'S NEGLECTED CHILD, *supra* note 1, at 35-47.

308. 1987 Medical Device Hearings, *supra* note 3, at 351-58, 388-89 (anecdotal reports).

309. FDA'S NEGLECTED CHILD, *supra* note 1, at 34-35.

310. *Id.* at 14 (footnote omitted). See also *Failed Pacemaker Leads*, *supra* note 3, at 169 (statement of then-Rep. Gore: "the generic problem of FDA failing to implement the law"); 1987 Medical Device Hearings, *supra* note 3, at 334 (statement of Chairman

FDA itself recognized the inadequacy³¹¹ and potential illegality³¹² of its premarket clearance policy. The Agency acted commendably in analyzing the program's weaknesses,³¹³ in shoring up the scientific quality of its review process, and in beginning to call for premarket approval applications for a few preamendment Class III devices and their post-enactment substantial equivalents.³¹⁴

FDA, in a 1986 guidance document, finally articulated its view of what constitutes "substantial equivalence."³¹⁵ This guidance document was designed in part to reduce inconsistent determinations by agency personnel, and may well have had that effect.³¹⁶ The policy, issued without notice-and-comment procedures, can be summarized as follows. The Agency compares the new device to a predicate device in two respects: (1) intended use, and (2) technological characteristics. If the new device has a new intended use, it will be considered not substantially equivalent to the predicate device. If the new device has the same intended use as the predicate, the new device will be considered substantially equivalent if (a) its technological characteristics are the same as the predicate's or any differences could not affect safety or effectiveness, or (b) it has new technological characteristics that could affect safety or effectiveness, but (i) it generates the same types of questions about safety or effectiveness, (ii) there are accepted scientific methods for evaluating whether safety or effectiveness has been adversely affected as a result of the new characteristics, and (iii) data are submitted demonstrating that the new technological features have not diminished safety or effectiveness. New devices not meeting criteria (a) or (b) above are considered not "substantially equivalent," and sponsor firms must obtain

Dingell: "[T]hrough negligence or by intention, the FDA has failed to implement the major provisions of the Medical Device Amendments."

311. See, e.g., FDA CDRH, REPORT OF THE PREMARKET NOTIFICATION CRITICISM TASK FORCE (1985); FDA, A PLAN FOR ACTION 17-19 (1985).

312. An FDA internal critique concluded that "the current [premarket notification] program may not be defensible legally because the Center evaluates what are sometimes important issues about devices with new technologies during 510(k) reviews instead of finding such devices NSE [not substantially equivalent]." FDA CDRH, REPORT OF THE PREMARKET NOTIFICATION CRITICISM TASK FORCE 7 (1985 draft).

Moreover, according to the Office of Technology Assessment, FDA's Office of General Counsel has stated that the practice of "piggybacking" equivalence determinations, see *supra* notes 297-300 and accompanying text, is not authorized by law. OTA REPORT, *supra* note 4, at 130 & n. 464.

313. See *supra* note 7.

314. See *supra* note 259 and accompanying text.

315. FDA CDRH, GUIDANCE ON THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH'S PREMARKET NOTIFICATION REVIEW PROGRAM (1986) [hereinafter PREMARKET NOTIFICATION GUIDANCE DOCUMENT].

316. See 1988 GAO REPORT, *supra* note 4, at 73-74.

PMA approval or reclassification.³¹⁷

It is evident from this description that FDA's policy is to attempt to determine the *comparative* safety and effectiveness of the new and predicate devices, rather than to make a determination that either device is safe and effective in the statutory sense. In theory, the policy should at least keep new products off the market that are potentially worse than the predicate products. Ideally, it would result in a gradual improvement of product quality as newly marketed devices displace older products that, on the whole, are presumably inferior.

The adequacy of this policy depends in large part on the quality of the information FDA requests and receives in premarket notification submissions, and on the Agency's interpretation of inherently ambiguous phrases such as: "same intended use," "same types of questions about safety and effectiveness," and "accepted scientific methods for evaluating" those questions. FDA interprets "same intended use," for example, as meaning not only the same indications for use, but also the "same diagnostic or therapeutic function" — a far broader conception.³¹⁸ In the past, the Agency has sometimes stretched the term "same intended use" almost beyond recognition.³¹⁹ Similarly, the Agency continues to permit "piggybacking" — the tracing of the equivalence chain back through one or more postamendment predicate devices to a preenactment device.³²⁰ These practices have raised concerns that, under the new policy, the proportion of new-model devices of uncertain merit cleared for marketing through the 510(k) process rather than by premarket approval remains much too high.³²¹

317. PREMARKET NOTIFICATION GUIDANCE DOCUMENT, *supra* note 315, at 4-5 (emphasis added). See also Benson, Eccleston & Barnett, *The FDA's Regulation of Medical Devices: A Decade of Change*, 43 FOOD DRUG COSM. L.J. 495, 501-02 (1988).

318. Address by Robert Sheridan, Deputy Director, CDRH Office of Device Evaluation, Food & Drug Law Institute Medical Device Update (June 24, 1987).

319. For example, FDA concluded that a test to diagnose Legionnaire's disease was "substantially equivalent" to a preenactment device even though no such tests existed prior to 1976 and, in fact, the disease itself had not even been identified at that time. 1988 GAO REPORT, *supra* note 4, at 47.

320. Address by Dr. Kshitij Mohan, Director, FDA CDRH Office of Device Evaluation, Food & Drug Law Institute Medical Device Update (June 24, 1987).

321. The following table indicates the percentage of all recent FDA substantial equivalence determinations resulting in a finding that the device was "not substantially equivalent" and thus subject to the premarket approval requirement:

FY 1985	FY 1986	FY 1987	FY 1988 (1s; 6 mos.)
2.8%	2.2%	2.1%	1.5%

MIDYEAR REPORT, FY 1988, *supra* note 265, at 17. The percentage of premarket notification submissions withdrawn or deleted has risen from seven percent in 1977 to 11% in 1986, however. 1988 GAO REPORT, *supra* note 4, at 23. Most deletions of section 510(k) submissions are attributable to manufacturers' failure to respond to FDA requests for information. *Id.* at 64. Withdrawals of submissions may reflect, in part, informal FDA

FDA has strengthened its requirements concerning the information that manufacturers of complex or critical devices must submit to obtain a favorable substantial equivalence determination. In some situations, the Agency requires, in a 510(k) submission, performance testing data that may include data on clinical investigations.³²² Some 510(k) submissions contain information quite similar in nature to that contained in premarket approval applications, although the quantity of clinical data required is typically less in a 510(k) than in a PMA, and the statistical analysis required is less rigorous in the former.³²³ These requirements for expanded premarket notification submissions have given rise to comments that FDA has instituted a system of "mini-PMAs"³²⁴ or "hybrid 510(k)s."³²⁵ Any doubts about FDA's legal authority for requiring such information for a demonstration of substantial equivalence, however, can be answered by reference to FDA's general statutory rulemaking authority.³²⁶

Thus, the Agency's basic response to congressional and public criticism of its reliance on the premarket notification program as the cornerstone of its premarket clearance process has been to strengthen the program's administration and clarify its procedures. However efficiently administered, though, the premarket notification program is untenable as a de facto substitute for the premarket approval process designed by Congress for new-model medical devices. The program bypasses the public accountability mechanisms Congress built into the law, prevents the Agency from attaching often-needed regulatory conditions to its premarket clearances, and will ultimately stretch the meaning of

signals to manufacturers that a premarket notification is likely to be found not substantially equivalent.

322. Performance testing data are required if (1) "a new device has an important descriptive difference in comparison to marketed devices within its type, and it is *not* clear from an initial review that the device has an intended use or technological change that makes it not substantially equivalent; or (2) the new device has descriptive characteristics that are too imprecise to guarantee that comparability in performance will be achieved even if the new device is produced as described." PREMARKET NOTIFICATION GUIDANCE DOCUMENT, *supra* note 315, at 12 (emphasis in original).

FDA currently obtains clinical data in only three percent of all section 510(k) submissions, and in only five percent of submissions for treatment devices. 1988 GAO REPORT, *supra* note 4, at 72, 76-77.

323. See, e.g., Kahan, *Medical Device Clinical Studies*, 311 CLINICA 13, 13 (1988). A recent GAO report surveying more than 100 premarket notification submissions found "[o]nly one trial with random [patient] assignment." 1988 GAO REPORT, *supra* note 4, at 77. Random assignment is an important method for assuring that a study is well-controlled. See, e.g., T. COULTON, STATISTICS IN MEDICINE 253-62 (1974).

324. E.g., Kaplan, *supra* note 292, at 162.

325. E.g., Kahan, *supra* note 157, at 522.

326. FDCA § 701(a); 21 U.S.C. § 371(a) (1982). For a convincing analysis of the legality of FDA's data requirements for premarket notifications, see Cooper, *supra* note 42, at 195-200.

"substantial equivalence" beyond recognition.

FDA's premarket notification program, as an ersatz premarket approval process, renders the Agency unaccountable for its decisions and is therefore procedurally unsound.³²⁷ The program excludes the public from its rightful place in the premarket clearance process for Class III devices,³²⁸ since substantial equivalence determinations are made without benefit of advisory panel review. As a recent GAO report has concluded, the program generates inadequate documentation of the basis of FDA determinations.³²⁹ Premarket notification decisions avoid the statutory requirement for a summary of safety and effectiveness information about marketed products,³³⁰ depriving product users and patients of critical comparative performance information. The lack of any justification for FDA's determinations violates the basic requirement that the Agency "articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'"³³¹ Combined with the lack of official notice of the making of substantial equivalence determinations,³³² the failure to provide any explanation for those determinations effectively insulates agency marketing decisions from administrative and judicial review, and from adequate oversight by Congress and the public.³³³

Moreover, FDA's overwhelming reliance on the 510(k) process prevents the Agency from using safeguards that Congress authorized FDA to employ, when necessary, as part of the premarket approval process. For example, FDA has statutory authority under the premarket approval provision to restrict the sale, distribution, or use of licensed devices.³³⁴ Likewise, the Agency can impose postmarketing surveillance requirements on manufacturers of Class III devices as a condition of

327. See *infra* notes 392-99 and accompanying text.

328. See *supra* notes 46-58 and *infra* notes 346-52, and accompanying text.

329. 1988 GAO REPORT, *supra* note 4, at 67, 77.

330. FDCA § 520(h)(1); see *supra* notes 65-71 and accompanying text.

331. *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). See also Garland, *Deregulation and Judicial Review*, 98 HARV. L. REV. 505, 542-49 (1985); Shapiro & Levy, *Heightened Scrutiny of the Fourth Branch: Separation of Powers and the Requirement of Adequate Reasons for Agency Decisions*, 1987 DUKE L.J. 387 (suggesting constitutional dimension to requirement of adequate reasons); *infra* notes 397-99 and accompanying text.

332. Unlike notices of approvals and denials of premarket approval applications, substantial equivalence determinations are not published in the Federal Register. While they are generally available under the Freedom of Information Act, 5 U.S.C. § 552, and are often reported in the trade press, this information may not be in public currency until after the product enters distribution in commerce.

333. See 1988 GAO REPORT, *supra* note 4, at 67 (difficulty of oversight of premarket notification process).

334. FDCA § 515(d)(1)(B)(ii); see 21 C.F.R. § 814.44(e)(1)(iii) (1988).

granting premarket approval.³³⁵ Such safeguards may become all the more necessary with the widespread entry on the market of home-use diagnostic test kits, which may be susceptible to incorrect use by lay persons. (When such products come on the market through 510(k) submissions rather than the premarket approval process, product labeling is not reviewed by an advisory panel, with its consumer representative to help render technical jargon understandable.)³³⁶ But even if such restrictions and conditions are essential to the safe use of the product or to the Agency's mission of overseeing the public's experience with the device, the Agency lacks authority to impose such restrictions and conditions as a concomitant of a "substantial equivalence" finding.³³⁷

Finally, FDA's premarket notification program raises concerns of logic. How long can the Agency convincingly maintain that generation after generation of new-model device is "substantially equivalent" to its horse-and-buggy 1976 predicate? As the equivalence chain becomes more attenuated, it becomes incrementally more evident that the structure of FDA premarket clearance policy has as its foundation a regulatory fiction.³³⁸

Defenders of FDA's premarket notification program emphasize its focus on comparative evaluation of new-model devices and currently marketed products. They raise the claim that the end result is a general increase in product quality, as safer and more effective new products oust inferior older products from the market.³³⁹ Proponents of this view argue that reliance on the alleged alternative—a premarket approval process measuring each new product against some abstract and absolute standard of safety and effectiveness rather than against currently marketed products—would have the perverse effect of inhibiting overall

335. 21 C.F.R. § 814.82(a)(2) (1988).

336. See *infra* text following note 348.

337. For example, postmarketing surveillance requirements could well have brought the problems with polyurethane pacemaker leads to FDA's attention in more timely fashion. *Failed Pacemaker Leads*, *supra* note 3, at 265 (FDA analysis). But the leads were cleared for marketing through the 510(k) process as they were found substantially equivalent to the silicone leads previously marketed. *Id.*

FDA can signal a manufacturer that a new-model device must be labeled in a certain fashion in order to obtain a substantial equivalence determination, see 21 C.F.R. § 807.87(e) (1988), or to avoid a misbranding charge, see FDCA § 502(a), (f). However, FDA can implement a broader range of needed controls through restrictions than through labeling. See FDCA § 520(e)(1)(B) (broad discretion allowed FDA in imposing conditions). Also, postmarketing surveillance obligations cannot be imposed through labeling requirements.

338. See Kessler, Pape & Sundwall, *supra* note 28, at 363 ("FDA's extensive reliance on the 510(k) pathway . . . is destined to fail.")

339. E.g., Kahan, *The Evolution of FDA Regulation of New Medical Device Technology and Product Applications*, 41 FOOD DRUG COSM. L.J. 207 (1986).

gains in product safety and effectiveness.³⁴⁰

This line of argument, however, fails to comprehend the actual workings of FDA's premarket approval process. In fact, premarket approval determinations are rarely made on the basis of abstract standards; rather, they routinely involve comparisons of the safety and effectiveness data on the product under review with the performance of competing products currently in use. Moreover, those comparisons are made on the basis of fuller information, and are subjected to a more thorough review, than the comparisons made through the 510(k) program.³⁴¹

3. *The Premarket Approval ("PMA") Process*

On the whole, the premarket approval process (to the extent it has been used) has worked in the fashion Congress intended. Manufacturers are required as a part of product development to document carefully their products' design and principles of operation, sponsor clinical trials to ascertain the products' safety and effectiveness, and subject the information developed to review by both agency staff and a representative panel of nongovernment experts in relevant fields of medicine and biomedical technology.³⁴² Though the process has allowed some injurious products to reach the market,³⁴³ the process does appear to have improved the overall reliability of marketed medical devices.

Since the enactment of the Medical Device Amendments in 1976, about 400 products have come on the market with approved PMA's. Of these, about two-fifths were "new" devices in the statutory sense, while the others were "transitional" products once regulated as drugs.³⁴⁴ In

340. Peter Huber has stated the general argument most eloquently, using examples of regulatory issues outside the fields of medical devices and drugs. Huber, *The Old-New Division in Risk Regulation*, 69 VA. L. REV. 1025 (1983).

341. See *infra* notes 350-51 and accompanying text.

342. See *supra* notes 44-49 and accompanying text.

343. For example, the Bjork-Shiley 60° convexo-concave heart valve, which caused a number of deaths due to a mechanical malfunction, had to be removed from the market. See 2 Med. Devices Rep. (CCH) § 17,947 (1986). See also Letter from FDA Assoc. Commissioner for Regulatory Affairs John Taylor to Baxter Healthcare Corp. (June 3, 1988) (Class I recall of defective Edwards-Duromedics heart valve) (on file with author). An estimated 20,000 valves had already been implanted at the time of the recall, leaving only 6,000 unimplanted valves to be returned to the manufacturer. See 2 Med. Devices Rep. (CCH) § 15,050.4 (1988).

344. FDA CDRH, REPORT OF THE PMA CRITICISMS TASK FORCE 46 (1985). Examples of "new" devices are the extracorporeal shockwave lithotripter; alpha-fetoprotein tests for detection of neural tube birth defects; most blood tests for postoperative cancer monitoring; and implantable cardiac defibrillators. "Transitional" devices include intraocular lenses; soft contact lenses; certain intra-uterine devices; and gonorrhea diagnostic tests. PMA applications for contact lenses and lens solutions have constituted a large proportion of FDA's transitional device PMA caseload. REPORT OF THE PRE-AMENDMENTS PMA CRITICISMS TASK FORCE, *supra* note 7.

each of these two statutory categories, a few products constituted trail-blazing innovations, while most represented relatively minor ("me-too") variations on previously marketed products.³⁴⁵

A hallmark of the premarket approval process is the influential character of advisory panel reviews. After an initial postenactment period in which panel members were educated on their legal responsibilities and the standards they were to apply, FDA has regularly followed its advisory panels' recommendations regarding approval of PMA applications.³⁴⁶ It is the author's experience, having served on one advisory panel and having appeared before several others, that some panel members scrutinize the technical information and clinical data with care, though there are always panel members who are less than diligent.

The tenor of FDA staff's preliminary evaluation of a PMA application often influences a panel's deliberations, but panelists usually raise criticisms not addressed by FDA staff in the preliminary assessments.³⁴⁷ Even when the panel recommends approval, it will often suggest changes in the conditions for marketing—suggestions routinely carried out by the Agency. For example, a company's expansive claimed indications for use of its product are commonly scaled back to conform to what the data in the application substantiate.³⁴⁸ Instructions and product

345. Of course, even "minor" variations often have a substantial effect on safety and effectiveness.

346. During the author's five-year tenure as consumer representative on the Immunology Devices Advisory Panel, the Agency adhered to the substance of every one of that panel's recommendations regarding approval or nonapproval of PMA applications.

Exceptions do occur. For example, FDA licensed three gonorrhea screening kits in 1979, contrary to an advisory panel's recommendations. After an administrative hearing occasioned by a Health Research Group petition, the Agency affirmed its decision to allow marketing of the products but revised and strengthened the products' labeling. See *Gonorrhea Antibody Test Kits*, 48 Fed. Reg. 335 (1983). On the other side of the coin, an advisory panel recommended approval of a PMA for an antibiotic bone cement, but the FDA (citing the absence of well-controlled clinical studies demonstrating effectiveness) denied the application. Howmedica, the manufacturer, petitioned for administrative review of the denial, but after a hearing before a separate expert advisory committee, which recommended denial, FDA affirmed its decision to reject the application. *Surgical Simplex P Antibiotic Bone Cement*, 53 Fed. Reg. 11,711 (1988). FDA has also overturned a number of PMA approval recommendations from the Ophthalmic Devices Advisory Panel, and has scaled back some of the panel's labeling recommendations. Personal communication from Charles Kyper, Director, FDA CDRH Premarket Approval staff (Aug. 11, 1988).

Advisory panels are also charged with reviewing product development protocols, the alternate route provided by Congress to a marketing license for Class III devices. See *supra* notes 83-85 and accompanying text. But manufacturers have virtually never used product development protocols, preferring the PMA process. See 1988 GAO REPORT, *supra* note 4, at 36 n. 11.

347. See, e.g., Transcript of Immunology Devices Advisory Panel meeting (June 17-18, 1985) (Centocor CA 19-9 and CA-125 tumor marker applications).

348. See, e.g., Transcript of Immunology Devices Advisory Panel meeting (Dec. 9, 1985) (recommendation limiting labeling claims for Hybritech Tandem-R PSA assay).

performance descriptions given in the labeling are frequently revised so that consumer and professional users will have a clearer understanding of the product's limitations and proper use. Sometimes postapproval studies are required to substantiate the product's usefulness in ordinary clinical settings not tested in premarket trials conducted under relatively optimal conditions.³⁴⁹

Panel deliberations generally involve comparisons of performance characteristics of the product under consideration with those of products already on the market. (Manufacturers typically include such comparisons as a centerpiece of their applications.³⁵⁰) This comparative analysis is particularly central to panel consideration of applications for "me-too" products. Even for the occasional trailblazing product representing a genuinely new technological application, panel discussions generally will focus on where the new product would fit in with existing treatment or diagnostic modalities. In this fashion, the premarket approval process in practice guards against the danger that new products that are less risky than currently marketed products will be kept off the market by application of an absolute rather than a comparative safety standard.³⁵¹ Advisory panels are composed of people with a practical sense of how technology is used in the world outside the laboratory, and the safety and effectiveness of new products are typically assessed in that comparative context.

These advisory panel reviews, transcribed and conducted primarily in

349. Immunology Device Panel recommendations for approval of several alpha-fetoprotein test kits for detection of neural tube birth defects, for example, contained all of the elements mentioned in this paragraph. FDA accepted the major points of virtually all such recommendations. See generally the reports of the Immunology Device Panel consumer representative to FDA Consumer Consortium for the years 1982 through 1987 (on file with author).

350. For example, successful applications for new tumor markers—blood tests to detect the recurrence of cancer after initial treatment—invariably include such comparisons when another marker for the same type of tumor is in current use. Likewise, intra-ocular lens PMA applications are handled largely on the basis of a "grid" comparing data from similar lenses. And the cervical cap was recently approved partly on the basis of tests showing its contraceptive effectiveness to be similar to that of the diaphragm. See 2 Med. Devices Rep. (CCH) ¶ 18,029 (1988).

An unfortunate but occasional result of this comparative approach is that considerations of marketing equity may take precedence over scientific standards. For example, FDA has licensed certain tumor markers for broader indications of use than those supported by the data in the applications, simply because similar products were previously approved under the broader indications and the panel believed the new products should not be placed at a competitive disadvantage. An example is the carcinoembryonic antigen (CEA) assay, which is licensed for use in the management of cancer patients in general despite the lack of proof of its clinical utility for breast and ovarian cancer management. See Transcript of FDA Immunology Devices Advisory Panel meeting (June 29–30, 1987).

351. See Huber, *supra* note 340, at 1073–85.

open session,³⁵² are central to the congressional plan for premarket clearance of Class III devices. They add legitimacy to FDA's decision-making process since panel members are broadly representative of, and generally respected among, the relevant medical, laboratory, consumer, and industry constituencies. They also add an indispensable practical leavening to the deliberations of the Agency, which otherwise may rely for its outside input primarily on communications from manufacturers. Finally, they provide a record that can serve as both a justification and a basis for review of the Agency's product licensing decisions.

The premarket approval process, then, is in general substantively superior to the 510(k) process from the standpoints of the quality of scientific review and public accountability. It also permits employment of regulatory controls, such as postmarket surveillance requirements and device restrictions, unavailable to FDA through 510(k) clearances.

Nevertheless, the premarket approval process does consume substantial resources on the part of both FDA³⁵³ and applicants for marketing licenses.³⁵⁴ These costs may inhibit the development of new products, at least by smaller firms, and may have an anticompetitive effect.³⁵⁵ Taking a practical view of the need to conserve scarce resources, proponents of the premarket approval process should be prepared to accept abbreviated reviews of Class III products in many cases, and to concede that some products placed by law in Class III no longer should be required to undergo premarket approval.

Sometimes full advisory panel review of a premarket approval application is unnecessary, as where the product under consideration is a "me-too" device employing principles and design substantially identical to other marketed products already reviewed by the panel and approved by FDA. Where supporting clinical data are well within the range of acceptability and where the application raises no new questions of science or policy, panel review is appropriately abbreviated.³⁵⁶ This course of action speeds the entrance of competitive products on the market without doing harm to the congressionally mandated structure of public

352. See *supra* notes 51-54 & 58 and accompanying text.

353. See *supra* note 277.

354. See *supra* notes 271-73 and accompanying text.

355. See *supra* note 276 and *infra* note 362 and accompanying text (discussions of "regulatory patents").

356. FDA has administratively adopted a "fast-track" system for efficient review of repetitive PMA's for certain "me-too" Class III products—primarily transitional devices such as soft contact lens solutions. Benson, Eccleston & Bartlett, *supra* note 317, at 506 & n. 40. FDA sometimes also conducts abbreviated panel meetings by conference telephone. See 21 C.F.R. § 14.22(g) (1988). Minor supplements to previously approved PMA's are commonly approved by the Agency without panel review.

accountability, as long as the Agency publishes a justification of its action.

By law, all new-model devices are placed into Class III unless found "substantially equivalent." If substantial equivalence determinations are to be phased out, as this Article suggests, FDA would face an enormous burden in reviewing, under standard premarket approval procedures, those products not presenting significant safety or effectiveness questions. Likewise, some contend that many products originally classified in Class III have become well enough established that premarket approval is no longer necessary.³⁵⁷ For these cases, it is important that an accessible and efficient procedure be available for reclassification to Class I or II.

4. Reclassification

A manufacturer of a Class III device may petition for reclassification under one of four provisions of the device law, depending on the basis of the device's Class III designation.³⁵⁸ The statutory standard for reclassification is simply whether the device's characteristics fit the definition of a Class I or Class II product, as the case may be,³⁵⁹ except that reclassification of an "old" preamendment Class III device (or its substantial equivalent) must be "based on new information."³⁶⁰ FDA requires reclassification petitions to be supported by "valid scientific evidence."³⁶¹

At issue in a reclassification proceeding, of course, is whether the proposed new classification would provide a reasonable assurance of the device's safety and effectiveness. Also at stake, however, is the relative market position of companies with approved PMA's for the device in

357. Trade groups representing manufacturers of certain transitional devices, such as the Contact Lens Manufacturers Association, have been particularly vocal in this contention.

358. For devices that are "new" in the statutory sense, the route to reclassification is through a section 513(f)(2) petition. "Old" preamendment Class III devices and their post-amendment substantial equivalents may be reclassified either through a section 513(e) petition or (after FDA proposes a section 515(b) regulation requiring submission of a PMA application) through a request for a change in classification leading to a section 513(e) proceeding. See FDCA § 515(b)(2)(A)(iv), (B). Finally, transitional devices may be reclassified by petition under section 520(1)(2). See *supra* notes 88-92 and accompanying text.

359. See, e.g., FDCA §§ 513(f)(2)(C)(i), 520(1)(2).

360. *Id.* §§ 513(e), 515(b)(2)(A)(iv). FDA interprets "new information" to include "information developed as a result of reevaluation of the data before the agency when the device was classified." See, e.g., Proposed Reclassification of Daily Wear Optically Spherical Hydrogel (Soft) Contact Lenses, 47 Fed. Reg. 53,411, 53,413 (1982); 51 Fed. Reg. 19,608, 19,608 (1986) (cardiopulmonary bypass oxygenator reclassification denied).

361. See 21 C.F.R. § 860.123(a)(6) (1988) (referencing standard of section 860.7(c); *supra* note 82 (explaining "valid scientific evidence").

question versus those without such approval. The former generally have a strong interest in maintaining the Class III status quo, since potential competitors must go through the rigors of a PMA application, at significant cost in time and expense. The latter favor a less stringent regulatory classification in order to lower the barrier to market entry that the PMA requirement represents. The barrier is especially significant because FDA may not use trade secret information submitted in one firm's premarket approval application as a basis for a reclassification decision requested by another firm.³⁶²

FDA has vacillated in its perspective on reclassification decisions, at times proposing reclassification and then later withdrawing the proposal while denigrating the same evidence it had previously endorsed.³⁶³ Some observers have detected a shift from a restrictive to a more lenient agency attitude toward reclassification,³⁶⁴ contrasting past denials of reclassification petitions³⁶⁵ with recent agency encouragement of reclassification efforts for high-technology devices such as magnetic resonance diagnostic devices.³⁶⁶ FDA pronouncements lend some support to this observation,³⁶⁷ and the Agency's 1985 self-study concluded that reclassifications ought to be more widely available, particularly for

362. FDCA § 520(c). This provision is designed to protect the competitive advantage of the originator of the information, thereby encouraging innovation. See HOUSE REPORT, *supra* note 11, at 50; Contact Lens Mfrs. Ass'n v. FDA, 766 F.2d 592, 600 & n.7 (D.C. Cir. 1985). An approved PMA thus gives its holder a kind of "regulatory patent." See Adler, *supra* note 227, at 520; Kahan, *supra* note 42, at 292.

363. See Contact Lens Mfrs. Ass'n v. FDA, 766 F.2d 592, 600 (D.C. Cir. 1985) (rigid gas permeable contact lenses); compare Proposed Reclassification of Daily Wear Optically Spherical Hydrogel (Soft) Contact Lenses, 47 Fed. Reg. 53,411 (1982), with 49 Fed. Reg. 17,523, 17,525-27 (1984) (withdrawal of proposal). See also Adler, *supra* note 227, at 524.

364. See, e.g., Kahan, *supra* note 42.

365. See, e.g., Contact Lens Mfrs. Ass'n v. FDA, 766 F.2d 592 (D.C. Cir. 1985); General Medical Co. v. FDA, 770 F.2d 214 (D.C. Cir. 1985).

366. See Kahan, *supra* note 42, at 302; Magnetic Resonance Diagnostic Device, 53 Fed. Reg. 7575, 7579 (1988) (FDA tentative findings favoring reclassification); Cutaneous Carbon Dioxide (PcCO₂) Monitor, 53 Fed. Reg. 27,878 (1988) (same). See also 53 Fed. Reg. 19,340, 19,340 col. 3 (1988) (FDA initiative to gather data supporting reclassification of total hip prosthesis including ceramic femoral head).

367. Address by James Benson, Deputy Director of the Center for Devices and Radiological Health, Food & Drug Law Institute Medical Device Update (June 25, 1987).

FDA's alleged recent leniency might be difficult to substantiate as an empirical matter. The Agency has not changed its formal standards for reclassification. Kahan, *supra* note 42, at 299. Many reclassification petitions were approved during the early years after the device law was enacted. See, e.g., Kahan, *supra* note 42, at 296-97 (clinical laboratory devices); 47 Fed. Reg. 49,021 (1982) (condom with spermicidal lubricant). A number of others recently have been denied. See, e.g., 51 Fed. Reg. 19,608 (1986) (cardiopulmonary bypass oxygenator); 50 Fed. Reg. 414 (1985) (immunoglobulin test systems). The Agency's stance on reclassification petitions is probably more influenced by the data available on each individual device, and by whether the petition is controverted or uncontested, than by any general change in agency policy.

certain transitional devices once regulated as drugs but for which Class III protections no longer appear necessary.³⁶⁸

One charge leveled at the Agency is that it has required virtually the same amount and quality of evidence to reclassify a device as to grant it premarket approval.³⁶⁹ To the extent this charge is currently accurate,³⁷⁰ it represents a valid criticism. The full panoply of premarket approval requirements is reserved by statute for Class III products. Meeting those requirements confers upon the applicant a private license—the payoff for the applicant's investment in gathering convincing scientific evidence of the product's safety and effectiveness. Congress intended Class II products, by contrast, to be marketed in open competition without requiring the extensive premarket review to which new Class III devices are subject. It would therefore be anomalous to impose a stringent PMA-like evidentiary burden on a firm desiring reclassification of its product into Class II, since the firm would not receive the competitive advantage afforded by an approved PMA.

Therefore, as long as a petitioner demonstrates that the statutory prerequisites for a Class II (or Class I) device are met, FDA should grant reclassification. The burden of proof should simply be to produce the same kind of valid scientific evidence required for an initial classification decision, rather than the heavier burden required to obtain premarket approval.³⁷¹ Under present law, the decision must be made through the

368. FDA CDRH, EXECUTIVE SUMMARY OF THE CRITICISMS TASK FORCES' REPORTS 10-11 (1985).

369. See Kahan, *supra* note 157, at 514; Kahan, *supra* note 42, at 304 (quoting Robert Adler, then-counsel to House Subcommittee on Health & the Environment); 1988 GAO REPORT, *supra* note 4, at 31-32; Contact Lens Mfrs. Ass'n v. FDA, 766 F.2d 592, 601 (D.C. Cir. 1985).

370. FDA's 1985 self-study lent some credence to this assertion. The study concluded (incorrectly) that the law requires FDA to "establish that a device is safe and effective before it can be classified, or reclassified, into any class other than class III." FDA CDRH, EXECUTIVE SUMMARY OF THE CRITICISMS TASK FORCES' REPORTS 6, 10-11 (1985). The implication was that FDA until then had required premarket approval-type proof of safety and effectiveness for reclassification.

In fact, the law allows reclassification as long as the controls in the new classification would provide a reasonable assurance of safety and effectiveness. See FDCA §§ 513(f)(2)(C)(i), 520(1)(2). FDA states that it is now following this less stringent standard. Eccleston & Barnett, *supra* note 317, at 502-03.

371. Caution on this point is necessary. Some classification decisions were based merely upon panel members' experience with and general knowledge about a device, rather than scientific studies. See, e.g., Contact Lens Mfrs. Ass'n v. FDA, 766 F.2d 592, 603 & n.10 (D.C. Cir. 1985). Reliance on such essentially anecdotal evidence concerning any device with significant potential for hazard, however, would seem to violate FDA's own standard for valid scientific evidence: "Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness." 21 C.F.R. § 860.7(c) (1988).

congressionally prescribed process of advisory panel review or notice-and-comment rulemaking, to ensure public accountability.³⁷² Reclassification of transitional devices for which safety and effectiveness evidence is scientifically uncontradicted can be readily accomplished by this process.³⁷³ In accordance with the existing congressional plan, premarket clearance of new-model devices not presenting significant safety and effectiveness questions should also generally be handled through reclassification, rather than by extension of the fiction that the new devices are somehow substantially equivalent to pre-amendment devices.³⁷⁴ If this procedure proves excessively burdensome, a change in the law will be required.

IV. FDA'S WELL-INTENTIONED UNLAWFULNESS

Congress decreed with particularity a premarket clearance process requiring FDA to review specified essential information about Class III devices, obtain advice through an open advisory committee process, make determinations of safety and effectiveness based preferentially (but not exclusively) on well-controlled investigations, summarize for the public the information forming the basis for its determinations, and afford the public an opportunity for review of its decisions.³⁷⁵ Cognizant of the wide variety of regulated products and of the importance of easing market access, Congress designed the process to allow FDA more latitude in the review of devices than of drugs.³⁷⁶ But to guard against abuses, Congress specified that the Agency perform its functions within a procedural structure carefully designed to ensure public accountability.³⁷⁷

Harried by the sheer volume of work, FDA set up a parallel structure, not envisioned by Congress, to handle most new-model device submissions.³⁷⁸ That parallel structure operates in largely unaccountable fashion, bypassing advisory panel consultation and offering no public justification for determinations that, as a practical matter, are not susceptible to administrative or judicial review.³⁷⁹ Under current FDA policy, the parallel structure will likely continue as the Agency's primary

372. See *supra* text accompanying note 93.

373. See, e.g., Kahan, *supra* note 42, at 299 (reclassification of stainless steel sutures). But see Contact Lens Mfrs. Ass'n v. FDA, 766 F.2d 592 (D.C. Cir. 1985) (safety evidence controverted).

374. See *supra* note 366 (magnetic resonance diagnostic devices).

375. See *supra* notes 35-69 and accompanying text.

376. See *supra* notes 72-108 and accompanying text.

377. See *supra* notes 44-108 and accompanying text.

378. See *supra* notes 151-66, 265-68, 283-323 and accompanying text.

379. See *supra* notes 177-81, 327-33 and accompanying text.

product review mechanism for the foreseeable future.³⁸⁰

FDA has essentially reserved the congressionally mandated process for two subsets of new-model products: transitional devices, to which Congress assigned first priority for premarket approval; and new-model devices that do not appear from sponsors' premarket notification submissions to be as safe and effective as similar products on the market and are thus found not substantially equivalent.³⁸¹ The Agency has virtually excluded all other Class III products—preenactment Class III devices, and the vast majority of postamendment new-model products, which are granted substantial, equivalence determinations—from the review process Congress designed.³⁸² The Agency's decision to concentrate its limited resources for intensive review on a small set of new-model products was a rational one in terms of administrative practice. But, however well-intentioned, this decision violates the letter and spirit of the law.

Agencies are granted considerable deference in interpreting their statutory charters.³⁸³ But that deference has limits. An agency is not free to ignore the explicit commands of Congress, ascertainable through the plain language of the law or traditional tools of statutory construction.³⁸⁴ In doing so, the Agency trespasses beyond the boundaries of its authority delegated by Congress.

In *Chevron U.S.A. v. NRDC*,³⁸⁵ the Supreme Court spelled out a two-step method for judicial review of agency statutory interpretations:

First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, . . . the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, . . . the statute is silent or ambiguous with respect to the specific issue, the question for the court

380. See *supra* notes 259–64 and accompanying text. The delay in implementing the congressional dispensation calls to mind the Agency's sluggishness in enforcing the efficacy requirement of the 1962 drug law. See *American Public Health Ass'n v. Veneman*, 349 F. Supp. 1311 (D.D.C. 1972) (prescription drugs); *Cutler v. Hayes*, 818 F.2d 879, 894–99 (D.C. Cir. 1987) (over-the-counter drugs).

381. See *supra* notes 185–86 and accompanying text.

382. FDA has implemented the process in a minor way for a few preenactment products, calling for premarket approval applications for only six of the approximately 150 types of preenactment devices. See *supra* note 259.

383. See, e.g., *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837 (1984); *Young v. Community Nutrition Inst.*, 106 S.Ct. 2360 (1986).

384. *Chevron*, 467 U.S. at 843 n.9.

385. *Id.* at 837.

is whether the agency's answer is based on a permissible construction of the statute.³⁸⁶

Judges and academic scholars have wrangled over the implications of *Chevron* regarding the circumstances in which courts should accord deference to agency interpretations.³⁸⁷ But in the case of medical device regulation, a number of convincing factors point to the conclusion that, under *Chevron*, FDA has overstepped its statutory authority.

Congress has already spoken with clarity and particularity about how Class III devices are to be regulated, as demonstrated above.³⁸⁸ Public participation is built into the process at various points. The Agency is under a statutory obligation to explain the basis for its marketing decisions.³⁸⁹ Administrative and judicial review is to be routinely available.³⁹⁰ But the parallel premarket clearance structure of the Agency's invention bypasses all of these safeguards.³⁹¹ As a "pure question of statutory construction," then, FDA's invention is vulnerable because it is arguably contrary to the plain language and structure of the statute.³⁹²

Conceivably, one might read an "ambiguity" into the law. The provision for temporary FDA acquiescence in the marketing of devices "substantially equivalent" to those in commerce before the Medical Device Amendments were enacted in 1976 contains no clear time limit. It might be argued that FDA's use of this provision as the principal foundation of

386. *Id.* at 842-43 (footnotes omitted).

387. A partial listing of writings, giving a sense of the diversity of approaches on the subject, includes Starr, Sunstein, Willard, Morrison & Levin, *Judicial Review of Administrative Action in a Conservative Era*, 39 ADMIN. L. REV. 353 (1987); Wald, Verkuil, Rabkin, Cutler, Bonfield & Susman, *The Contribution of the D.C. Circuit to Administrative Law*, 40 ADMIN. L. REV. 507 (1988); Starr, *Judicial Review in the Post-Chevron Era*, 3 YALE J. ON REG. 283 (1986); Garland, *Deregulation and Judicial Review*, 98 HARV. L. REV. 507 (1985); Saunders, *Agency Interpretations and Judicial Review: A Search for Limitations on the Controlling Effect Given Agency Statutory Constructions*, 30 ARIZ. L. REV. 769 (1988); Saunders, *Interpretative Rules with Legislative Effect: An Analysis and a Proposal for Public Participation*, 1986 DUKE L.J. 346; Shapiro & Glicksman, *Congress, the Supreme Court, and the Quiet Revolution in Administrative Law*, 1988 DUKE L. J. 819; Pierce, *Chevron and Its Aftermath: Judicial Review of Agency Interpretations of Statutory Provisions*, 41 VAND. L. REV. 301 (1988); Note, *Coring the Seedless Grape: A Reinterpretation of Chevron U.S.A. Inc. v. NRDC*, 87 COLUM. L. REV. 986 (1987); and Note, *The Chevron Legacy: Young v. Community Nutrition Inst. Compounds the Confusion*, 73 CORNELL L. REV. 113 (1987).

388. See *supra* notes 44-108 and accompanying text.

389. FDCA § 520(h); see *supra* notes 65-69 and accompanying text.

390. See *supra* notes 63-64 and accompanying text.

391. See *supra* notes 177-81, 327-33 and accompanying text.

392. *INS v. Cardoza-Fonseca*, 107 S. Ct. 1207, 1221 (1987). See also *ETSI Pipeline Project v. Missouri*, 108 S.Ct. 805 (1988).

its regulatory structure for the foreseeable future is a "permissible construction of the statute."³⁹³

However, Congress evidently did not intend the substantial equivalence provision to play a major long-term role in device regulation. Substantial equivalence determinations were not among the agency "actions . . . that have immediate and substantial impact"³⁹⁴ for which Congress provided judicial review. Thus Congress apparently intended substantial equivalence determinations to have less significance than the other FDA actions listed in the judicial review provision, less even than relatively innocuous actions such as good manufacturing practice variances and disapprovals of investigational device exemptions.³⁹⁵

The absence of open proceedings and public accountability, and the impracticability of obtaining review of agency decisions,³⁹⁶ take FDA's premarket notification process out of the category of instances where deference to the Agency's statutory interpretation is appropriate. The Agency's failure to provide explanations for any of its substantial equivalence determinations is at least as offensive as, and more pervasive as a matter of general agency practice than, the National Highway Traffic Safety Administration's illegal failure to "supply a reasoned analysis" of its rescission of its passive restraint regulation.³⁹⁷ The premarket notification process undercuts both Congress' clearly expressed concern for procedural fairness and the principle of judicial review as a check on agency power.³⁹⁸ These "danger signals" indicate that whatever the latitude that Congress intended to grant the Agency in implementing the medical device law, the Agency has strayed outside the permissible zone.³⁹⁹

FDA's general rulemaking authority is an inadequate basis for the Agency's premarket review program. True, the Agency's rulemaking power is broad.⁴⁰⁰ True, FDA has duly promulgated regulations setting

393. *Chevron*, 467 U.S., at 843.

394. HOUSE REPORT, *supra* note 11, at 53.

395. FDCA § 517(a). See *supra* notes 178-81 and accompanying text.

396. See *supra* note 290.

397. *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 57 (1983).

398. One post-*Chevron* case in which the Supreme Court struck down an agency's statutory interpretation was *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986). In that case the Court emphasized the "strong presumption that Congress intends judicial review of administrative action," which can be overcome "only upon a showing of 'clear and convincing evidence' of a contrary legislative intent." *Id.* at 670-71 (citation omitted). No such showing is possible in the case of the medical device law.

399. See generally Note, *Coring the Seedless Grape: A Reinterpretation of Chevron U.S.A. v. NRDC*, 87 COLUM. L. REV. 986, 999-1007 (1987).

400. FDCA section 701(a) gives the Secretary authority "to promulgate regulations for the efficient enforcement of [the] Act."

out its premarket notification process.⁴⁰¹ But those regulations as applied have had the effect of displacing the congressionally mandated structure for premarket review. Use of the general grant of rulemaking authority to subvert the particularized requirements of the statute is illegitimate.

FDA's premarket notification process does not offer an appropriate instance for deference to the Agency's interpretation based on its specialized expertise. Admittedly, the Supreme Court has granted FDA substantial latitude in interpreting its statutory charter, most recently in *Young v. Community Nutrition Institute*.⁴⁰² a case involving unavoidable environmental contaminants in food. But that case (like the landmark decision in *Chevron*) concerned agency discretion on a science policy decision within the Agency's special competence — "whether tolerance levels [for the contaminants] are necessary to protect the public health."⁴⁰³ In the case of the premarket notification system for medical devices, by contrast, the Agency's interpretation implicates far more than a health policy choice best left to the discretion of the expert agency. The procedures FDA has contrived largely bypass the express strictures of the congressionally mandated open public process, so a court attentive to the accountability principle should have no obligation to uphold the Agency's system. Deference on the basis of expertise is particularly unwarranted when the Agency fails to "articulate a satisfactory explanation,"⁴⁰⁴ or for that matter any explanation whatsoever, for the individual decisions reached as a result of the process.

Finally, defenders of the premarket notification process might

401. 21 C.F.R. § 807.81-.97 (1988).

402. 106 S. Ct. 2360 (1986). In *Community Nutrition*, the Court upheld the Agency's construction of statutory language arguably requiring the setting of tolerances for poisonous or deleterious substances unavoidably added to food. FDA interpreted the law to permit the Agency not to promulgate tolerances, if the Agency considered them unnecessary for the protection of public health. After quoting the *Chevron* formula, the Court determined the language in question to be ambiguous, and found FDA's interpretation "sufficiently rational to preclude a court from substituting its judgment for that of the FDA." *Id.* at 2365.

403. *Id.* at 2365.

Professor Saunders, criticizing the *Community Nutrition* decision, has argued that the ambiguity the Court discovered in the statutory language does not require administrative expertise for its resolution, but merely tools of statutory construction; thus, the decision cannot be explained as founded on deference to administrative discretion within the Agency's area of special competence. Saunders, *Agency Interpretations and Judicial Review: A Search for Limitations on the Controlling Effect Given Agency Statutory Constructions*, 30 ARIZ. L. REV. 769, 780-81 (1988). In fact, however, the ambiguity in the law (assuming generously that one actually exists) presented FDA with a clear policy choice: to regulate the contaminants at issue by promulgating formal tolerances, or to decline to set the regulatory machine in motion. As a practical matter, the Agency's interpretive choice was no doubt profoundly affected by its assessment of the hazards of the contaminants in question in comparison with other regulatory priorities.

404. *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

advance a separate justification based on cases such as *McIlwain v. Hayes*⁴⁰⁵ upholding long agency delays in carrying out tasks assigned by statute, on the ground that decisions about where to expend limited agency resources are matters for agency discretion. The argument would essentially be that FDA's decision to adopt a slow pace in issuing section 515(b) regulations, which call for submission of premarket approval applications for preamendment Class III products and their post-amendment substantial equivalents, is within the Agency's discretion. By implication, FDA's use of premarket notification as an alternate screening process pending completion of the section 515(b) regulations is justified.

The argument has some plausibility, since agencies have wide discretion in setting their regulatory agendas and applying their limited resources to the tasks they deem most urgent.⁴⁰⁶ That discretion is not unlimited, however, as the D.C. Circuit has emphasized in a series of important cases both recognizing claims of unreasonable agency delay and often compelling agencies to speed up their activities.⁴⁰⁷ Evaluating a claim of excessive FDA delay in drug regulation, that court in *Cutler v. Hayes* trenchantly observed that

the consequences of dilatoriness may be great. . . . "[T]here must be a 'rule of reason' to govern the time limit to administrative proceedings. Quite simply, excessive delay saps the public confidence in an agency's ability to discharge its responsibilities and creates uncertainty for the parties, who must incorporate the potential effect of possible agency decisionmaking into future plans." Moreover, unjustifiable delay may undermine the statutory scheme and could inflict harm on individuals in need of final action. In some cases, agency delay may collide with the right to judicial review.⁴⁰⁸

405. 690 F.2d 1041 (D.C. Cir. 1982) (food color dyes).

406. See *Sierra Club v. Gorsuch*, 715 F.2d 653, 658-59 (D.C. Cir. 1983); *NRDC v. SEC*, 606 F.2d 1031, 1056 (D.C. Cir. 1979); cf. *Heckler v. Chaney*, 470 U.S. 821 (1985) (enforcement discretion).

407. See, e.g., *Public Citizen Health Research Group v. Brock*, 823 F.2d 626 (D.C. Cir. 1987); *Farmworker Justice Fund, Inc. v. Brock*, 811 F.2d 612, 631-33 (D.C. Cir. 1987), vacated as moot, 817 F.2d 890 (D.C. Cir. 1987); *Public Citizen Health Research Group v. Commissioner*, 740 F.2d 21 (D.C. Cir. 1984); *Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150 (D.C. Cir. 1983); *Potomac Elec. Power Co. v. ICC*, 702 F.2d 1026 (D.C. Cir. 1983); *MCI Telecommunications Corp. v. FCC*, 627 F.2d 322 (D.C. Cir. 1980). See also *Public Citizen v. Heckler*, 653 F. Supp. 1229 (D.D.C. 1986); Note, *Judicial Review of Agency Delay and Inaction Under Section 706(1) of the Administrative Procedure Act*, 55 GEO. WASH. L. REV. 635 (1987).

408. 818 F.2d 879, 896-97 (D.C. Cir. 1987) (footnotes omitted) (quoting *Potomac Elec. Power Co. v. ICC*, 702 F.2d 1026, 1034 (D.C. Cir. 1983)).

The *Cutler* court set out three factors to assist "in determining whether an agency's foot-dragging constitutes unreasonable delay"⁴⁰⁹ under the Administrative Procedure Act.⁴¹⁰ The first is the "length of time since the agency came under a duty to act," and the "prospect of early completion."⁴¹¹ Congress in 1976 "required" all Class III devices to obtain premarket approval,⁴¹² although it left open a grace period of about five years⁴¹³ or more before preamendment products and their substantial equivalents could be removed from the market for failure to meet the requirement. There is no prospect that FDA will complete the regulations calling for premarket approvals in the foreseeable future: the Agency has scarcely begun.⁴¹⁴

The second *Cutler* factor is the reasonableness of the delay "in the context of the statute" which authorizes the agency's action.⁴¹⁵ In considering this factor, the court is to "estimate the extent to which delay may be undermining the statutory scheme."⁴¹⁶ As demonstrated above, in the case of premarket clearance policy for Class III medical devices, the effect of FDA's delay is nothing less than the subversion of the congressionally prescribed structure of agency accountability to the public.⁴¹⁷

The final factor in *Cutler* is what substantive consequences may result from the Agency's delay. The court noted that "delays that might be altogether reasonable in the sphere of economic regulation are less tolerable when human lives are at stake."⁴¹⁸ At issue here is the unproven safety and effectiveness of over 140 types of device in the device law's most risk-laden category.

In view of these considerations, the claim that FDA's premarket clearance policy is within the bounds of agency discretion cannot withstand scrutiny. FDA's regulatory regime combines a misinterpretation of the law with excessive delay in fulfilling the Agency's statutory obligations. However well-intentioned in terms of conservation of agency resources, the review structure FDA has invented is an unacceptable departure from the democratic principles explicitly legislated by

409. *Cutler*, 818 F.2d at 897.

410. The Administrative Procedure Act directs the reviewing court to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

411. *Cutler*, 818 F.2d at 897.

412. FDCA § 515(a).

413. See *supra* notes 187-91 and accompanying text.

414. See *supra* notes 259-60 and accompanying text.

415. *Cutler*, 818 F.2d at 897 (quoting *Public Citizen Health Group v. Auchter*, 702 F.2d 1150, 1158 (D.C. Cir. 1983)).

416. *Cutler*, 818 F.2d at 897-98.

417. See *supra* notes 177-81, 194-201, 327-38 and accompanying text.

418. *Cutler*, 818 F.2d at 898 (quoting *Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150, 1157 (D.C. Cir. 1983)).

Congress. The Agency is not empowered to rewrite the law, however proper its motivations. That is the prerogative of Congress.

V. REFORM OF THE MEDICAL DEVICE LAW

Representatives John Dingell (D-Mich.) and Henry Waxman (D-Cal.), chairmen, respectively, of the House Committee on Energy and Commerce and of its Subcommittee on Health and the Environment, last autumn pushed a major revision of the medical device law through the House of Representatives: the Medical Device Improvements Act of 1988.⁴¹⁹ Although the bill was opposed by the Reagan Administration⁴²⁰ and was not approved by the Senate, it is likely to form the basis of legislation to be considered in 1989. Consequently, its major provisions are analyzed below in some detail, and suggestions for strengthening some provisions are offered from the perspective of enhancing FDA's administration of the law while preserving the principle of public accountability.

The Waxman/Dingell bill represents the conclusion of the House of Representatives that "FDA has been unable to implement the [medical device] law in the manner that the Congress intended."⁴²¹ To facilitate achievement of the major goals of the regulatory enterprise, the legislation would have changed current law in four main areas: premarket clearance, standards-writing, reporting of device-related deaths and injuries, and FDA authority to act against defective devices on the market.

A. The Premarket Clearance Process

The 1988 Waxman/Dingell bill was designed to focus FDA's limited resources for intensive product review where they are most needed, to move the Class III device review process along at a speedier pace, to clarify and legitimize the Agency's method of substantial equivalence review, and to provide, for the first time, information to the public about some "substantially equivalent" new products. The bill created tension at certain points between the goals of facilitating new-product review and preserving public accountability.

First, the bill would have set deadlines by which the Agency must

419. H.R. 4640, *supra* note 9. Professor Robert Adler, who was counsel to the Subcommittee at the time of the bill's drafting, has set out a persuasive explanation of the need for the legislation. Adler, *supra* note 227.

420. Letter from Health and Human Services Secretary Bowen to Rep. Dingell (June 10, 1988).

421. H.R. REP. NO. 782, 100th Cong., 2d Sess. 10 (1988).

review each "old" Class III type of device to determine whether the premarket approval requirement is still necessary. The premise of the bill was that some types of device, particularly transitional devices formerly regulated as drugs in 1976 and before, may now be sufficiently well established that premarket approval has become an unnecessary burden on the Agency and the industry.⁴²² Within three years in the case of transitional devices,⁴²³ and five years in the case of preamendment Class III devices and their substantial equivalents,⁴²⁴ FDA would conduct a notice-and-comment proceeding for each type of device to determine whether to retain it in Class III or to reclassify it to Class I or II. (FDA would first require manufacturers of these devices to submit known adverse safety and effectiveness information to the Agency, for use in the review.⁴²⁵) The statutory standard dividing Class II from Class III devices would be revised, making it slightly easier than at present to reclassify a device down to Class II.⁴²⁶

Second, to accelerate the process of gathering and evaluating safety and effectiveness information for preamendment and substantially equivalent devices that still pose sufficient uncertainty to merit Class III status, the bill would have required FDA to "establish by regulation a schedule for the promulgation, as promptly as is reasonably achievable, of a section 515(b) regulation for each device" still in Class III.⁴²⁷ Although the Agency would have discretion in setting the deadlines in the schedule under what might be called the "APAIRA" standard,⁴²⁸ failure to meet those deadlines "would constitute agency action unreasonably delayed."⁴²⁹

Third, the bill would have defined and legitimized the substantial equivalence review of premarket notification submissions. For a new-

422. *Id.* at 25.

423. H.R. 4640 § 4(c)(2) (proposed FDCA § 520(i)(5)(B)). The bill provides a two-year deadline which can be extended at FDA's discretion by an additional year. H.R. 4640 § 4(c)(2) (proposed FDCA § 520(i)(5)(B)-(C)).

424. *Id.*

425. H.R. 4640 § 4(c)(1) (proposed FDCA § 515(i)(1)-(2)). FDA decisions would be reviewable only through a reclassification petition. *Id.*

426. A device would fall into Class III under the proposed law only if "insufficient information exists to determine that a performance standard is appropriate to assure the safety and effectiveness of the device," rather than, as under current law, if "insufficient information exists for the establishment of a performance standard" to provide such an assurance. See *id.* § 5(a)(2) (proposed amendments to FDCA § 513(a)(1)(C)) (emphasis added).

427. H.R. 4640 § 4(c) (proposed FDCA § 515(i)(3)). The schedule would have to be promulgated within a year of the completion of the five-year classification review. *Id.*

428. "As promptly as is reasonably achievable."

429. H.R. REP. NO. 782, 100th Cong., 2d Sess. 25 (1988). Such a finding could subject FDA to court-ordered sanctions under the Administrative Procedure Act, 5 U.S.C. § 706(1). See *supra* note 404.

model product to be considered substantially equivalent to a predicate device already on the market, the new-model device first would have to have the "same intended use" as the predicate device.⁴³⁰ Under this Waxman/Dingell approach, new-model products with new technological characteristics would be compared, not to products on the market in 1976, but rather to "comparable devices which are currently being sold in interstate commerce."⁴³¹ Only if the manufacturer demonstrated that the new-model device was "as safe and effective"⁴³² as the comparable device, could FDA grant a substantial equivalence determination. Manufacturers' submissions would need to include all known adverse safety and effectiveness data.⁴³³ To establish equivalence, FDA could require that clinical data also be submitted.⁴³⁴ If clinical data were required, the manufacturer would need to prepare a detailed summary of the data, including adverse health effects. FDA would then release that summary to the public after making its determination, whether the device was found substantially equivalent or not.⁴³⁵

Fourth, the bill would have revised the premarket approval process, increasing its administrative efficiency at some potential cost to public accountability. FDA would be permitted to dispense with some of the previously required elements of a premarket approval application, if it determined on the basis of valid scientific evidence that those requirements had already been met. The Agency would be required to give a public explanation of this determination in its summary of safety and effectiveness data accompanying the product's approval.⁴³⁶ Most significantly, advisory panel review of premarket approval applications would become discretionary rather than mandatory, unless the applicant requested review.⁴³⁷

There is little question that the Waxman/Dingell proposed revision of

430. H.R. 4640 § 4(b)(1) (proposed FDCA § 520(m)(1)(A)-(B)).

431. *Id.* § 4(b)(1) (proposed FDCA § 520(m)(1)(B)). The bill's standard in this respect is similar to current FDA practice. See H.R. REP. NO. 782, 100th Cong., 2d Sess., at 22-23 (1988); *supra* notes 315-21 and accompanying text.

432. H.R. 4640 § 4(b)(1) (proposed FDCA § 520(m)(1)(B)).

433. *Id.* § 4(b)(2) (proposed FDCA § 513(f)(3)).

434. *Id.* § 4(b)(1) (proposed FDCA § 520(m)(1)(B)).

435. *Id.* § 4(b)(1) (proposed FDCA § 520(m)(2)). This provision was strongly opposed by the Reagan Administration, which stated: "[W]e do not understand what purpose would be served by making manufacturers' summaries available to the public." Bowen letter, *supra* note 420, at 3.

436. H.R. 4640 § 4(a)(2) (proposed amendment to FDCA § 515(c)(1)). If one device received such a determination, all others of the same type would be accorded the same treatment unless FDA determined for good cause that any should not. *Id.*

437. *Id.* § 10(c) (proposed amendment to FDCA § 515(c)(2)). Competitors, medical groups, or consumer organizations would lack the applicant's power to obtain review by the advisory panel. Advisory panel review requested by the applicant could still be denied if the application substantially duplicated information previously reviewed by the panel. *Id.*

the premarket clearance process generally would have reduced the Agency's review burden. Whether the 1988 bill would have provided a net gain in public accountability is more doubtful.

On one hand, under the Waxman/Dingell approach, some substantial equivalence determinations would at last be accompanied by safety and effectiveness information permitting purchasers, physicians, and patients to evaluate and compare new-model products' performances. However, this information would be available only for those products for which FDA requested clinical data as part of the premarket notification submissions.⁴³⁸ At present, FDA obtains clinical data for only three percent of 510(k) submissions.⁴³⁹ Performance data other than clinical data will be significant for many users and potential purchasers and should be released for all products cleared through premarket notification review. Otherwise, the unacceptable status quo, under which FDA makes the vast majority of its decisions without explanation or adequate documentation, would continue.⁴⁴⁰

Moreover, substantial equivalence determinations would continue to be made without public participation. This is so even when a premarket notification submission involves important questions of public information—as will frequently be the case, for instance, with home-use diagnostic test kits—or involves science policy. For example, though the bill itself was silent on the meaning of "same intended use" (one essential criterion for a finding of substantial equivalence), the House committee report accompanying it would have sanctioned a very broad reading of the term. According to the report, a new-model device could be found substantially equivalent even if its intended use claim bore no relation to the labeled or promoted intended uses of the predicate device, as long as the new-model device's variant intended use was "scientifically documented as being safe and effective and is widely accepted."⁴⁴¹ While it is conceivable that such a claim may in some cases be valid, it is precisely the function of an expert public advisory committee to inform the Agency about the legitimacy of such claims. Likewise, issues relating to the scientific validity of clinical data presented in premarket notification submissions⁴⁴² will sometimes make outside expert review advisable. At the least, the law should give FDA explicit authority to convene the appropriate advisory panel on a discre-

438. *Id.* § 4(b)(1) (proposed FDCA § 520(m)(2)).

439. 1988 GAO REPORT, *supra* note 4, at 72 (Table 4.10). Only five percent of 510(k) submissions for treatment devices contained clinical data. *Id.* at 76–77.

440. *Id.* at 67, 77.

441. H.R. REP. NO. 782, 100th Cong., 2d Sess., 22–23 (1988).

442. *See supra* note 323 and accompanying text.

tionary basis to review such claims, when they raise questions of public importance.

The changes to the Waxman/Dingell bill suggested above would enable the Agency to create a record facilitating administrative and judicial review of its substantial equivalence determinations. While the presumption should be that those determinations are in fact reviewable,⁴⁴³ neither the present law nor the Waxman/Dingell bill clearly says so. The House report on the bill provided an indication of congressional intent of reviewability,⁴⁴⁴ but new legislation should make that conclusion explicit.

One part of the bill, if enacted, could significantly refocus FDA's resources: the classification review provisions for transitional devices and for preamendment Class III devices and their substantial equivalents. (These provisions would also represent a triumph for small device manufacturers seeking to avoid the expense and uncertainty of mounting the clinical trials necessary for premarket approvals.⁴⁴⁵) To the extent that the classification review process is carried out faithfully by FDA in accordance with valid scientific evidence, resources currently expended on unnecessary premarket approvals could be more fruitfully channeled to review new technologies with uncertain potential. The danger in the classification review would be if FDA sweeps dozens of types of device out of Class III in a mass, haphazard housecleaning. These are products once judged lacking in proof of safety or effectiveness by both an expert advisory panel and FDA itself, and it behooves the Agency to conduct a careful, device-by-device review. The provision for public comment on proposed reclassifications, and the prospect of congressional oversight and repeated criticism if newly reclassified devices turn out to be public hazards, should mitigate the possibility of agency errors.

Reflecting congressional concern with the halting pace of FDA's calls for safety and effectiveness information on preamendment Class III devices and their substantial equivalents, the Waxman/Dingell approach seeks to speed up the process.⁴⁴⁶ But rather than setting specific deadlines in the legislation for completion of the task, the 1988 bill left it to the Agency to promulgate the premarket approval requirements "as

443. *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670-71 (1986); see *supra* note 398.

444. See H.R. REP. NO. 782, 100th Cong., 2d Sess. 23 (1988) ("A determination . . . that a device is substantially equivalent to another device is a final agency action . . ." and therefore reviewable.).

445. See *id.* at 25. The leading industry proponent of these provisions in the congressional maneuvering over the bill was probably the Contact Lens Manufacturers Association.

446. See *id.* at 24-25.

promptly as is reasonably achievable."⁴⁴⁷ Though this language at least conveyed a sense of congressional urgency, recent experience suggests that it left sufficient latitude such that court proceedings could be necessary to move the Agency along.⁴⁴⁸ If an absolute legislative deadline is infeasible, perhaps the hazard to public health consequent upon agency delay could be limited. For example, Congress could mandate that no further substantial equivalence determinations be predicated on any "old" Class III type of device subsequent to a specified date, such as two years after completion of the classification review. After that date, new-model devices would either undergo premarket approval or obtain reclassification under a newly-relaxed Class II standard.⁴⁴⁹ preferably under a streamlined process but at the least requiring a public justification by the Agency.

One of the more disturbing and unbalanced features of the Waxman/Dingell proposal was the provision making advisory panel review of premarket approval applications discretionary rather than mandatory. It is true that some applications for "me-too" products present no new issues of science or policy; panel review of these applications can appropriately be abbreviated or perhaps even dispensed with.⁴⁵⁰ However, under the language of the 1988 Waxman/Dingell bill, FDA would have excessive discretion to do away with panel review of any or all premarket approval applications, not just repetitive ones. The sole exception would be if the applicant (not other interested parties) requested panel review and if the application did not "substantially duplicate" information previously reviewed by the panel. A solution that would be more fair to non-applicants (e.g., competitors, medical groups, consumer organizations) and more faithful to the principle of public accountability would be to continue mandatory panel review except for applications that FDA finds substantially duplicative of those a panel has previously reviewed.

B. The Standards-Writing Process

Under the Waxman/Dingell approach, the procedure for establishing a performance standard would be sufficiently simplified so that Class II designation would have more than illusory meaning. All the current obfuscatory procedures concerning applications for standards, acceptance of existing standards or of offers to develop standards, and qualifications

447. H.R. 4640 § 4(c)(1) (proposed FDCA § 515(i)(3)).

448. See, e.g., cases cited *supra* notes 380 & 407.

449. See *supra* note 427; H.R. 4640 § 5(a).

450. See *supra* note 356 and accompanying text.

for offshoots.⁴⁵¹ would be repealed. In their place would be substituted a relatively straightforward notice-and-comment procedure, preceded by an opportunity for firms whose products would be subject to a standard-writing proceeding to request reclassification.⁴⁵² This proposal, conceptually akin to but less drastic than legislation offered by the Reagan Administration in 1987,⁴⁵³ would breathe life back into Class II, although it is unlikely that more than a few of the vast number of device types within that classification would become subject to standards during this century. The proposal would enable FDA to focus its standards-development resources on the highest-priority Class II devices and would lend to the Agency's efforts at least some prospect for success.

C. Reporting of Potentially Device-Related Deaths and Injuries

Responding to the GAO report about inadequacies in FDA's system for reporting on incidents involving potentially defective devices,⁴⁵⁴ the House-passed legislation would have taken a number of steps (strongly opposed by the Reagan Administration)⁴⁵⁵ to improve the Agency's reporting system. Under the Waxman/Dingell approach, hospitals, ambulatory surgical facilities, and nursing homes would be required to report all potentially device-related deaths, life-threatening illnesses and injuries, and serious device malfunctions to the device manufacturer and ultimately to FDA.⁴⁵⁶ To encourage liability-fearing health care facilities

451. See *supra* notes 129-50 and accompanying text.

452. H.R. 4640 § 6 (proposed amendment to FDCA § 514).

453. The Reagan Administration proposal would have abolished Class II entirely, but would have provided for development of a performance standard for any device at FDA's discretion through notice-and-comment proceedings accompanied by advisory panel review. S. 1928, 100th Cong., 1st Sess., 2, 3 (1987).

454. See 1986 GAO REPORT, *supra* note 4; see also notes 209-266 and accompanying text.

455. The Administration viewed the paperwork burden for both FDA and reporting facilities as excessive, and the utility of the information to be reported as "marginal" or "counterproductive." See Bowen letter, *supra* note 420, at 1-3.

456. H.R. 4640 § 2(a) (proposed FDCA, § 519(b)(1)). Deaths would be promptly reported to FDA directly, as well as to the manufacturer. Life-threatening illnesses and injuries would initially be reported only to the manufacturer, though FDA could require direct reporting to the Agency. Serious device malfunctions would be reported to the manufacturer. Manufacturers would investigate all reports received, winnow them, and send FDA all confirmed reports of device-related deaths, injuries, or malfunctions as required by section 519(a) and its implementing regulations. *Id.* § 2(a) (proposed FDCA § 519(b)(6)); see 21 C.F.R. § 803 (1988). As a check on the completeness of manufacturers' reports to FDA, health care facilities would send quarterly summaries to FDA of their reports to manufacturers. H.R. 4640 § 2(a) (proposed FDCA § 519(b)(1)(D)); see H.R. REP. NO. 782, 100th Cong., 2d Sess., 16-18 (1988).

FDA objected to the hospital reporting provision on the ground that the resulting increase in reports of device problems would create an enormous burden for agency personnel. But GAO concluded that FDA's forecast was "biased and not representative" of typical hospi-

to carry out their reporting obligations, these reports would be confidential and could not be admitted in evidence in private civil actions.⁴⁵⁷ Subsequent manufacturers' reports to FDA would be disclosed to the same extent currently allowed under the Freedom of Information Act,⁴⁵⁸ and would be admissible in private civil actions to the extent allowed by the law of the governing jurisdiction.

To discourage health care facilities from flouting the reporting obligation, the Waxman/Dingell legislation would prohibit them from retaliating against employees for submitting reports on potential device hazards.⁴⁵⁹ Facilities could also be subject to a \$10,000-a-day fine, up to \$500,000, for failure to report.⁴⁶⁰ But FDA's authority to levy the fines would not have taken effect for four years following enactment, and would have been triggered only if the Agency either reported a lack of substantial compliance by any of the three covered categories of health care facilities⁴⁶¹ or failed to report to Congress on compliance within the four years.⁴⁶²

Plugging one hole in the current law,⁴⁶³ the Waxman/Dingell reforms would have required FDA to include independent distributors in its

tals' likely reporting behavior, thereby exaggerating the number of personnel needed to analyze the new reports. GENERAL ACCOUNTING OFFICE, MEDICAL DEVICES: FDA'S FORECASTS OF PROBLEM REPORTS AND FTEs UNDER H.R. 4640, 4 (1988).

457. H.R. 4640 § 2(a) (proposed FDCA § 519(b)(2)-(3)); H.R. REP. NO. 782, 100th Cong., 2d Sess. 18-19 (1988).

458. 5 U.S.C. § 552; H.R. REP. NO. 782, 100th Cong., 2d Sess. 19 (1988). The House Report stated: "It is appropriate for public access to adverse health and safety information reported to the FDA pursuant to this law to be governed under the policy reflected in . . . Public Citizen Health Research Group v. FDA, 704 F.2d 1280 (D.C. Cir. 1983)," a decision calling for relatively liberal disclosure of device hazard information. *Id.*

459. H.R. 4640 § 2(a) (proposed FDCA § 519(b)(4)). Such employees would have a federal cause of action for violation of their rights. *Id.* § 2(b)(2) (proposed amendment to FDCA § 302(a)). An earlier draft of the legislation would have permitted FDA to assess a fine of up to \$50,000 against hospitals for retaliating against employees. H.R. 2595, 100th Cong., 1st Sess. § 2(a) (1987) (proposed FDCA § 519(b)(5)(B)). That provision disappeared from H.R. 4640 in a legislative trade-off. Sanctions against employers for retaliating presumably would be limited either to whatever remedies state law provides for wrongful discharge, or to remedies developed by federal courts in section 519(b)(4) litigation as a matter of federal common law.

460. H.R. 4640 § 2(a) (proposed FDCA § 519(b)(5)(A)).

461. "Substantial compliance is to be determined separately for each of the three classes of facilities—hospitals, ambulatory surgical facilities, and nursing homes. If facilities within one of those three classes are found not to be in substantial compliance with the reporting requirement, the civil money penalties will take effect with respect to that class of facilities." H.R. REP. NO. 782, 100th Cong., 2d Sess. 20 (1988).

If FDA initially determined that a class of facilities was in substantial compliance, the Agency could later by regulation revoke that determination and subject those facilities to civil penalties. H.R. 4640 § 2(d)(2)(B)(iii)(II).

462. *Id.* § 2(d)(2)(B)(i), (iii)(I). GAO was to push FDA to report accurately, by doing its own study of compliance just before FDA's report was due. *Id.* § 2(f).

463. See *supra* note 225 and accompanying text.

reporting regulation.⁴⁶⁴ The 1988 bill would not, however, have affected commercial laboratories or doctors' office laboratories, neither of which are now required to report malfunctions in diagnostic products. Manufacturers and distributors would have to report recalls and field repairs to FDA if they involve violations or health risks.⁴⁶⁵

Reform of the law relating to reporting of device hazards is necessary, and the 1988 Waxman/Dingell bill contained a number of helpful provisions. However, the proposal needs strengthening. First, even if FDA determines after four years that each of the three classes of covered health care facilities *in general* is substantially complying with the reporting requirement, the Agency should have the authority to fine *individual* facilities that continue to flout the law. Second, the fine against facilities that retaliate against employees who report device-related deaths and injuries should be reinstated.⁴⁶⁶ Third, commercial and doctors' office laboratories, not just hospital laboratories, should be required to report to manufacturers about product malfunctions resulting in inaccurate diagnostic information that could lead, in turn, to patients' deaths or serious injuries or illness.

Fourth, preemption of state law relating to admissibility in private civil actions of institutional records is uncalled for where it does not serve the purposes of the federal device law. It is understandable that health care facilities' reports should be inadmissible in actions *against the reporting entity or its personnel*, in order to encourage compliance with the reporting requirement. But the 1988 Waxman/Dingell bill's prohibition of the disclosure and use of the reports in any civil action, including actions against the manufacturer of the device in question, was broader than necessary to advance that goal.⁴⁶⁷ If such reports are of sufficient relevance and reliability to be admissible as a matter of state law, Congress should not interfere with their use in establishing the facts

464. H.R. 4640 § 3.

465. *Id.* § 7(c) (proposed FDCA § 518(d)).

466. See *supra* note 459.

467. In fact, this approach may create an incentive for a manufacturer, upon receiving a confidential injury report from a hospital, not to investigate the report for fear that the device hazard might be confirmed. Confirmation would require the manufacturer to send FDA a section 519(a) report, which would be disclosable under the Freedom of Information Act, whereas under H.R. 4640 the unconfirmed hospital report would not be disclosable. By contrast, making the hospital report both disclosable and admissible (while maintaining the confidentiality of the hospital, its personnel, and its patients) would encourage the manufacturer to make a full investigation in order either to exonerate the device or to correct any flaws.

of individual personal injury cases against manufacturers of possibly defective products.⁴⁶⁸

D. FDA Authority Concerning Defective Marketed Devices

The last major provision of the 1988 Waxman/Dingell bill amplified FDA authority to require repair, replacement, or refund of defective products already on the market. FDA has been reluctant to use its authority under section 518 of the current law, in part because the Agency apparently believes that it would have difficulty proving one of the criteria for issuance of an order under that section: that "there are reasonable grounds to believe that the device was not properly designed and manufactured with reference to the state of the art as it existed at the time of its design and manufacture."⁴⁶⁹ H.R. 4640 would have permitted the Agency to go to court to seek a repair, replacement, or refund remedy even if the device was state of the art when designed and manufactured, as long as the device presented an unreasonable risk attributable to the manufacturer or others in the distribution chain and neither notification of users nor the manufacturer's response is sufficient to resolve the problem.⁴⁷⁰

FDA would surely find helpful the additional authority that the proposed legislation would have provided.⁴⁷¹ Patients and physicians using defective devices would have occasion to welcome FDA action taken under new authority of this kind. In one respect, however, the 1988 proposal was perplexing: FDA determinations that a device presents an "unreasonable risk," or that reasonable grounds exist to believe the device met the state of the art at the time of design and manufacture, would be inadmissible for any purpose in private civil actions.⁴⁷² This provision, unexplained in the House report, has no apparent purpose other than to forbid jurors from learning of the judgments of the federal institution in the best position to judge. Even more than the provision making health care facility reports inadmissible, this language would serve

468. Product liability actions, of course, are an important adjunct to federal regulation as a social risk assessment mechanism. Among the most interesting recent works on this topic is Furrow, *Governing Science: Public Risks and Private Remedies*, 131 U. PA. L. REV. 1403 (1983).

469. FDCA § 518(b)(1)(A)(ii). Given the deference properly accorded the Agency on matters of judgment within its area of expertise, *see Chevron*, 467 U.S. 837, the Agency's hesitancy in asserting its view of "reasonable grounds" for these purposes is somewhat surprising. *But see* Adler, *supra* note 227, at 526-29 (arguing that section 518 procedures leave FDA "hogtied").

470. H.R. 4640 § 7 (proposed FDCA § 518(b)(1)(C)-(E)).

471. *See, e.g., Failed Pacemaker Leads*, *supra* note 3.

472. H.R. 4640 § 7(a) (proposed FDCA § 518(b)(1)(C) (last sentence)).

only to interfere with the operation of the nation's civil law courts.

VI. CONCLUSION

Any assessment of FDA's implementation of the medical device law should be guided by the compass of the law's goals. The two major objectives of the law are the protection of public health through risk prevention and the encouragement of technological innovation.⁴⁷³ Congress directed FDA to pursue and reconcile these sometimes contradictory goals through a system carefully designed to ensure that the Agency be publicly accountable for its actions. This Article has attempted to demonstrate that FDA has departed widely from the structure of accountability that Congress created. But if the Agency's past and continuing variations from the letter of the law have been necessary to achieve the law's two fundamental purposes, perhaps any disparagement of the Agency's regulatory program ought to be correspondingly muted.

Few would question that technological innovation has flourished since the Medical Device Amendments were enacted in 1976. One could debate, however, the extent to which the plethora of new products can be attributed to a relatively lax regulatory system or to other factors, such as the liberal Medicare reimbursement system for capital expenditures⁴⁷⁴ and the high-technology culture prevalent in much of American medicine. But let us posit for the sake of argument that FDA's implementation of the device amendments has earned at least a passing grade in encouraging biomedical innovation.⁴⁷⁵

In contrast, the extent to which the goal of protection of public health through risk prevention has been achieved is entirely open to question. As documented in congressional hearings and reports,⁴⁷⁶ device failures have been widespread. Because of the past inadequacy of FDA's reporting system,⁴⁷⁷ it is unclear how much damage defective devices have wrought. As a general matter, one might speculate that the gradual replacement on the market of older devices with newer ones has increased the overall level of safety in medical practice. But whether such an increase, if real, is of the magnitude Congress and the public

473. See *supra* note 20 and accompanying text.

474. See, e.g., Kessler, Pape & Sundwall, *supra* note 28, at 361, 363-64; OFFICE OF TECHNOLOGY ASSESSMENT, DIAGNOSIS RELATED GROUPS (DRGs) AND THE MEDICARE PROGRAM: IMPLICATIONS FOR MEDICAL TECHNOLOGY (1983).

475. See Foote, *Coexistence, Conflict, and Cooperation: Public Policies Toward Medical Devices*, 11 J. HEALTH POL., POLICY & L. 501, 503 & nn. 27-29 (1986).

476. See *supra* notes 1 & 3; see also *supra* note 343.

477. See *supra* notes 209-26 and accompanying text.

expected from enactment of the medical device law can never be known.

These questions about public health protection should serve to focus public attention on the procedures FDA has employed for the review of medical devices. Some things are clear about FDA's regulatory enterprise. First, it has been carried on chiefly by a process of the Agency's invention, a process bearing at best only a superficial resemblance to the regulatory structure Congress designed. Second, that process has permitted FDA to perform its premarket review function in relatively efficient fashion. Third, the process has been destructive in many respects of the law's fundamental axiom of public accountability.

This regulatory history tends to buttress claims that American science policy decision-making has been shifting, to some extent, from a democratic approach incorporating public participation, exemplified by the environmental, health, and open government legislation passed by Congress during the Nixon and Ford administrations,⁴⁷⁸ to a technocratic process dominated by an expert elite more concerned with efficiency than with accountability.⁴⁷⁹ With regard to FDA's regulatory program for medical devices, the question must be raised: Has the cost in undermining democratic processes been worth the gain, however conjectural, in technological innovation allegedly spurred by the regulatory shortcuts, and the demonstrable savings in agency resources? Those who share the author's understanding that public participation in agency decision-making generally enhances the quality of scientific review and broadens the agency's perspective on regulatory issues,⁴⁸⁰ must reject the suggestion. Any reform of the structure of the medical device law aimed at

478. See *supra* note 70.

479. See, e.g., D. DICKSON, *THE NEW POLITICS OF SCIENCE* 5-6, 219-20, 300-06 (1984). One need not endorse Dickson's suggestion that greater public participation may perversely reduce democratic control over science policy by disguising existing power structures, *id.* at 258, to recognize the merit of his description of the "reascendancy of the technocratic approach," *id.* at 220. In fairness, it should be noted, however, that recent examples of democratic science policy decision-making do exist. See, e.g., Emergency Planning and Community Right-to-Know Act of 1986, 42 U.S.C. §§ 11.001-050 (Supp. V 1987).

480. Although the range of opportunities for public participation in FDA decision-making has been dramatically limited by the Agency's interpretation of the medical device law, within that restricted scope, public input has occasionally had an important and, I believe, beneficial impact. For a few examples of public participation affecting medical device regulation, see, e.g., *supra* notes 5 (listing Health Research Group petitions, reports, and testimony), 68 (gonorrhea screening test), 235 (alpha-fetoprotein regulation proposal initiated in part by Health Research Group petition), 261 (petition for issuance of section 515(b) regulations), 303 (critique of substantial equivalence policy), 343 (defective Bjork-Shiley heart valves removed from market after Health Research Group exposé), 346-49 (consumer participation on advisory panel), and 458 (congressional committee approval of *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280 (D.C. Cir. 1983)). The list could, of course, be vastly expanded by reference to activities of other public interest, professional, and industry organizations.

rationalizing the Agency's task must maintain the principle of public accountability as a central tenet.