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Closing the Loopholes in the Regulation of Medical Devices: The Need for Congress to Reevaluate Medical Device Regulation

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NOTE

CLOSING THE LOOPHOLES IN THE REGULATION OF MEDICAL DEVICES: THE NEED FOR CONGRESS TO REEVALUATE MEDICAL DEVICE REGULATION

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INTRODUCTION

Recent high-profile failures of medical devices manufactured by Guidant[1] and other companies have highlighted the need to revisit medical device regulation. These are not isolated instances. The Food and Drug Administration (FDA) estimates that problems with medical devices cause 300,000 deaths and injuries a year.[2] The FDA, which is responsible for the pre- and post-market regulation of medical devices, bills itself as the "Nation's Foremost Consumer Protection Agency."[3] Despite the Agency's proclaimed role as a consumer protection advocate, the FDA has lost sight of that goal regarding medical devices. The current statutory and regulatory scheme for medical devices is rife with loopholes that place patients at increased risk of injury or death. The FDA has become willing to trade careful pre-market review of medical devices for a quicker introduction of new devices into the market. This Note proposes that Congress should reevaluate the current statutory and regulatory scheme in which the

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[1] *See, e.g.*, Barry Meier, *Internal Turmoil at Device Maker as Inquiry Grew*, N.Y. TIMES, Feb. 28, 2006, at A1.

[2] Ross Kerber, *FDA Halts Expansion of Network to Monitor Medical Device Safety: Agency Backs Off Goal of Linking 500 Hospitals to System Aimed at Early Detection of Problems*, BOSTON GLOBE, July 14, 2005, at D1.

[3] FOOD & DRUG. ADMIN., DEP'T HEALTH & HUMAN SERVS., FDA'S GROWING RESPONSIBILITIES FOR THE YEAR 2001 AND BEYOND (2001), http://www.fda.gov/oc/opacom/budgetbro/budgetbro.html.

FDA functions to determine whether an alternative statutory framework for approving medical devices would better protect medical device users.

Part I of this Note outlines a factual situation involving a recent lawsuit against a hospital and Steris, a device manufacturer, as well as a factual situation involving Guidant, a manufacturer of pacemakers. The Steris lawsuit was in response to an infection outbreak traced to a sterilizer for bronchoscopes that affected several patients. The nature of the device defects discussed in Part I illustrates some of the current problems facing the FDA and the consumers it is supposed to protect. Part II describes the different pre-market processes the FDA uses to ensure new medical devices are safe and effective before allowing device manufacturers to market them. That section will also discuss the policy rationales behind the pre-market controls and some of the problems they raise. Part III examines some of the post-market controls in place that are intended to ensure that a device remains safe and effective once on the market. It also raises some of the issues that undermine the ability of the FDA to effectively regulate devices on the market. Part IV suggests proposals for reforming the current system of medical device regulation.

I. FACTUAL SCENARIO: FAULTY DEVICES SLIPPED THROUGH REGULATORY SYSTEM CRACKS

According to news reports, a bacterial outbreak occurred among sixteen patients at Allegheny General Hospital (AGH) in Pittsburgh in the fall of 2002.[4] One patient died as a result of the infection.[5] The hospital claimed the infections resulted from problems with a bronchoscope cleaning machine manufactured by Steris, the System I sterilizer.[6] The hospital alleged two problems with the device. First the hospital argued that the filters that were supposed to sterilize the water used to wash the bronchoscopes were ineffective.[7] Second, Steris allegedly failed to provide adequate notice about defects in connectors that attached the bronchoscopes to the sterilizer, and the hospital was not adequately notified of the recall of the connectors.[8]

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[4] *See, e.g.*, Christopher Snowbeck, *AGH Blames Sterilizer Maker for Outbreak That Killed 1, Sickened* 15, PITTSBURGH POST-GAZETTE, Jan. 22, 2003, at B8, *available at* http://www.post-gazette.com/healthscience/20030122scopes4.asp.

[5] *Id.*

[6] *Id.* Bronchoscopes are "small, flexible tubes about the width of a pencil that are threaded through a patient's nose or mouth into the upper airways and lungs." *Id.*

[7] *Id.*

[8] *Id.*

Steris could not produce letters documenting that it communicated the recall information to the hospital.[9]

The hospital further alleged that the FDA had previously expressed concerns to Steris regarding the bronchoscope cleaning machine filters and connectors.[10] Steris claimed it addressed FDA questions about the filters in 2002, and the FDA failed to follow up on Steris's response. Steris considered the issues resolved.[11] The hospital also claimed that Steris interfered with attempts to investigate the source of the outbreak; a Steris representative visiting the hospital allegedly removed the sterilizer filters and threw them in a sink, which made testing impossible.[12]

Steris, in turn, blamed the hospital, stating that its "analysis . . . indicated the cause was improper hospital operating procedures in using the equipment."[13] The company also stated it was unaware of any other hospitals ceasing to use the sterilizer.[14]

The FDA investigated the dispute between Steris and the hospital but ended its investigation in May 2003 without reaching a decision. The agency could not "pinpoint a cause for the outbreak."[15] Frustrated, two groups of patients and their families sued the hospital for negligence in March 2004.[16] The groups also alleged negligence against Steris.[17]

Interestingly, in April 2003, a former Steris employee, Larry Joslyn, made allegations echoing the hospital's argument that defects in the sterilizer resulted in bronchoscopes becoming contaminated.[18] In a suit for wrongful discharge, Joslyn alleged that Steris's sterilization system failed to "properly sterilize hospital equipment as represented in label claims" because of "a systematic contamination problem."[19]

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[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] *See id.*

[13] *Id.*

[14] Luis Fabregas & Marisol Bello, *Finger-Pointing Follows AGH Deaths*, PITTSBURGH TRIB.-REV., Oct. 12, 2003, *available at* http://www.pittsburghlive.com/x/tribune-review/specialreports/hospital/s_159477.html.

[15] *Id.*

[16] Luis Fabregas, *AGH Is Sued Over Deadly Outbreak*, PITTSBURGH TRIB.-REV., Apr. 14, 2004, *available at* http://www.pittsburghlive.com/x/search/s_189219.html.

[17] *Id.*

[18] Christopher Snowbeck, *FDA Unable to Decipher Bacterial Outbreak at AGH*, PITTSBURGH POST-GAZETTE, May 14, 2003, at A3, *available at* http://www.post-gazette.com/healthscience/20030514fda0514p5.asp.

[19] Complaint at 7, Joslyn v. Steris Corp., No. CV 03 499847 (C.P. Cuyahoga

Joslyn further alleged that Steris destroyed evidence as a result of Joslyn voicing concerns about the risk posed by Steris's sterilization products.[20]

More troubling are allegations that Steris was already aware of the concerns raised by Joslyn. During the course of his employment, Joslyn allegedly learned that Steris System 1—the system at issue in the AGH case—did not properly sterilize hospital equipment.[21] Joslyn also allegedly learned that this issue had already been raised by regulators.[22] Upon meeting with a Steris vice president to discuss the problems with System 1, Joslyn claims he was told that Steris was aware that "sterilization inadequacies had resulted in the sale of adulterated and misbranded products."[23] Joslyn further alleges that he was told upper management was aware of this problem.[24]

In 2004, a group of patients at Stanford Hospital in California may have been exposed to tuberculosis after a Steris sterilization machine used to sterilize endoscopes failed to work properly.[25] The machine apparently failed to function on certain days.[26] While the risk of exposure to tuberculosis was very slight, after contacting the state Department of Health Services, the hospital learned that eleven other hospitals in California had experienced the same problem.[27] While the

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County Dec. 16, 2003).

[20] *Id.* at 3.

[21] *Id.* at 7.

[22] *Id.*

[23] *Id.* For a definition of adulterated and misbranded in this context, see 21 U.S.C. §§ 351-52 (2006). Adulterated devices include devices "prepared, packed, or held under insanitary conditions," devices that do not conform to FDA good manufacturing practices or performance standards, and devices for which an application for pre-market approval was not timely filed or approved or has been suspended. 21 U.S.C. § 351(a)(1), (e), (f)(1)(A-B) & (h) (2006). A device is considered mislabeled "[i]f its labeling is false or misleading in any particular." 21 U.S.C. § 352(a) (2006).

[24] Complaint, *supra* note 19, at 7. Joslyn later filed a notice of dismissal, and the case was dismissed with prejudice. Journal Entry, Joslyn v. Steris Corp., No. CV 03 499847 (C.P. Cuyahoga County Dec. 16, 2003). Three months prior to the dismissal, though, the parties failed to appear for a case management conference. Journal Entry, Joslyn v. Steris Corp., No. CV 03 499847 (C.P. Cuyahoga County Sept. 11, 2003). A motion to continue the case management conference was filed based on a tentative settlement agreement. *Id.* Regardless of why Joslyn filed a notice of dismissal, his complaint contains serious allegations that are particularly relevant given their similarity to those made by the plaintiffs in the Allegheny General Hospital case.

[25] Dave Murphy, *92 Patients Told of Possible Exposure to TB: Medical Devices in Hospital Surgeries Weren't Sterilized*, S.F. CHRON., Feb. 11, 2005, at B4, *available at* http://www.sfgate.com/cgi-bin/article.cgi?file=/c/a/2005/02/11/BAG6CB9KAK1.DTL&type=printable.

[26] *Id.*

[27] *Id.*

results of the sterilization machine failure at the Stanford Hospital differed from those at Allegheny General Hospital, the same equipment appears to have failed at both places (and possibly others).

The failure of the Steris devices shows the harmful, and even deadly, consequences of the approval and market placement of defective devices. It also highlights the flawed nature of a regulatory system that approves such devices. The Steris device was approved through the 510(k) pre-market notification process, a streamlined approval process that allows a device manufacturer to get the FDA approval needed to market the device quickly.[28] Less than a year after Steris submitted its application to the FDA for approval to market the bronchoscope sterilization system, the FDA found the device to be substantially equivalent[29] to a predicate device and approved it.[30] The device was then placed on the market.

While the Steris case suggests that pre-market controls were inadequate to protect patients, the case of Guidant heart devices demonstrates the inadequacy of post-market controls to ensure device safety. Defects in heart devices manufactured by Guidant are alleged to have resulted in seven known deaths due to short circuits.[31] Guidant recalled the devices in June of 2005, after coming under criticism for not promptly warning physicians and patients about the risk of short circuits.[32] But, as early as 2002, Guidant had learned that one of its heart devices was prone to short-circuiting. This raises serious questions about whether Guidant took any precautions regarding the possibility of other heart devices short-circuiting after it knew of the problem.[33]

The Steris and Guidant cases indicate that defective, and deadly, devices are surviving the FDA approval process and are being marketed to health care providers. The failure of the FDA to notice and

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[28] *See infra* pp. 10-13.

[29] Substantial equivalence is one of the primary mechanisms in the 510(k) process for ensuring the safety and effectiveness of medical devices. *See infra* pp. 13-18.

[30] CTR. FOR DEVICES & RADIOLOGICAL HEALTH, DEP'T OF HEALTH & HUMAN SERVS., 510(K) PREMARKET NOTIFICATION DATABASE (2007), http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=14106. "Approval" in this context means that the device is "substantially equivalent" to another device that is similar to yet another device marketed prior to 1976. 21 U.S.C. § 360e(b)(1) (2000). This implicitly means the approved device is, among other things, safe and effective. *See* 21 U.S.C. § 360e(d)(2) (2000).

[31] Barry Meier, *More Deaths Are Linked To Device*, N.Y. TIMES, Dec. 14, 2005, at C1.

[32] *Id.*

[33] *Id.*

remedy such defects is a function of the shortcomings of the regulatory scheme for medical devices.

II. PRE-MARKET CONTROLS ON MEDICAL DEVICES

The 1976 Medical Device Amendments (MDA) to the Food, Drug, and Cosmetics Act (FDCA) split medical devices into three categories: Class I, Class II, and Class III devices.[34] Class I devices pose "little or no threat to public health."[35] Class II devices "pose a threat to public health . . . but are not generally life-threatening."[36] Tongue depressors are an example of Class I medical devices, while tampons are an example of Class II devices.[37]

This Note is primarily concerned with Class III devices. A Class III device is one that (a) cannot be classified as a Class I or II device because the FDA lacks information to determine if general or special controls are adequate to ensure its safety and efficacy and (b) is intended to be used to support human life or perform an important function in maintaining health or poses a high risk of illness or injury.[38]

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[34] 21 U.S.C. § 360c(a)(1) (2000).

[35] Theresa J. Pulley Radwan, *Meeting the Objectives of the MDA: Implied Preemption of State Tort Claims by the Medical Device Amendments*, 10 J.L. & HEALTH 343, 345 (1995); *see also* 21 U.S.C. § 360c(a)(1)(A) (2000).

[36] Radwan, *supra* note 35, at 345; *see also* 21 U.S.C. § 360c(a)(1)(B) (2005).

[37] Radwan, *supra* note 35, at 345.

[38] 21 U.S.C. § 360c(a)(1)(C) (2000). The entire definition of a Class III device:

> Class III, Premarket Approval.--
> A device which because--
> (i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and
> (ii)(I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or
> (II) presents a potential unreasonable risk of illness or injury,
> is to be subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness.
> If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

Id.

An example of a Class III device is a pacemaker[39] (or a sterilization device). Class III devices are subject to pre-market approval,[40] while Class I and II devices are not.[41]

By their nature, then, Class III devices are more dangerous and possess greater potential for helping patients than other classes of devices. As such, any regulatory scheme designed to ensure device safety must have ensuring the safety and effectiveness of Class III devices as a primary goal.

Medical device manufacturers face a choice between two options when applying for pre-market approval from the FDA to market their devices. The manufacturers can choose the pre-market approval (PMA) process or the pre-market notification (510(k)) process.

A. Pre-market Approval (PMA)

The pre-market approval process is intended to evaluate the safety and effectiveness of class III devices. Given the "level of risk associated with Class III devices," the FDA has determined that "general and special controls" are not enough to ensure the safety and efficacy of Class III devices.[42] PMA, then, is required for Class III devices pursuant to §515 of the FDCA (unless, as discussed below, a 510(k) application may be submitted for the device instead).[43]

The requirements for submitting a PMA are substantial. The FDA has 180 days from receipt of an application to review the application and decide whether to approve or deny the application or send an "approvable" or "not approvable" letter to the applicant.[44] The PMA application must satisfy a lengthy list of requirements.[45] Examples of the requirements include: summaries of non-clinical laboratory studies and clinical studies involving human subjects; an explanation of device functioning; alternative practices or procedures that would also accomplish the goal of the device; the history of the marketing of the device by the applicant and other manufacturers, if known; a detailed description of the device; a bibliography of all reports that the applicant knows about or should reasonably know about regarding the

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[39] Radwan, *supra* note 35, at 345.

[40] 21 U.S.C. § 360c(a)(1)(C) (2000).

[41] *See id.*; 21 U.S.C. § 360e (2004).

[42] CTR. FOR DEVICES & RADIOLOGICAL HEALTH, U.S. FOOD & DRUG ADMIN., PREMARKET NOTIFICATION 510(K): REGULATORY REQUIREMENTS FOR MEDICAL DEVICES, 1-6 (1995).

[43] *Id.*

[44] 21 C.F.R. § 814.40 (2006).

[45] *See* 21 C.F.R. § 814.20 (2005). Section 814.20 includes a list of requirements that is over five pages long.

safety or effectiveness of the device; and an environmental assessment.[46]

The burden placed on Class III device manufacturers and the FDA is heavy. This explains why the less burdensome and more flexible 510(k) process has become favored by the medical device industry and the FDA.[47]

B. Pre-market Notification (510(k) Process)

The pre-market notification process is known as the 510(k) program after the original section of the FDCA dealing with pre-market notification. A manufacturer intending to introduce a medical device into commercial distribution is required to submit a pre-market notification, or 510(k), to the FDA at least ninety days before distribution is to begin.[48] There are two possible outcomes of the FDA 510(k) review process that result in approval of a device. First, a device is approved if it is found to be substantially equivalent to a similar device—known as a predicate device—that was sold prior to 1976.[49] Second, a device is approved if found to be substantially equivalent to another device that was found to be substantially equivalent to a pre-1976 device through the 510(k) process.[50]

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[46] *Id.*

[47] *See* Medtronic, Inc. v. Lohr, 518 U.S. 470, 479-80 (1996). In 1983, a House Report found that 1,000 out of about every 1,100 Class III devices that had been placed on the market since 1976 were approved through the 510(k) process. By 1990, eighty percent of Class III devices were still being introduced to the market through the 510(k) process. *Id.* (citing SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS OF THE H. COMM. ON ENERGY AND COMMERCE, 98TH CONG., MEDICAL DEVICE REGULATION: THE FDA'S NEGLECTED CHILD 34 (Comm. Print 1983); H.R. REP. NO. 101-808, at 14 (1990)).

[48] CTR. FOR DEVICES & RADIOLOGICAL HEALTH, DEP'T OF HEALTH & HUMAN SERVS., THE NEW 510(K) PARADIGM—ALTERNATE APPROACHES TO DEMONSTRATING SUBSTANTIAL EQUIVALENCE IN PRE-MARKET NOTIFICATIONS—FINAL GUIDANCE 1 (1998); *see also* 21 U.S.C. § 360(k) (2000).

[49] 21 U.S.C. § 360e(b)(1) (2000). The entire text of 21 U.S.C. § 360e(b)(1) (2000) states:

> (1) In the case of a class III device which--
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> (A) was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976; or
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> (B) is (i) of a type so introduced or delivered, and (ii) is substantially equivalent to another device within that type, the Secretary shall by regulation, promulgated in accordance with this subsection, require that such device have an approval under this section of an application for premarket approval.

Id.

[50] CTR. FOR DEVICES & RADIOLOGICAL HEALTH, *supra* note 42, at 2-1.

Congress designed the 510(k) process to be less strict than the PMA process.[51] Because Congress sought to avoid withdrawing existing medical devices from the market while the FDA completed the new PMA analysis for them, pre-1976 devices were permitted to remain on the market until the FDA initiated and completed a PMA for the devices.[52] Congress was concerned that device manufacturers of such "grandfathered devices" would monopolize the market while new devices waited to complete the PMA process and wanted to ensure improvements to existing devices could reach the market quickly.[53] Devices "'substantially equivalent' to pre-existing devices," then, were permitted to avoid the PMA process.[54] Congress's intent in creating the 510(k) process to circumvent the PMA scheme appears to have been to create a short-term solution to ensure devices were available to consumers.

In contradiction to the apparent intent of Congress, the "overwhelming majority" of new-model devices are approved through the 510(k) process.[55] This process has been described as "a relatively speedy and efficient procedure for pre-market review and quasi-approval."[56] One scholar notes that "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) pre-market notification."[57]

The U.S. Supreme Court has noted the device industry's heavy reliance on the 510(k) process to place devices on the market quickly and easily.[58] Device manufacturers have embraced the relative speed with which a device can be approved through the 510(k) process.[59] While a PMA review takes an average of 1,200 hours to complete, the § 510(k) process only lasts an average of twenty hours.[60] The Court quoted one commentator, who summarized the situation: "The attraction of substantial equivalence to manufacturers is clear. [Section]

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[51] *See* Medtronic, Inc. v. Lohr, 518 U.S. 470, 477-78 (1996).

[52] *Id.*

[53] *Id.* at 478.

[54] *Id.*

[55] Robert B. Leflar, *Public Accountability and Medical Device Regulation*, 2 HARV. J.L. & TECH. 1, 28 (1989).

[56] *Id.* (quoting Richard M. Cooper, *Clinical Data Under Section 510(k)*, 42 FOOD DRUG COSMETIC L.J. 192, 193 (1987)).

[57] Leflar, *supra* note 55, at 28.

[58] *Medtronic*, 518 U.S. at 479.

[59] *See id.* at 480.

[60] *Id.* at 478-79.

510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly."[61]

The FDA has also come to embrace pre-market notification. While Congress believed the FDA would be capable of quickly completing the PMA process for Class III devices, "the substantial investment of time and energy necessary for the resolution of each PMA application, the ever-increasing numbers of medical devices, and internal administrative and resource difficulties" precluded the FDA from keeping up with the "rigorous PMA process."[62] Section 510(k) submissions, in contrast to PMAs, do not require consultation with an advisory panel, and the FDA does not need to oversee the preparation of a summary of the device's safety and effectiveness.[63] Determinations of substantial equivalence, moreover, are very rarely subjected to administrative or judicial review.[64]

The primary problem with the 510(k) process is the speed and flexibility it allows device manufacturers in placing devices on the market. While this speed and flexibility may be hailed by many as means of allowing manufacturers to quickly provide devices to hospitals and patients, the reality is that it creates a large regulatory loophole that manufacturers exploit in great numbers. The results are devices being placed on the market that average only twenty hours of FDA review.[65] The policy issue raised is whether, having imposed a governmental regulatory scheme, Congress should allow the FDA to spend less than three working days examining a Class III device that can sustain human life or pose an unreasonable threat to life. Given that the FDA itself estimates that 300,000 deaths and injuries a year occur from medical devices, [66] the rational answer seems to be no.

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[61] *Id.* (quoting Robert Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 FOOD DRUG COSMETIC L.J. 511, 516 (1988)).

[62] *Medtronic*, 518 U.S. at 479.

[63] Leflar, *supra* note 55, at 48.

[64] *Id.*

[65] As discussed below, device manufacturers, obviously, must test the device internally before submitting notification to the FDA, and post-market control measures exist. The issue remains, though, whether twenty hours of pre-market review is adequate to protect patients.

[66] *Testimony Before S. Comm. on Appropriations Subcomm. on Agriculture, Rural Development, and Related Agencies*, 107th Cong. (2001) (statement of Bernard Schwetz, Acting Principal Deputy Commissioner, Food and Drug Admin.). This statistic does not distinguish between devices approved through the PMA process and the 510(k) process. It is worth emphasizing, though, that the majority of devices placed on the market are approved through the 510(k) review process.

C. Substantial Equivalence

The substantial equivalence requirement for approving new devices is one of the only pre-market controls included in the 510(k) process.[67] As such, this determination plays a key role in ensuring device safety and efficacy. The FDA may issue an order of substantial equivalence after determining the device at issue "is as safe and effective as a legally marketed device."[68] As part of demonstrating substantial equivalence, the FDA requires device manufacturers to submit the following with its 510(k) notification: For a device that a manufacturer claims is substantially equivalent to a Class III predicate device that was marketed prior to 1990, the manufacturer must submit (1) a summary of any safety and effectiveness problems associated with the type of devices to which the proposed device is being compared and (2) certify that it has searched all information known about the device and similar devices.[69] These requirements, clearly, are far less burdensome than those required for the more stringent PMA process.[70]

Examining the evolution of the concept of substantial equivalence illustrates some of the problems in relying on the determination of substantial equivalence to ensure device safety and efficacy. As noted earlier, the 1976 amendments focused on whether a device was substantially equivalent to a device already on the market in 1976.[71] But the 1976 regulatory scheme generated complaints from observers. The most troubling aspect of the old substantial equivalence requirement was that it "untenably postpone[d] the law's requirement that all Class III devices go through the process required to provide a reasonable

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[67] *See* Benjamin A. Goldberger, *The Evolution of Substantial Equivalence in FDA's Premarket Review of Medical Devices*, 56 FOOD & DRUG L.J. 317, 337 (2001). While substantial equivalence was originally intended to be a "minor feature" in the new 510(k) scheme, it has become the FDA's "primary gatekeeping criterion for medical devices. Although Congress ultimately approved the dominance of this standard, it is a standard adopted more out of necessity than planning." *Id.*

[68] CTR. FOR DEVICES & RADIOLOGICAL HEALTH, *supra* note 48, at 1. ("Section 513(i) of the Act states that FDA may issue an order of substantial equivalence only upon making a determination that the device to be introduced into commercial distribution is as safe and effective as a legally marketed device . . . FDA has, however, discretion in the type of information it deems necessary to meet those content requirements. For example, to allocate review resources more effectively to the highest risk devices, FDA developed a tiering system based on the complexity and the level of risk posed by medical devices. Under this system, the substantial equivalence determination for low risk devices is based primarily on descriptive information and a labeling review, while the decision for higher risk devices relies on performance data").

[69] 21 C.F.R. § 807.87(j) (2006).

[70] *See supra* p. 238.

[71] *See, e.g.*, Medtronic, Inc. v. Lohr, 518 U.S. 470, 478 (1996).

assurance of safety and effectiveness"[72]—it did not require devices to immediately undergo PMA review. The idea of a "'no worse than 1976' marketing threshold" did little to protect device users, since the safety and effectiveness of many pre-1976 predicate devices had not been shown by scientific studies.[73] New products that were "substantially equivalent to dross [were] likely to be dross themselves."[74] In other words, unlike the PMA process, the 510(k) process did not provide satisfactory assurances of a device's safety and effectiveness. The reason for this was that the pre-1976 device that the new device was linked to was never sufficiently shown to be safe and effective.

This problem of the uncertainty over a device's safety and effectiveness was exacerbated by the idea of "equivalence creep:" the FDA allowed a new device to be approved "as long as its sponsor could trace its ancestry to a device on the market before 1976 and [] the equivalency chain was not interrupted by . . . 'unanswered questions' of safety and effectiveness."[75] The FDA, moreover, approved products where the manufacturer "had traced different aspects of the product to different predicate devices," leaving the device with "only a distant resemblance to the preenactment devices to which it was supposedly substantially equivalent."[76] Not only was the safety and effectiveness of the predicate device in doubt, but the new device might not even have been directly related to that device or any pre-1976 device.[77] The FDA's substantial equivalence determination, then, may have said absolutely nothing about the safety and effectiveness of the device.

In 1990, Congress attempted to address some of these problems with the 510(k) process by enacting the 1990 Safe Medical Devices Act (SMDA). The SMDA required the FDA to obtain PMAs for Class III pre-enactment devices.[78] The SMDA also forced a manufacturer arguing that a new device is substantially equivalent to a pre-1976 device that has never been approved through the PMA process to search for all information available on the device's safety and efficacy and reference any adverse findings.[79] The SMDA further required the FDA to issue a formal order declaring that a new device is substan-

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[72] Leflar, *supra* note 55, at 32-33.

[73] *Id.* at 33.

[74] *Id.*

[75] *Id.* at 51.

[76] *Id.*

[77] Goldberger, *supra* note 67, at 325.

[78] *Id.* at 326-27.

[79] Howard M. Holstein & Edward C. Wilson, *Developments in Medical Device Regulations*, in 2 FUNDAMENTALS OF LAW AND REGULATION: AN IN-DEPTH LOOK AT THERAPEUTIC PRODUCTS 257, 267 (David G. Adams, Richard M. Cooper & Jonathan S. Kahan eds., 1997) (citing 21 U.S.C. § 360c(i)(1)(A)).

tially equivalent to a predicate device before it can be placed on the market.[80]

While these provisions seem to represent a step forward in ensuring device safety, however small it might be, the SMDA also retreated a step: it created the current substantial equivalence scheme that allows manufacturers to claim substantial equivalence to any device that was on the market prior to 1976 *or* to a device that has been shown to be substantially equivalent to a pre-1976 device.[81] A device with "different technological characteristics" is still substantially equivalent to a predicate device if information submitted with it indicates that the device is as safe and effective as a predicate device and does not present new questions of safety and effectiveness.[82] Now any type of legally marketed device may serve as a predicate device; a device manufacturer no longer has to look to a pre-1976 device.[83] While the SMDA created some new protections for device consumers, then, such as requiring pre-1976 devices to be submitted to the PMA process and requiring manufacturers submitting a 510(k) notification to cite adverse findings, it also reduced the already light burden on device manufacturers to demonstrate substantial equivalence.

Under the SMDA, the FDA is still limited in what information it can request to show that devices with differing technological charac-

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[80] *Id.*

[81] Holstein & Wilson, *supra* note 79, at 267 (citing 21 U.S.C. § 360c(i)(1)(A)(ii)(II)).

[82] 21 U.S.C. § 360c(i)(A)(1)(ii)(2000).

[83] Goldberger, *supra* note 67, at 326; *see also* 21 U.S.C. § 360c(i)(1)(A)(ii), 360e(b) (2006). 21 U.S.C. § 360c(i)(1)(A)(ii) (2006) describes the substantial equivalence determination process:

> (i) Substantial equivalence.
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> (1)
>
> (A) For purposes of determinations of substantial equivalence under subsection (f) and section 520(l) [21 U.S.C. § 360j(l)], the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device--
>
> (i) has the same technological characteristics as the predicate device, or
>
> (ii) (I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 523 [21 USCS § 360m], that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.

teristics are substantially equivalent. The FDA can only request information that is necessary to making the substantial equivalence determination and must consider the "least burdensome means of demonstrating substantial equivalence and request information accordingly."[84] This means that most manufacturers submit pre-clinical data rather than clinical data,[85] using laboratory studies rather than testing on human subjects, for example.[86] The emphasis on substantial equivalence also encourages manufacturers to focus device testing on demonstrating substantial equivalence. Such testing does not have much value outside of the 510(k) process.[87] The Food and Drug Administration Modernization Act of 1997 reinforced this last problem by limiting FDA data submission requirements to information regarding substantial equivalence only.[88]

The lack of public accountability in the process of determining substantial equivalence also undermines the ability of the 510(k) process to protect the safety of device users. The review for substantial equivalence is an internal agency process that is not open to the public, and no public record of the proceedings exists.[89] Unlike the PMA process, substantial equivalence decisions are not accompanied by summaries regarding the device's safety and effectiveness.[90] Moreover, the FDA does not release information about product performance, leaving device purchasers without reliable information upon which to base purchasing decisions.[91] Both the public and device users, such as health care facilities, then, are unable to review the decision of the FDA regarding one of the key safeguards of the 510(k) process.

While the public at large may not wonder about the transparency of a substantial equivalence determination or the safety and effectiveness of devices,[92] health care administrators and personnel are likely to be motivated to investigate the safety and efficacy of medical devices. The inability of such providers to obtain information to evaluate the functionality of a device can limit their ability to effectively serve those in their care. But, at the same time, consumer culture may put

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[84] 21 U.S.C. § 360c(i)(1)(D) (2000).
[85] Goldberger, *supra* note 67, at 330.
[86] *See* Leflar, *supra* note 55, at 11.
[87] Goldberger, *supra* note 67, at 330.
[88] *Id.* (citing 21 U.S.C. § 360c(i)(1)(D)).
[89] Leflar, *supra* note 55, at 33.
[90] *Id.*
[91] *Id.*
[92] Roger W. Bivans, Note, *Substantially Equivalent? Federal Preemption of State Common-Law Claims Involving Medical Devices*, 74 TEX. L. REV. 1087, 1087 (1996).

pressure on health care providers to embrace the latest medical device technology in spite of a lack of information regarding the device's safety and effectiveness.[93]

The Steris case highlights the problems with relying on substantial equivalence for 510(k) approval. The facts surrounding the failure of the sterilization equipment suggest that some aspect of the System 1 sterilizer was defective. The manufacturer, moreover, may have known about the defects and concealed them. The FDA was not able to determine what caused the illness at AGH. Substantial equivalence review precluded the FDA from inquiring too closely into the functioning of the System 1. The patients and health care providers at AGH and Stanford hospital, then, were left without adequate regulatory protections to help ensure the devices they were using were safe and effective, and no method to independently investigate and evaluate the information submitted to the FDA.

D. Another Type of 510(k) Process: The Special 510(k) for Device Modifications

The regulatory scheme for device modifications is even less burdensome than the 510(k) process for new devices. The FDA's 1998 guidance document regarding the "New 510(k) Paradigm" introduced the concept of the "special 510(k)," which is an additional 510(k) process for approval of device modifications.[94] Device manufacturers are required to submit a new 510(k) for device modifications that could "significantly affect safety and effectiveness."[95]

Manufacturers may create an internal design control system to form the basis of this substantial equivalence determination.[96] Device modifications are subject to the submission requirements of 21 C.F.R. § 807 and the design control requirements of 21 C.F.R. § 820.30.[97] Device manufacturers must have "a systematic set of requirements and activities for the management of design and development, including documentation of design inputs, risk analysis, design output, test procedures, verification and validation procedures, and documentation of formal design reviews. In this process, the manufacturer must ensure that design input requirements are appropriate so the device will

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[93] Judy Foreman, *Book Review: Hope or Hype: The Obsession with Medical Advances and the High Cost of False Promises By Richard A. Deyo and Donald L. Patrick*, 352 NEW ENG. J. MED. 1615, 1615-16 (2005).

[94] CTR. FOR DEVICES & RADIOLOGICAL HEALTH, *supra* note 48, at 3; *see also* Goldberger, *supra* note 67, at 329.

[95] CTR. FOR DEVICES & RADIOLOGICAL HEALTH, *supra* note 48, at 3.

[96] *Id.*

[97] *Id.*

meet its intended use and the needs of the user population."[98] The design specifications resulting from this testing form the basis for the device master record which is subject to inspection by the FDA.[99] But the manufacturers are free to perform this testing internally.

Based on this internal testing, a device manufacturer may then decide that a device modification does not require a new 510(k) submission. A manufacturer can use the FDA guidance document "*Deciding When to Submit a 510(k) for a Change to an Existing Device*" to guide this decision.[100] In deciding whether to submit a new 510(k), the modified device may be compared to a device of the manufacturer that has already been cleared, a more recent legally marketed version of that device, another manufacturer's device, or a pre-1976 device.[101] Changes in a device must be compared collectively to other changes made since the last 510(k).[102] When a particular change, considered together with all previous changes since the last 510(k) clearance, leads a manufacturer to conclude that it must submit a new 510(k), it must submit a new 510(k) incorporating the changes.[103]

The guidance document includes several flowcharts (such as "When to file a 510(k)," "Is it a labeling change?" and "Is it a technology or performance change?") to assist a manufacturer in deciding when to submit a 510(k) for a device change.[104] The flowcharts lead manufacturers to either "New 510(k)" or "Documentation."[105] "New 510(k)" means "strongly consider submitting a new 510(k)," and "Documentation" means "document . . . analysis [of whether a new 510(k) is required] and file it for future reference."[106] A manufacturer, then, is free to change a device and make a decision not to notify the FDA the device has changed. The manufacturer is only required to document testing that is performed in order to show that the device remains safe and effective.[107] Given the time and budget constraints under which the FDA operates, the likelihood that the FDA will regularly inspect the documentation of decisions not to submit new 510(k)s for modified devices is small. And while manufacturers might

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[98] *Id.*

[99] *Id.*

[100] CTR. FOR DEVICES AND RADIOLOGICAL HEALTH, DEP'T OF HEALTH & HUMAN SERVS., DECIDING WHEN TO SUBMIT A 510(K) FOR A CHANGE TO AN EXISTING DEVICE (1997).

[101] *Id.* at 5.

[102] *Id.* at 6.

[103] *Id.*

[104] *See, e.g., id.* at 28-32.

[105] *Id.*

[106] *Id.*at 9.

[107] *Id.* at 8.

seem to have a market-based incentive not to sell updated devices unless they are certain the modified devices are safe, the high number of injuries and deaths that occur annually suggest that defective devices are regularly placed on the market. Perhaps manufacturers recognize that the potential profits from placing a device on the market sooner rather than later outweigh concerns about a potential defect coming to light in a few years.

E. Regulatory "Blacklists"

The FDA was once able to use what device manufacturers characterized as a blacklist to protect consumers. The blacklist consisted of manufacturers in violation of the FDA's good manufacturing practices (GMP) for devices.[108] The FDA would refuse to find substantial equivalence for these manufacturers' devices and defer 510(k) approvals until the manufacturers remedied the GMP violations.[109] Congress explicitly outlawed this practice in Food and Drug Modernization Act, except where the GMP violation "potentially present[s] a serious risk to human health."[110] Congress believed "the 510(k) program [was] intended for premarket review determinations and should not be used as an enforcement tool."[111]

The banning of an enforcement practice that ensured compliance with GMP was unfortunate. The ease with which 510(k)s are granted approval by the FDA, at least compared to the PMA process, does not place much pressure on manufacturers to ensure their devices are truly safe and effective. To require manufacturers to comply with GMP before allowing devices to be sold would be a small and reasonable step to protect device users.

III. POST-MARKET CONTROLS ON MEDICAL DEVICES

The FDA's "relaxed, multi-level premarket review system" was intended to be offset by the strict post-market surveillance system.[112] The pre-market review was meant to function as part of a system under which the FDA would require device users to report defects and problems and aggressively follow up on the reports. That, however, is not the way the system actually works.

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[108] Goldberger, *supra* note 67, at 328.

[109] *Id.*

[110] *Id.* at 329.

[111] *Id.* (citing S. REP. NO. 105-43, at 29 (1997)).

[112] LARS NOAH & BARBARA A. NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY 256 (2002).

A. Device Reporting

One means of post-market surveillance is the requirement under the MDA that all manufacturers submit medical device reports to the FDA "whenever deaths, serious injuries, or dangerous malfunctions occurred in association with the use of a medical device."[113] This requirement was broadened in 1990 to require distributors and user facilities to file medical device reports. As a result, the number of reports has increased dramatically. The FDA now receives more than 100,000 medical device reports a year.[114]

This system sounds better in theory than it works in practice, though. Physicians who encounter device problems are only required to report deaths, not serious injuries, to the FDA.[115] Physician reports of serious injuries are sent to device manufacturers who are then responsible for reporting the problems to the FDA.[116] The response of manufacturers to such individual physician reports often is to blame the physicians using the device.[117] Critics also argue the device manufacturers "downplay" the problem to the FDA.[118]

B. MedSun

A solution to these difficulties that has interested the FDA is the implementation of the Medical Device Surveillance Network (MedSun), a computer network for reporting device problems that links user facilities, such as hospitals.[119] MedSun uses a "representative subset of user facilities to perform a more targeted and thorough collection and investigation of" Medical Device Reports.[120] Physicians at hospitals connected to the network use it to report problems with certain devices directly to the FDA.[121] The reports can then be forwarded

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[113] *Id.*

[114] *Id.* at 256-57; *see* 21 C.F.R § 803.10 (2005). Congress, however, later exempted distributors from reporting requirements. NOAH & NOAH, *supra* note 112, at 273.

[115] Kerber, *supra* note 2, at D1; 21 U.S.C. § 360i(b)(1)(A) (2005).

[116] Kerber, *supra* note 2, at D1; 21 U.S.C. § 360i(b)(1)(B-C) (2005).

[117] Kerber, *supra* note 2, at D1.

[118] *Id.*

[119] NOAH & NOAH, *supra* note 112, at 273-74; *see generally* Neal I. Muni et al., *Challenges in Regulating Breakthrough Medical Devices*, 60 Food & Drug L.J. 137, 139 (2005). "MedSun provides a secure, Internet-based data entry system that automates [the reporting] process and helps gather other additional data that can help FDA, device manufacturers, and clinical facilities proactively address safety concerns before serious injuries or deaths occur." Welcome to MedSun, http://www.medsun.net/about.html (last visited March 9, 2006).

[120] NOAH & NOAH, *supra* note 112, at 274.

[121] *See* Kerber, *supra* note 2, at D1.

to the device manufacturer.[122] MedSun users are directed to enter a brief description of the event, check a box specifying whether the report is an initial one or a follow-up, and enter the date of the event.[123] Participating health care facilities must commit to use MedSun for twelve months and must appoint at least two representatives to use the system.[124] MedSun participants, but not other health care facilities, receive a monthly newsletter summarizing the reports received in the last month.[125]

Despite the fact that the FDA aimed to connect 500 of the nation's 5,000 hospitals to the system, the Agency has stopped at 350 hospitals and will not fund further expansion in the next several years.[126] One member of Congress argued that the lack of further funding is "consistent with the pattern of the FDA under [the Bush administration], to act in a way that is complicit with the entities they're supposed to regulate."[127] The FDA, then, has foregone an opportunity to collect reliable information directly from device users at a relatively low cost.

This is certainly not to say the MedSun reporting program is ideal. It, for example, only sends monthly reports to participating health care facilities, which does not help the majority of providers monitor device safety. But it would help the FDA track device problems, assuming the FDA would decide to act on the reports received.

C. Audits

Given the reluctance of the FDA to gather information about device safety and effectiveness once a device is on the market, one might expect the FDA to at least aggressively review the records that device manufacturers are supposed to maintain regarding complaints, complaint investigations, and decisions not submit a new 510(k) for an updated device. FDA inspections of Class III device manufacturers, by law, are supposed to occur every two years.[128]

But FDA inspections of complaint files, and likely other files, have not been an effective regulatory method. Inspection of files is labor-intensive and inefficient, and inspections every two years are insufficient to discover many problems. Manufacturers, moreover,

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[122] MedSun, Frequently Asked Questions, http://www.medsun.net/faq.asp#one (last visited Mar. 9, 2006).

[123] MedSun, Sample Data Entry Page, http://www.medsun.net/sample.asp (last visited Mar. 9, 2006).

[124] MedSun, Frequently Asked Questions, *supra* note 122.

[125] *Id.*

[126] *See* Kerber, *supra* note 2, at D2.

[127] *Id.* (quoting Congressman Maurice Hinchey).

[128] 21 U.S.C. § 360(h) (Supp. 2006); *see also* Leflar, *supra* note 55, at 38.

have been working to minimize their record-keeping.[129] Considering these problems, there is minimal value in having the FDA spend its resources inspecting manufacturer files prior to a problem arising.

The post-market controls that the medical device regulatory scheme depends on are insufficient. Problems with devices that cause injuries and deaths often go unreported, and required inspections are unlikely to turn up any problems.

IV. POSSIBILITIES FOR REFORM

Given the shortcomings in both pre-market and post-market regulation of Class III medical devices, Congress should revisit the medical device regulatory scheme again. An effective reform package could be implemented that is not overly burdensome to device manufactures and requires only a slight increase in government funding of the FDA.

First, Congress should leave the 510(k) process in place. For almost thirty years the process has provided a means for new and potentially life-saving devices to reach the market and patients quickly. While the relative speed of the 510(k) process, as compared to the PMA, increases the likelihood of defective products reaching the market, prolonging the approval process could delay the marketing of breakthrough technology that could "fill a significant unmet clinical need and/or offer substantial improvements to patient health compared to existing therapies."[130] And requiring all devices to be submitted to the PMA process could greatly slow the pace of technological development in the field of Class III medical devices. Congress, therefore, should merely modify the 510(k) process and post-market processes as a means of ensuring greater device safety.

The substantial equivalence process makes sense, despite the shortcomings discussed earlier, because it efficiently allows a device manufacturer to build on the work it or another manufacturer has done. But Congress should provide the FDA with the discretion to request information beyond that required for the least burdensome means of showing substantial equivalence. Requiring manufacturers to produce greater information is not necessary; the threat of the FDA requesting more information—if it were backed up by real enforcement—would be enough to encourage manufacturers to move away from testing solely for substantial compliance and look more closely at issues of safety and effectiveness. Requiring the FDA to consider

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[129] Leflar, *supra* note 55, at 38-39.

[130] *See* Muni et al., *supra* note 119, at 138.

more information could prove overly burdensome to the Agency. The best option, then, is to allow the FDA to request more information where it has concerns about the safety and efficacy of a device.

Second, Congress should provide the FDA with the discretion to compile a list of manufacturers who violate the FDA's GMPs. If device manufacturers are to be permitted to continue to use the quick and efficient 510(k) process for pre-market approval and the special 510(k) process for device modification (and be trusted to decide when to submit a 510(k) for a device modification), device manufacturers should be required to show that they can adhere to a minimum standard of safety. Observing the FDA's GMPs indicates the manufacturers are willing to accept a basic duty to produce safe devices.

To show the potential effectiveness of such a sanction, consider Guidant's response to the FDA's suspension of further approval of some products due to a lack of "adequate controls, procedures[,] and methods to validate product improvements it was making."[131] Guidant stated that "it would 'promptly respond to the warning letter'" implementing the suspension and claimed it had already completed a majority of the commitments it made following the FDA's inspection three months earlier that identified the violations.[132] Given Guidant's quick response once the suspension was implemented,[133] if the FDA were allowed to compile a list of all manufacturers not in compliance and to not process their applications until the violations were corrected, the potential economic impact on manufacturers would likely result in their becoming more diligent in observing good manufacturing practices.

The FDA, moreover, had sent a warning letter to Guidant a week prior to the letter imposing the suspension threatening regulatory actions such as "seizure, injunction, and/or civil money penalties" without notice.[134] But only a week later, the FDA moved to suspend consideration of new applications rather than implement one of the threatened regulatory actions. This suggests that the FDA believes that suspending applications is an effective remedy for some violations. It

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[131] Vikas Bajaj, *F.D.A. Puts Restrictions on Guidant*, N.Y. TIMES, Dec. 28, 2005, at C1.

[132] *Id.*

[133] It should be noted here that Guidant was in the midst of a bidding war between two potential buyers in December of 2005. *See id.*

[134] Letter from W. Charles Becoat, Dir., Minneapolis Dist., F.D.A., to James M. Cornelius, Chairman & CEO, Guidant Corp., (Dec. 22, 2005), *available at* http://www.fda.gov/foi/warning_letters/g5657d.htm.

also supports Dr. Sidney Wolfe's assertion that the current system of civil fines is rarely used.[135]

Third, to compensate for the 510(k) process, Congress should design a more effective post-market set of controls. The centerpiece of post-market regulation should be the expansion of the MedSun program to include a representative number of hospitals and other health care facilities. Physicians and other health care workers use medical devices daily and are likely to be the first to identify problems with devices and/or defective devices. An effective MedSun program would increase the ability of the FDA to learn of device defects quickly. It would also reduce the need to make biannual inspections of manufacturers.

Putting aside potential political objections to the MedSun program, implementing such a program requires the FDA to invest such scarce resources as money and time in setting up a computer network and encouraging physician participation. The pilot MedSun program, moreover, lagged far behind a similar program set up to monitor new drugs.[136] But, interestingly, at least one reformer is not calling for significantly greater expenditures for device reporting. Dr. Wolfe points out that FDA "cheerleading" efforts significantly increased physician reporting of adverse drug reactions.[137] FDA officials requested that physicians assist them in monitoring post-market drug safety and supplied incentives such as gift certificates to encourage participating in reporting programs.[138] Dr. Wolfe believes a similar approach would successfully encourage physician participation in a program such as MedSun.[139] The MedSun program, thus, should be reborn as a voluntary, web-based reporting system, in which physicians are encouraged to file device reports with the FDA directly.

While there is a minority view against requiring further device reporting, and the medical device industry does not like it,[140] post-market device reporting is the most efficient and effective way for the FDA to learn about device problems. The alternative to such reporting

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[135] Sidney M. Wolfe, Dir., Public Citizen's Health Research Group, Roundtable Discussion at Case Western Reserve University School of Law (Nov. 16, 2005); *see also* Barry Meier, *F.D.A. Says Flaws in Heart Devices Pose High Risks*, N.Y. TIMES, July 2, 2005, at C2.

[136] *See* Marc Kaufman, *Cardiac Devices May Need Replacing; Guidant Confirms Defects in Up to 28,000 Pacemakers*, WASH. POST, July 19, 2005, at D01.

[137] Wolfe, *supra* note 135.

[138] *Id.*

[139] *Id.*

[140] *Id.*

would be waiting for device failures, as in the case of the Steris sterilization system or the Guidant pace makers.

An increased focus on device reporting should be coupled with efforts to make the results of the reports more accessible to the public. This would assist the medical community, and the general public, to make better choices about which devices should be used in treating health problems. The FDA also recently announced it would make safety reports filed by device manufacturers more accessible to the public, although it declined to provide details.[141] At the very least, such a measure would encourage the FDA to be more diligent in monitoring the safety information being provided by the device manufacturers.

Fourth, Congress should institute fines to ensure manufacturers keep detailed files of complaints, testing results, and other data. Random inspections should be made to enforce this policy. Such visits would encourage manufacturers to maintain such records while minimizing the amount of resources that would need to be spent for a new program. The inspections would ensure that manufacturers are adequately documenting decisions whether to submit new 510(k)s for modifications for existing devices. It would also help ensure that manufacturers have adequately researched substantial equivalence and safety and effectiveness since complete evidence of such research must be available to FDA officials.

Congress should also implement heavy punitive fines for defective devices where the manufacturer and/or its agent purposefully or negligently manufactured a defective product. While the FDCA provides for remedies such as recall of and reimbursement for defective devices,[142] additional protections are necessary. Heavy monetary fines would place the burden on the manufacturer, rather than on the FDA, to thoroughly test the device before submitting it to the FDA. This would increase the reliability of the 510(k) process since only devices that the company believes are safe and effective would be submitted to the FDA. The purpose of such a measure would be to deter companies from intentionally placing defective products on the market, or even continuing to market them. While civil suits might be expected to have a similar deterrent effect, they are apparently not effective enough since manufacturers like Guidant and Steris allegedly continued to market defective devices. Congress should create a presumption in administrative proceedings that a manufacturer acted

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[141] Barry Meier, *Plan to Require More Data on Safety Issues*, N.Y. TIMES, Jan. 21, 2006, at C13.

[142] *See* 21 U.S.C. § 360h (2005).

negligently and should be fined when a device is found to not be safe or effective. Such a presumption could be rebutted by evidence showing the manufacturer took reasonable precautions in terms of research to ensure a device is safe and effective.

The counterargument to implementing such a penalty is that placing too great a burden on manufacturers will discourage them from investing in the development of new life-saving technologies. But such penalties would not result in a significant increase in the FDA regulatory structure; it merely would serve as an enticement to device manufacturers to use more care in conducting pre-market research. If the manufacturer took reasonable precautions to ensure the safety and effectiveness of the device, moreover, the manufacturer would avoid paying the fine. A manufacturer merely is burdened to the extent that it must act reasonably, which is not excessive given the potential harm that can result from a defective product.

An alternative proposal would be to sanction individual employees responsible for a defective product being submitted to the FDA or for providing deliberate misleading information that resulted in FDA approval of the 510(k) device. If the FDA found an employee of a device manufacturer was involved in deliberately providing misleading information to the FDA, the FDA could ban the employee from working in the medical device industry for a period of time.[143] This would be similar to the sanctioning approach used by the Nuclear Regulatory Commission (NRC) in punishing employees of NRC-licensed companies.[144]

CONCLUSION

While some observers may be willing to trust the marketplace to discourage device manufacturers from exploiting loopholes in the device regulatory scheme and selling products that are less than completely safe and effective, the reality is that defective products make it into commerce, such as in the case of the Guidant pacemakers and the Steris sterilization systems. By providing a streamlined process for approving medical devices but also implementing a means to discourage abuse of that system, some simple reforms could encourage

[143] Implementing such a penalty as a result of negligence might be unduly harsh given the burden that would be placed on such an employee in terms of finding work after being barred from the medical device industry. Subjecting the manufacturer to fines for negligent or willful misconduct and barring individuals from the industry for deliberate misconduct should be sufficient to discourage misconduct.

[144] *See* 10 C.F.R § 2.202 (2006); *see, e.g., In re* Steven Moffitt, IA-05-054 (Nuclear Reg. Comm. Jan. 4, 2006) (Order).

manufacturers to quickly place safe and effective devices on the market. Any decrease in speed would likely be accompanied by an increase in device safety.