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# **Reassessing Pre-Market Regulation of Class III Medical Devices**

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## **Reassessing Pre-Market Regulation of Class III Medical Devices**

### Abstract

Regulation of medical devices has evolved over the past twenty-five years. Initially, Congress created a regime where the safety and efficacy of all medical devices would be reviewed to varying degrees, depending on the risk posed by the device. Class III devices, the most dangerous class of devices, were to each have a safety and efficacy review. To permit new market entrants on similar grounds as those marketing devices prior to the 1976 Amendments, Congress also created a premarket notification program, under which new devices were regulated in the same way as the pre-Amendment counterparts. However, the premarket notification program has evolved and taken over market authorization for all devices, including Class III devices. This paper argues that the premarket notification program has changed so much that it should be entirely eliminated for Class III medical devices.

## Introduction

Over the past fifty years, technology has advanced by leaps and bounds. Thus, medical devices have likewise made substantial technological advances, and resulted in just as substantial advances in patient care. Although progress in medical device technology has been steady, the law regulating medical devices has been stagnant for long periods. Furthermore, to address new problems, the law regulating medical devices has built upon the existing statutory framework. Thus, the law is composed of temporary fixes, with one patch aimed at fixing a particular problem serving as the foundation for the solution for a wholly different problem. One area in which this patchwork pattern is particularly evident is in the premarket notification process, or 510(k). The program, which was initially adopted to ease the transition from an era of virtually no medical device regulation to one requiring premarket regulation, has morphed into a separate mechanism for marketing approval. However, this mechanism focuses review on an irrelevant question (namely is a new device “substantially similar” to a pre-Amendment device) and creates both motive and opportunity for

manufacturers to largely skirt any type of relevant substantive review.

This paper will argue that the medical devices that pose the most risk, the “Class III devices,” ought to be reviewed only for safety and efficacy. While a determination of “substantial equivalence” may be appropriate for devices which are generally considered safe, this type of review, especially given the way the FDA interprets “substantially equivalent,” is wholly unsuited for devices which are by definition inherently less safe. The American public does and must continue to rely on the Food and Drug Administration (FDA) to protect it from potentially harmful medical products. Thus the FDA should take its charge seriously, and look at Class III devices only for safety and efficacy, not “substantial equivalence.”

## HISTORY

When Congress passed the 1938 Food Drug and Cosmetic Act (FDCA), the Food and Drug Administration (FDA) only had authority to regulate medical devices if they were misbranded (*i.e.*, contained false or misleading claims) or adulterated (*i.e.*, unsanitary or unsafe).<sup>1</sup> Thus, the FDA had no authority to review products *prior* to marketing. Instead, the FDA served as the Consumers Union of the medical device field by ridding the marketplace *after the fact* of devices which were misbranded or adulterated.

In 1976, Congress amended the Food, Drug and Cosmetic Act and authorized the FDA for the first time to regulate medical devices for more than adulteration and misbranding.<sup>2</sup> In 1962, in response to the Thalidomide disaster, Congress passed the Drug Amendments of 1962 permitting premarket review of drugs.<sup>3</sup> At that time, there was also a proposal to permit premarket review of medical devices. However, in order to get the drug amendments passed quickly, Congress removed the sections regulating medical devices from the bill. Therefore, between 1962 and 1976, a few devices that the FDA wanted to regulate were facetiously classified as drugs by the FDA (with judicial support) in order to give the FDA power to regulate them.<sup>4</sup>

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<sup>1</sup>Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1802 (1996).

<sup>2</sup>Medical Device Amendments of 1976.

<sup>3</sup>Merrill, *supra* note 1, at 1764.

<sup>4</sup>*See* United States v. An Article of Drug ...Bacto-Unidisk, 394 U.S. 784 (1969). *See also* PETER BARTON HUTT and

When the 1976 Amendments provided the FDA with statutory authority to actively regulate medical devices prior to marketing, the FDA no longer had to regulate any medical devices as drugs.

By statute, Congress acknowledged that a very broad range of items could, and should, be regulated by the FDA in order to ensure public safety. The definition of “medical device” reflects this intent. The FDCA defines a medical device as:

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is... (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of a man or other animal, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.<sup>5</sup>

Therefore, Congress defined “medical device” as everything but a drug that is remotely related to medicine.

Some devices should clearly be reviewed prior to marketing, such as implantable items like pacemakers and intraocular lenses. After all, it was problems with items like these which spurred a significant amount of pressure toward FDA regulation of medical devices.<sup>6</sup> Implantable items like these should be regulated in order to insure long-term safety to the extent possible and minimize the need for subsequent corrective surgeries and the resulting potential for permanent harm. However, more mundane items such as catheters, needles, and surgical scissors are also regulated to some extent in order to insure patient safety.

One drawback of Congress’s broad definition of “medical device” was that the FDA immediately had an extremely large number of products to regulate. Because of the enormous number of medical devices in existence even in 1976, as well as the difference in complexity between different devices, Congress and the FDA realized that regulating medical devices appropriately (*i.e.*, in a cost- and time-effective manner) would not be conducive to a one-size-fits-all solution. Instead, Congress created a scheme in which devices were

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RICHARD A. MERRILL, FOOD AND DRUG LAW, 732-3 (2d ed. 1991).

<sup>6</sup>H. Rept. No. 853, 94th Congress, 2d Session (1976) *reprinted in* Hutt & Merrill, *supra* note 4, at 743.

divided up into three classes based on the level of regulatory oversight required to ensure patient safety and product efficacy. Thus, from the very beginning, the scheme included “tailor[ing] the degree of regulatory control to the nature of the device.”<sup>7</sup> Class I devices were those which were assumed safe, providing that the proper manufacturing controls were in place. Class II devices were presumed safe if the proper manufacturing controls were in place and the devices met a device-specific performance standard which the FDA was to create. Finally, Class III devices were the devices which were life sustaining (or presented a potential unreasonable risk), implantable, or all post-1976 devices.<sup>8</sup> The devices in Class III were to all go through a review of safety and efficacy (called the premarket approval process, or PMA) at some time. Class III devices that were new had to be reviewed prior to marketing. However, in order to allow continued use of Class III devices already on the market, the statute permitted continued marketing of Class III devices already on the market, but required that the FDA call for a PMA to review safety and efficacy at some future point for those devices.<sup>9</sup>

In order to rectify any inequities between device manufacturers who marketed their products prior to the 1976 Amendments and those marketing their products after the Amendments, Congress permitted products which were new to the market but similar to pre-Amendment products to be marketed until the FDA called for a safety and efficacy review for all the devices of that type. The manufacturer could simply notify the FDA that the new product was substantially equivalent to a pre-Amendment “predicate” device 90 days before initiating marketing. As long as the FDA did not notify the manufacturer that the new device and proposed predicate were not substantially equivalent (NSE), the manufacturer was free to market the new device. This process was called premarket notification (PMN) or 510(k). Thus, using this submission, if a device manufacturer could show that its device was “substantially equivalent” to a device on the market

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<sup>7</sup>Peter Barton Hutt et al., *The Standard of Evidence Required for Premarket Approval Under the Medical Device Amendments of 1976*, 47 FOOD DRUG COSM. L.J. 605, 614 (1992).

<sup>8</sup>21 U.S.C. §360c(a)(1).

<sup>9</sup>Hutt & Merrill, *supra* note 4, at 753.

prior to the 1976 Amendments, the new device would be regulated the same way that the pre-Amendment counterpart was regulated. Thus, the new device was temporarily exempt from a lengthy and costly review of safety and efficacy.

One foreseeable consequence of regulating devices post-1976 is that the FDA became overburdened. The Agency was required to classify all medical devices on the market, call for PMA's for all Class III devices, create performance standards for all Class II devices, and review all the incoming PMA's and 510(k)'s for new devices that manufacturers wanted to begin marketing. Simply keeping up with the incoming applications was a substantial burden, and the government and public demanded both speed and a high standard of safety and efficacy in the review process.

#### *Premarket Approval*

As stated above, a full review of a product's safety and efficacy is done through the premarket approval (PMA) process. Unlike its drug counterpart, the PMA has only to provide "reasonable assurance" of safety and effectiveness.<sup>10</sup> After all, "all medical products are associated with some level of risk, and a product is considered safe if its risks are determined to be reasonable given the magnitude of the benefit expected."<sup>11</sup> In determining safety and efficacy, the FDA was to consider the end user, conditions of use prescribed in the labeling, and the benefit weighed against the risk posed.<sup>12</sup> Thus for example, devices used solely by physicians or other trained professionals are regulated differently than those to be used by a layperson. The statute specifically noted that the standard for medical devices is more flexible than that of drugs, by stating that clinical trials may not be appropriate in all circumstances.<sup>13</sup> Thus the FDA has great latitude to determine the amount of data necessary for these submissions.

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<sup>10</sup>21 U.S.C. §360e(d)(2), 360(c)(i), and Benjamin A. Goldberger, *The Evolution of Substantial Equivalence in FDA's Pre-market Review of Medical Devices*, 56 FOOD DRUG COSM. L.J. 317, 318 (2001).

<sup>11</sup>UNITED STATES GENERAL ACCOUNTING OFFICE, EFFECT OF USER FEES ON DRUG APPROVAL TIMES, WITHDRAWALS, AND OTHER AGENCY ACTIVITIES 6 (2002).

<sup>12</sup>21 U.S.C. §360c(a)(2).

<sup>13</sup>Compare 21 U.S.C. §355(d) (the standard for drugs) with 21 U.S.C. §360c(a)(3) (the standard for devices).

510(k)

In a 510(k) submission, the manufacturer does not have to show safety or efficacy despite the fact that the purpose of the 1976 Amendments was to “protect the public from unsafe and ineffective medical devices with the minimum possible level of regulation.”<sup>14</sup> Instead, a manufacturer merely provides comparative information between the new device and the predicate.<sup>15</sup> Thus, at the core of the process, the premarket notification process does not connote a product’s safety and effectiveness.<sup>16</sup> Instead, the premarket notification process merely opines that two devices are “substantial equivalents” and thus should be regulated in the same way. Because “substantial equivalence” does not appear in any other place in the FDCA, the FDA had considerable discretion in defining what makes devices substantially equivalent. The drafters of the statute intentionally chose language that differed from the language describing drug review in order to demonstrate that devices were to be reviewed under a different, and more relaxed, standard. However, the constraints of the more relaxed standard were not clear to industry and not necessarily uniform throughout the FDA. It was not until 1986 that the FDA promulgated an advisory document notifying device manufacturers what factors were being considered in order to determine whether a device was substantially equivalent to another.<sup>17</sup> This guidance document, having no statutory authority, was later codified in 1990.<sup>18</sup>

The FDA’s interpretation of “substantially equivalent” was based first on the intended use of the product and second on the technological characteristics. Under 21 U.S.C. §360c(i)(1), a device can *only* be found to be substantially equivalent to another device if the two devices have the same “intended use.” Unfortunately, the definition of “intended use” is also unclear, thus giving the FDA considerable latitude in determining whether two devices have the same intended use. Because intended use is the threshold question (without

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<sup>14</sup>Remarks by Arthur Hull Hayes, Jr., Commissioner of Food and Drugs, at the Health Industry Manufacturers Association Annual Meeting, as quoted by Hutt et al, *supra* note 7, at 606.

<sup>15</sup>CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, GUIDANCE ON THE CDRH PREMARKET NOTIFICATION REVIEW PROGRAM (1986). Available at <http://www.fda.gov/cdrh/k863.html>.

<sup>16</sup>Robert B. Leflar, *Public Accountability and Medical Device Regulation*, 2 HARV. J.L. & TECH. 1, 28 (1989).

<sup>17</sup>CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, *supra* note 15.

<sup>18</sup>21 U.S.C. §360c(i).

it two devices simply cannot be substantially equivalent), the way in which the FDA exercises its discretion is of monumental importance to device manufacturers.<sup>19</sup> If the two devices have the same intended use and also have the same technological characteristics, the two devices are substantially equivalent.<sup>20</sup> However, if the two devices have different technological characteristics and the differences have no adverse effect on safety and effectiveness (and the new device does not raise different questions of safety and efficacy), the devices are considered substantial equivalents. Under the latter prong, the manufacturer generally has to demonstrate that the new device's unique technological characteristics have no adverse effect on safety and efficacy through some type of scientific test. Initially, it was not clear whether the FDA had the implied authority from Congress to request clinical and/or preclinical data from manufacturers in support of a 510(k). However, the manufacturers were inclined not to protest because the alternative route to marketing was going through the PMA process.<sup>21</sup> Thus, the “mini-PMA” or “hybrid 510(k)” was born.<sup>22</sup>

The FDA is required by statute to use the “least burdensome means” to establish that their objective has been met.<sup>23</sup> In other words, for 510(k)'s, the FDA must use the least burdensome means to determine that one device is substantially equivalent to another, and for a PMA, the FDA must use the least burdensome means to establish a reasonable assurance of safety and efficacy. “Least burdensome means” is another statutory term which defies a strict definition. The industry proffered one structure, where the FDA would have to sequentially step through levels in order of increasing difficulty to the manufacturers, and stop at the

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<sup>19</sup>CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, *supra* note 15 lists examples of devices that are substantially equivalent, as well as those that are not.

<sup>20</sup>21 U.S.C. §360c(i)(1)(B) states that changes in design, materials, and energy source are examples when technological characteristics may differ. CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, *supra* note 15 states that to determine if a technical difference exists, consider 1) whether the new device and the predicate device pose the same type of questions regarding safety and effectiveness, 2) whether scientific methods exist to evaluate if safety and effectiveness have been adversely affected as a result of the new technical characteristics, and 3) whether the data shows that the new technical characteristics have not adversely affected safety and effectiveness.

<sup>21</sup>Goldberger, *supra* note 10 at 324.

<sup>22</sup>Leflar, *supra* note 16 at 55.

<sup>23</sup>21 U.S.C. 360c(i)(1)(D).

least burdensome possible step where the FDA received the data that it needed. The FDA posed the opposite structure, where the question asked initially is whether a randomized trial is the least burdensome means to provide reasonable assurance of safety/effectiveness (in PMA) or substantial equivalence (for 510(k)).<sup>24</sup> In the end, Congress has determined that the burden is on the FDA to show that the information they request is necessary and that there is no easier way to obtain that information.

The “substantial equivalence” review is entirely internal to the FDA. Although most Agency actions “that have immediate and substantial impact” are challengeable by statute,<sup>25</sup> “the substantial equivalence review process is a black box, entirely shielded from the public scrutiny that Congress deemed essential to the premarket clearance process.”<sup>26</sup> Although many manufacturers would not dare judicially challenge an FDA decision because of future adverse ramifications,<sup>27</sup> the fact that manufacturers have no opportunity to challenge the FDA despite the significant impact an NSE finding can have on a company is troubling. Furthermore, the lack of information available regarding the devices and any testing done for the 510(k) hinders physicians and anyone else looking into product performance from learning about the product.<sup>28</sup> As a concession to manufacturers, the FDA agreed to seal much of the applications on grounds that the information is proprietary. The summaries which are available to the public frequently simply state that the product was tested and found to be at least as safe and effective as the predicate.<sup>29</sup> However, if the Agency is unwilling to mark the product “safe and effective for its intended use,” thus putting the onus

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<sup>24</sup>John J. Smith and Anne M. Shyjan, *Defining “Least Burdensome Means” Under the Food and Drug Administration Modernization Act of 1997*, 55 FOOD DRUG COSM. L.J. 435, 445-446 (2000).

<sup>25</sup>Judicial review is sprinkled throughout the statute. For example, see 21 U.S.C. §360g.

<sup>26</sup>Leflar, *supra* note 16 at 34.

<sup>27</sup>See *Allegations of FDA Abuses of Authority: Hearing Before the Subcomm. on Oversight and Investigations*, 104th Cong. (1996).

<sup>28</sup>Leflar, *supra* note 16 at 33, 55.

<sup>29</sup>A searchable database of recent 510(k) summary sheets or letters is available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>.

on the physicians, hospitals and insurance companies to determine a device's safety prior to use, the FDA should not shield the relevant information under a cloak of secrecy.

#### CONGRESSIONAL APPROVAL OF 510(k) REGULATIONS

As noted above, when the 1976 Amendments were written, the 510(k) was envisioned to be a temporary fix that prevented unduly disadvantaging post-Amendment devices compared to their virtually identical pre-Amendment counterparts. However, the FDA used their regulatory authority to change the 510(k) scheme from one of simple notification to a clearance requirement for market approval.<sup>30</sup> Prior to 1990, both industry and the FDA assumed that after the 90 day period had elapsed, if the manufacturer had not been given either a “substantial equivalence” or “NSE” determination, the manufacturer was free under the statute to market the device at its own risk. However, regulations created by the FDA required a “substantial equivalence” determination prior to marketing. In 1990, the FDA's regulations were codified.<sup>31</sup> Thus, the FDA *had to* give a determination of substantial equivalence before a manufacturer could market a device. The FDA therefore created a second, substantially less onerous method for medical devices to be reviewed prior to marketing.<sup>32</sup> As a result, the 510(k) has become the predominant method of approval. In fiscal years 1998 to 2001, the FDA received between 4200 and 4625 original applications per year,<sup>33</sup> where approximately 99% of these applications were 510(k) applications. Given that approximately 99 percent of 510(k)'s receive “substantially equivalent” determinations and only about 75-84 percent of PMA's are approved,<sup>34</sup> the disparity between the number of approved PMA's and approved 510(k)'s is even greater.

The reason that there are such large numbers of 510(k)'s is not because technology has been stagnant

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<sup>30</sup>Rodney R. Munsey, *Trends and Events in FDA Regulation of Medical Devices over the Last Fifty Years*, 50 FOOD DRUG COSM. L.J. 163, 168 (1995).

<sup>31</sup>Smith and Shyjan, *supra* note 24, at 437.

<sup>32</sup>Mohan memorandum stated when 510(k)'s were the appropriate mechanism for market clearance. *See* Munsey, *supra* note 30 at 168.

<sup>33</sup>An “original” application is one that is not a supplemental 510(k), a special 510(k), or a supplemental PMA.

<sup>34</sup>OFFICE OF DEVICE EVALUATION, FISCAL YEAR 2002 ANNUAL REPORT Part 7 (2002). ODE Annual Report, 2002, *available at* [www.fda.gov/cdrh/annual/fy2002/ode/toc.html](http://www.fda.gov/cdrh/annual/fy2002/ode/toc.html).

since 1976. Clearly advances in medicine have been monumental over the last 25 years. However, to alleviate the workload in the FDA, the Agency permits “piggybacking.”<sup>35</sup> Thus many devices which are not substantially equivalent to any pre-Amendment device (and therefore otherwise would have had to go through the PMA process) can be approved for marketing using the substantially less onerous 510(k) route if they are substantially equivalent to any legally marketed device. Thus, a device merely needs to show substantial equivalence to a device that is substantially equivalent to a pre-Amendment device in order to qualify for the PMN process. Piggybacking was meant to allow incremental changes to a device while avoiding the PMA process.<sup>36</sup> Medical device manufacturers commonly make incremental changes to their devices, so lowering the regulatory barriers for improved devices was important in the medical device field. However, because manufacturers often cite a number of medical devices as predicates in order to claim that aspects of the device under review are similar to aspects of older devices, the “equivalence” of the new device and the pre-amendment device(s) can become diluted to the point that they are unrecognizable.<sup>37</sup>

Although review is substantially more abbreviated for 510(k)’s, the FDA occasionally demanded data showing safety and efficacy (as is required in a PMA).<sup>38</sup> Manufacturers rallied against the FDA and got Congressional support for a more limited scope of review. Thus, Congress limited the FDA to inquiring into the question presented; thus for 510(k)’s the FDA is limited to inquiring whether the product is substantially equivalent to the predicate device.<sup>39</sup> Therefore the FDA is actually constrained from inquiring into the safety of a device.

Congress has additionally limited the scope of FDA review in another way. In the 1997 Amendments, Congress prohibited the FDA from considering uses other than the stated use when determining substantial equivalence (or safety and efficacy) of a device. Because doctors are permitted to use devices for off-label

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<sup>35</sup>Munsey, *supra* note 30 at 169.

<sup>36</sup>Smith and Shyjan, *supra* note 24, at 436.

<sup>37</sup>Leflar, *supra* note 16, at 51.

<sup>38</sup>*Id.*

<sup>39</sup>21 U.S.C. §360c(i)(1)(D).

uses, and because so much rides on the “intended use” of a medical device (*i.e.*, if a post-Amendment device does not have the same intended use as a pre-Amendment device, it is impossible for the devices to be substantially equivalent), device manufacturers have been known to submit 510(k)’s listing a *possible* use of their device as the intended use in order to have the device approved quickly for marketing. Once the device is approved for marketing, the manufacturer can then subtly get information to the physicians about other off-label uses (including potentially the “real” intended use). In this way, manufacturers are able to make an end run around the regulations.<sup>40</sup> Congressional disdain for this type of action was universal, and there was considerable concern about how to regulate manufacturers who seek regulatory loopholes in order to market their product. Congress thus found a compromise between the position of the FDA (who thought that it should be able to review all foreseeable uses) and industry (who thought that the FDA should be limited to reviewing the stated intended use) by limiting FDA investigation to the stated intended use but allowing the FDA to impose labeling requirements regarding unapproved but foreseeable uses.

#### A MODEST PROPOSAL

Because the PMN process has morphed into a completely different requirement than what was originally envisioned, the alternative (PMA) route has almost become a punishment. One attorney stated, “If an arguable basis exists for making a claim of substantial equivalence, a company would be remiss in not trying the 510(k) route.”<sup>41</sup> Because counsel advise their clients to try the 510(k) route in hopes of quick and inexpensive approval, one must take a second look at the process and product to determine whether they are desirable. In 1976, the goal in the minds of Congress and the FDA was to ensure public safety

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<sup>40</sup>U.S. Surgical created a device intended to remove breast tumors. However, they marketed the device (thus the “intended use” of the device) was for removing biopsy samples. The company created a video marketing the product for removal of breast tumors and distributed it in Canada. The FDA found that because the device excised ten times the tissue of standard biopsy devices, and because the same product was marketed abroad for different indications, the company facetiously listed biopsy as the intended use, when the real intended use was to remove tumors. as referred by Congress. *See Regulating Innovation: FDA’s Medical Device Approval Process: Hearing Before the Subcomm. on Investigation and Oversight*, 101st Cong. (1994).

<sup>41</sup>Kahan, 39 FOOD DRUG COSM. L.J. 510 (1984), *reprinted in* 2 HARV J. L. TECH. 1, 47-48.

and device efficacy. The 510(k) was introduced as a patch to provide regulatory parity between competing manufacturers. It seemed unfair that later entrants to the market would have had significantly greater regulatory burdens to bear. Because the 510(k) was intended to supplement, not supplant, the PMA's, Congress allowed the focus for 510(k) submissions to be on "substantial equivalence." After all, in the statutory scheme, the FDA was supposed to call for PMA's for all Class III devices at some point in the near future. Class II devices would likewise all have device-specific performance standards. Thus, safety would be addressed for all devices eventually.

However, because most devices are currently "approved" for marketing via 510(k)'s, safety and efficacy of the devices is not relevant, except at the margin. Reviewers at the FDA simply determine whether the new product is at least as safe and effective as the predicate.<sup>42</sup> If changes to the device adversely affect safety and efficacy, the FDA scrutinizes the changes to determine whether the risk is worth any benefit gained. However, if the predicate device is flawed in the same way that the new device is flawed, the new device can be marketed under the current regulations. Thus a finding of substantial equivalence is clearly not equivalent to a finding of safety and/or efficacy.<sup>43</sup>

The folly in this regulatory scheme can be seen by reviewing problems associated with silicone implants. Silicone implants were on the market prior to 1976. Therefore, under the 1976 Amendments, they could continue their marketing until the FDA called for a PMA from device manufacturers. Additionally, later manufacturers of silicone implants could simply state that their implants were substantially equivalent to those which were on the market prior to 1976, without ever questioning whether the pre-1976 devices were themselves safe or effective. Only after numerous significant problems the FDA pulled silicone implants off the market. The FDA was delayed largely because the manufacturer of the implants argued that secondary issues, such as the grade of silicone, were the cause of many of the medical issues experienced. Additionally,

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<sup>42</sup>Leflar, *supra* note 16, at 54.

<sup>43</sup>*Id.* at 28, and 21 C.F.R. 807.97.

after the devices were shown to be dangerous at least in some tissues, the manufacturer refused to pull all the implants off the market on the grounds that the remaining products were targeted for another use. If silicone implant manufacturers had to show in any way that silicone implants were safe, potentially fewer difficulties would have been suffered by the recipients of these implants.

Thus, Congress should reinstate the PMA as the single way in which Class III devices can enter the market. FDA resources are limited, and critics undoubtedly would argue that all Class III devices could not possibly be reviewed under PMA standards in a relatively short amount of time. Additionally, increased costs related to PMA applications are a concern for the manufacturers, especially because the medical device field, unlike the drug field, has many small manufacturers. However, a closer look at what the regulatory scheme would be like if 510(k)'s were eliminated demonstrates that elimination of the 510(k)'s as premarket review for Class III devices would not substantially harm manufacturers or the FDA, and would be of great benefit to the public.

#### *Public Benefit*

The public would benefit from creating a regulatory regime where all Class III medical devices are screened for safety and efficacy, and “substantial equivalence” to a pre-Amendment device is irrelevant. Currently, important safety and testing data collected to support 510(k) submissions are unavailable to the public due to the manufacturers’ desires to protect their proprietary information. However, because the FDA is unable to denote a product “safe” or “effective” simply by noting that the device is substantially equivalent to a legally marketed device, users, physicians, hospitals, and insurance agencies are left to determine for themselves which devices are truly safe. These parties do not have access to the relevant information under the current scheme.

Furthermore, some medical devices are approved for marketing through the PMA process, and thus are considered both safe and effective by the FDA. The public has no easy way to determine how any given

device came to market, and thus has no way of gauging how extensively the FDA has investigated the safety and efficacy of any particular device. Therefore, to eliminate the problem of information flow and inability to determine beforehand how any given device was approved for marketing, the FDA ought to simply ensure that all devices on the market are safe and effective. That is what the public relies on them for.

Before the 1997 Amendments were passed, industry complained that the FDA was looking into irrelevant information, such as 1) the cost of the new device, 2) determining whether the new device was more effective than the devices currently available, and 3) whether the device had clinical utility.<sup>44</sup> This brought a lot of debate, and some argued that although the FDA was requiring extraneous information, “the Office of Device Evaluation needs to focus its reviews on the issues that are important to ensure *safety* and *effectiveness*.”<sup>45</sup> Furthermore, device manufacturers noted with concern that the “FDA is emphasizing the science more rather than the assumption that they have accepted in the past.”<sup>46</sup> Manufacturers were correct in complaining about FDA’s information requests regarding cost and relative effectiveness of the new device. The FDA should not be looking into the potential for commercial success of the medical device. After all, the market should take care of any deficiencies in these areas, as long as information is available. On the other hand, the FDA *should* be looking into clinical utility. The industry’s brashness in stating that the FDA should not be looking into clinical utility should only be slightly more shocking than the fact that the FDA actually should not have been looking into clinical utility of a 510(k) submission.

Furthermore, the public will be well served by requiring all Class III devices to go through the PMA process because the 510(k) language is vague and has been interpreted broadly. For example, piggybacking results in devices which look wholly dissimilar to anything on the market prior to 1976 having “substantially equivalent” findings. The Office of Device Evaluation (ODE) releases a report every year which, among other things,

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<sup>44</sup>Larry R. Pilot and Daniel R. Waldmann, *Food and Drug Administration Modernization Act of 1997: Medical Device Provisions*, 53 FOOD DRUG COSM. L.J. 267, 273 (1998).

<sup>45</sup>*Regulating Innovation*, *supra* note 40, at 33 (statement of Robert O’Halla, Chairman of Health Industries Manufacturers Association, Product Approval Task Force and VP of Regulatory Affairs at Johnson & Johnson), emphasis added.

<sup>46</sup>*Id.* at 45.

lists “significant medical device approvals.” These are devices which, in the view of the ODE, “represent significant medical breakthroughs because they are first-of-a-kind, *e.g.*, they use new technology or energy source, or they provide a major diagnostic or therapeutic advancement....” Given that definition, one might assume that these “breakthroughs” in medical devices that are “first-of-a-kind” all went through the PMA process. After all, the entire function of a PMA is to review an item that is novel. However, this is not the case. For example, in 2002, nearly half of the devices on this list had gone through the 510(k) process.<sup>47</sup> In 2000, *more* devices that made this list were cleared through the 510(k) process than the PMA process.<sup>48</sup> Approximately 10 to 25 “substantially equivalent” devices made it to this list each year between 1999 and 2002.<sup>49</sup>

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<sup>47</sup>OFFICE OF DEVICE EVALUATION, *supra* note 34. 13 of 32 were approved via the PMN process.

<sup>48</sup>OFFICE OF DEVICE EVALUATION, FISCAL YEAR 2000 ANNUAL REPORT 8-11 (2000), *available at* <http://www.fda.gov/cdrh/annual/fy2000/ode/ode-annual.fy00.pdf>. 25 of 40 devices went through the PMN process.

<sup>49</sup>OFFICE OF DEVICE EVALUATION, *supra* notes 47 and 48, and OFFICE OF DEVICE EVALUATION, FISCAL YEAR 2001 ANNUAL REPORT 10-15 (2001), *available at* <http://www.fda.gov/cdrh/annual/fy2001/ode/annualreport2001.pdf>.

## Time and Money

Critics of eliminating the 510(k) program charge that small businesses will be hurt by eliminating 510(k)'s. After all, PMAs are significantly more costly and time consuming than 510(k)'s. However, a number of small companies currently file PMA's.<sup>50</sup> Thus, many small companies are already dealing with the expense and more time-consuming nature of PMA's. Additionally, because the FDA must scale review to the level of danger posed by the device, manufacturers will not be unduly hampered by simply making a different and arguably a more relevant inquiry: that is, whether the device is safe and effective as opposed to whether it is substantially equivalent to a pre-1976 device. For both 510(k)'s and PMA's the FDA is charged with requiring the "least burdensome means" available to answer the relevant question. Eliminating the 510(k) for Class III devices will therefore simply focus the FDA's attention to a question of more concern to the public.

Discontinuing the PMA would also not be a substantial burden on the manufacturer because the difference in complexity between 510(k)'s and PMAs is narrowing. As stated above, hybrid 510(k)'s have become commonplace, and most manufacturers submit data to support the application without being asked.<sup>51</sup> At one time, the median 510(k) application was 10 pages and the average PMA application was 1000 pages.<sup>52</sup> Additionally, one group found that a 510(k) with no clinical data costs between \$50 and \$2000 to submit, whereas a PMA could cost as much as \$830,000.<sup>53</sup> However, many manufacturers have begun including significant amounts of clinical and pre-clinical data to support their 510(k) applications.<sup>54</sup> Most also require

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<sup>50</sup>Of the PMA approvals in 2000 and 2001, x% of them were filed by companies which had a revenue of less than \_\_\_\_\_. (This data considers not only the company itself, but any parent or other affiliated company to the company submitting the application. Information here was obtained from the companies' annual reports, SEC filings, and online data at the company website. Some companies were privately held and therefore this information was unavailable.)

<sup>51</sup>Manufacturers sometimes put more information than they think is necessary in order to head off questions that may arise and expedite the review. *Regulating Innovation*, *supra* note 40, at 81. *See also* Hutt and Merrill, *supra* note 6, at 755.

<sup>52</sup>Leflar, *supra* note 16, at 47.

<sup>53</sup>*Id.*

<sup>54</sup>Although the 510(k) and PMA applications are not public record, many of the summary sheets for the 510(k)'s and PMA's are. The summary sheets sometimes summarize in some detail the preclinical and clinical trials done in support of the

some external regulatory legal counsel.<sup>55</sup> Thus the \$50-\$2000 application is rare if existent today.

Moreover, when looking at the relative costs and time periods involved for market authorization via the 510(k) or PMA routes, one must consider that significantly different devices are being compared. A device going through the PMA process is new and potentially harmful, and thus all types of questions about the device must be answered. On the other hand, devices going through the 510(k) route may be substantially more “established” and thus very little may be required for the FDA. Therefore the discrepancy in cost and review time between PMA’s and 510(k)’s are not only a factor of the different question being answered (*i.e.*, whether the device is safe and effective versus whether the device is substantially equivalent to a predicate device), but also the technical complexity and novelty of the device itself. Therefore, merely comparing the time and cost of PMA’s and 510(k)’s does not give a realistic picture of what the regulatory scheme would be like if 510(k)’s were eliminated for Class III devices.

At first glance, it would appear that eliminating the 510(k) for Class III devices would impose a significant burden on manufacturers in terms of time to market. One recurring complaint about the FDA is that the review times are too long, even for 510(k) submissions. PMA submissions take a longer time on average to review. Small manufacturers claim that the

delay in regulatory approval puts them particularly at a disadvantage, because they need the income

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application. The 510(k) summary for the Hylashield CL contact lens lubricating eyedrop by Biomatrix lists 17 full preclinical studies, 14 supportive studies, and clinical studies. In all, the device was tested in rats, owl monkeys, rabbits, guinea pigs, a mouse cell line, mice, horses, and primate eyes.

<sup>55</sup>One medical device manufacturer testified that the cost of preparing the documentation (simply putting the document together) exceeded \$17,000. In other words, the \$17,000 figure excluded the cost of testing. *Regulating Innovation*, *supra* note 40, at 56 and 81 (statement of Brad Kohl, President and CEO of Medical Safety Technologies).

from the sales of their devices as soon as possible in order to remain solvent.<sup>56</sup> The above graph<sup>57</sup> depicts the average review time, from initial filing by the manufacturer to final decision by the FDA. As noted in the graph, the difference in review times between original PMA's and original 510(k)'s is fairly substantial. However, one must remember that the devices which are approved for marketing via the 510(k) route are reviewed quickly largely because presumably a similar predicate device exists. Therefore, the original 510(k) applications are probably more appropriately compared to PMA supplements than original PMA applications. As can be seen from the graph below, the PMA supplements generally have a review time which is much more similar to that of the 510(k). Although the PMA supplements have a slightly longer review time than 510(k)'s, the FDA reviews safety and efficacy, which can be expected to take longer. However, because the difference in review time is only marginal, and the end product is a determination of safety and efficacy (something the public cares about), this incremental delay in marketing should be acceptable.

Furthermore, eliminating the 510(k) may actually speed up the reclassification process in some circumstances. §513(f)(2) of the 1997 amendments allow the FDA to reclassify a Class III device which has been found not substantially equivalent (NSE). Thus, in order for a manufacturer to take advantage of this provision, the manufacturer must have submitted a 510(k) with whatever supporting material it deemed appropriate, had a finding of NSE by the FDA, and then initiated this process. The process itself would consider a novel invention and the potential for harm it poses, and determine from that information whether the product (deemed Class III because it was new) should be redesignated to Class I or Class II.<sup>58</sup> In other words, the process takes longer because it must go through a secondary supplemental process in order to approve the device for marketing. A manufacturer cannot request reclassification under this program until an NSE finding has been made. If 510(k)'s were eliminated for all Class III devices, presumably a manufacturer could request reclassification before submitting a PMA. If the manufacturer first had to submit a PMA, the manufacturer would have no incentive to file for reclassification as well. Thus, Class III devices which should be reclassified may actually reach the market more quickly if 510(k)'s were eliminated for all Class

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<sup>56</sup>*Id.* at 68 (statement of Mr. Joseph Mooibrock, President and CEO of American Medical Electronics, Inc.). Mr. Mooibrock testified that not only are the delays costing the company significant amounts of money, but required some employees to lose their jobs.

<sup>57</sup>OFFICE OF DEVICE EVALUATION, *supra* note xxx?.

<sup>58</sup>OFFICE OF DEVICE EVALUATION, NEW SECTION 513(f)(2) – EVALUATION OF AUTOMATIC CLASS III DESIGNATION, GUIDANCE FOR INDUSTRY AND CDRH STAFF (1998), *available at* <http://www.fda.gov/cdrh/modact/classiii.html>.

III devices.

#### *User Fees*

Additionally, collection of user fees ought to speed up the review process. The GAO reviewed the drug user fee program (which has been in effect since 1992) to determine whether the objectives of the program were being obtained. The GAO found that drug user fees decreased all review times in drugs by allowing the FDA to hire additional examiners and move resources within the FDA to work on drug approval.<sup>59</sup> According to the GAO, the average approval time went down from 27 months in 1993 to 14 months in 2001. The GAO also found that there was a higher number of withdrawals for safety reasons, indicating that potentially the quality of review has suffered. However, the FDA stated (and the GAO acknowledged) that the number of drugs withdrawn for safety reasons was so small that a small change in the number of withdrawn drugs leads to a large fluctuation in percent of drugs withdrawn.<sup>60</sup> Hopefully from the lessons learned with respect to drug user fees, the medical device user fees will be able to avoid some of the difficulties experienced with the drug user fees. At the very least, FDA hopefully will be able to decrease the attrition problem,<sup>61</sup> which leads both to longer review times and frustration among the manufacturers when the reviewer changes just prior to market approval, and the new reviewer requires new tests.<sup>62</sup>

An additional benefit to eliminating the 510(k)'s for all Class III devices is that a large amount of money

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<sup>59</sup>UNITED STATES GENERAL ACCOUNTING OFFICE, EFFECT OF USER FEES ON DRUG APPROVAL TIMES, WITHDRAWALS, AND OTHER AGENCY ACTIVITIES 8 (2002).

<sup>60</sup>*Id.* at 24.

<sup>61</sup>*Id.* at 18.

<sup>62</sup>*Regulating Innovation*, *supra* note 40 at 85 (statement of Mr. Mooibroek). For one of his company's products, he had four reviewers in three years. He testified that one frustration of his company was that they would reach the point where they needed one more piece of data, and when the data came in, another reviewer would be in charge of the application and would require a whole different set of information.

could be collected by the FDA in user fees. User fees are scaled on the amount of work the FDA assumed it would require to review the application. Thus, for example, a PMA, panel track supplement<sup>63</sup>, and efficacy supplement<sup>64</sup> all cost the same, probably because of the amount of data required in the submission. A 180-day supplement<sup>65</sup> costs 21.5% of the PMA, a real time supplement<sup>66</sup> costs 7.2% of a PMA, and a 510(k) costs 1.75% of a PMA.<sup>67</sup> The 510(k) and 180-day supplement percentages are subject to adjustment up if the FDA finds that the revenue from device user fees is not as much as it expected.<sup>68</sup> Under the current user fee structure, a PMA costs \$154,000, and a 510(k) costs \$2187.<sup>69</sup> Reduced fees for small manufacturers is already built into the statute, where the first PMA for a small manufacturer is free, and subsequent PMA's cost 10% of the fee charged to the larger companies.

#### *Data Requirements*

Critics should also recognize that like the spectrum of devices, the Agency has authority to regulate devices commensurate with the amount of risk posed, *i.e.*, require the “least burdensome means” to show safety and effectiveness for that type of device.<sup>70</sup> Currently, even under 510(k) review, the manufacturer must guess what is necessary to show that changes made to the device raise no new questions of safety and efficacy. Manufacturers routinely submit preclinical and clinical data to demonstrate the safety and efficacy of the device under review, and the FDA review is appropriately scaled to the amount of difference and potential

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<sup>63</sup>Used when the new device requests a significant change in design or performance of the device, or a new indication for use of the device, and for which clinical data are generally necessary to provide a reasonable assurance of safety and effectiveness. *See infra*, p. 26.

<sup>64</sup>An application that requires substantive clinical data.

<sup>65</sup>A supplement that is not panel-track, which requests a significant change in components, materials, design, specification, software, color additives or labeling. *See infra*, p. 26.

<sup>66</sup>An application that requests minor changes to a device, such as minor changes to the design, software, manufacturing, sterilization, or labeling, and for which application has required, and Agency has approved a meeting or similar forum to jointly review and determine the status of the supplement. *See infra*, p. 26.

<sup>67</sup>H.R. REPT. NO. 107-728, pt. 1 (2002), *available at* <http://www.lexis.com>.

<sup>68</sup>*Id.*

<sup>69</sup>21 U.S.C. §379j(c)(5).

<sup>70</sup>21 U.S.C. §360c(a)(3)(D)(ii), (i)(1)(D), Smith and Shyjan, *supra* note 24, at 435.

danger posed by the device. The PMA process is likewise scaled to the level of novelty and perceived threat.<sup>71</sup> Thus, the Agency should simply allow manufacturers to submit whatever data seems appropriate, and allow the FDA to request additional data should the reviewer deem it necessary.<sup>72</sup> While some might argue that this will create a regime of overtesting, this is the current standard now.<sup>73</sup>

To prevent this from becoming an unwieldy burden on the FDA and fledgling companies, the FDA should also allow device manufacturers to provide data from similar devices in order to show safety and efficacy. Critics undoubtedly would charge that if data from similar devices is allowed, any statutory change eliminating 510(k)'s for Class III devices would exalt form over substance. However, this is not the case. First of all, although manufacturers would be permitted to provide data from other devices to show safety and efficacy, the bottom line question is whether or not any given device is safe and effective. In contrast, the underlying question now for 510(k)'s is whether a device is substantially similar to a pre-1976 device, regardless of how safe and effective the pre-1976 device is. Secondly, there are no Class III devices which would be exempted from this requirement. Therefore, even if for argument's sake the manufacturers essentially submit a 510(k) stating that they are similar to another device, the manufacturer must then also show that the predicate device is also safe and effective. Therefore, tragedies like the ones related to silicone implants will be largely eliminated.

This is not entirely different than the requirement now, so manufacturers should not oppose the proposal too strenuously. Currently, all 510(k) submitters must certify that a reasonable search of all information relating to adverse safety and effectiveness of a device has been made. Manufacturers are also required to provide a summary of the discovered information, as well as the relevant citations in the 510(k).<sup>74</sup> Although one large

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<sup>71</sup>Leflar, *supra* note 16, at 61.

<sup>72</sup>FDA already has statutory authority to do this. With 510(k)'s, the data requested is generally less extensive and analyzed less rigorously than that in a PMA. Leflar, *supra* note 16, at 55. Thus the current regulations turn 510(k)'s into "mini PMA's" or "hybrid 510(k)'s." *Id.*

<sup>73</sup>*Regulating Innovation*, *supra* note 40, at 81 (statement of Mr. Kohl). Mr. Kohn testified that his company "provided maybe more information on occasion in order to head off a question that we might have failed to address..."

<sup>74</sup>21 U.S.C. 360c(f).

difference is that if the information does not exist, a manufacturer would have to test a device for safety and efficacy if the device were being reviewed under a PMA. Under the current statute, a manufacturer merely has to search for relevant data that exists. Nonetheless, the fact that Congress added this requirement in 1997 indicates an acknowledgement that a showing of substantial equivalence really does not indicate safety and effectiveness.

### *Alternative Submissions*

Supplemental PMA's exist which may further ease the burden on the FDA and manufacturers. A guidance document promulgated by the FDA stated how to know when to submit an original PMA versus a supplement, and what type of supplement to submit.<sup>75</sup> According to this document, an original PMA is only required when “*completely* new pre-clinical and clinical data are needed for assuring safety and effectiveness of the modified device.”<sup>76</sup> However, if the old-preclinical data is applicable to the new device but new clinical data is required to show safety and efficacy, a PMA supplement should be submitted.<sup>77</sup> Likewise, if the old clinical data supports use of the modified device but new pre-clinical data is required to show safety and efficacy, a PMA supplement is sufficient.<sup>78</sup>

As noted by the guidance document, a PMA supplement is generally required when there are: 1) new indications for use for the device, 2) labeling changes, 3) the use of a different facility or establishment to manufacture, process, or package the device, 4) changes in the sterilization procedures, 5) changes in packaging, 6) changes in the performance or design specifications, circuits, components, ingredients, principle

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<sup>75</sup>CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, DEVICE ADVICE: PREMARKET APPROVAL (PMA), *available at* <http://www.fda.gov/cdrh/mdufma/guidance/1201.pdf>.

<sup>76</sup>*Id.* at 2, emphasis added.

<sup>77</sup>*Id.*

<sup>78</sup>*Id.*

of operation, or physical layout of the device, or 7) extension of the expiration date of the device based on data obtained under a new or revised stability or sterility testing protocol that has not been approved by the FDA.<sup>79</sup> This list of changes was divided up into categories which each correspond with a different submission. For example, the panel-track supplement is defined as “a supplement to an approved premarket application or premarket report under section 515 that requests a significant change in design or performance of the device, or a new indication for use of the device, and for which clinical data are generally necessary to provide a reasonable assurance of safety and effectiveness.”<sup>80</sup> This definition is vague, and the related regulation does not further clarify when this type of submission should be used.<sup>81</sup> Thus, the FDA currently requests panel-track supplements when there are new indications for use of the device, or significant changes in device design or performance that could significantly affect clinical outcome.<sup>82</sup>

Another type of PMA supplement, called the 180-day supplement, is statutorily defined as “a supplement to an approved premarket application or premarket report under section 515 that is not a panel-track supplement and requests a significant change in components, materials, design, specification, software, color additive, and labeling.”<sup>83</sup> Thus, when there is a significant change in the principle of operation, control mechanism, device design performance, labeling (specifically labeling of contraindications), or new testing requirements or acceptance criteria, the FDA suggests that a manufacturer submit a 180-day supplement.

Finally, the real time supplement is the third type of supplement. It is statutorily defined as required when the manufacturer “requests a minor change to the device, such as a minor change to the design of the device, software, manufacturing, sterilization, or labeling, and for which the applicant has requested and the agency has granted a meeting or similar forum to jointly review and determine the status of the supplement.”<sup>84</sup>

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<sup>79</sup>21 C.F.R. 814.39(a) *reprinted in Id.* at 3.

<sup>80</sup>Section 747(4)(B) of MDUFMA, *reprinted in Id.*

<sup>81</sup>*Id.* at 4.

<sup>82</sup>*Id.*

<sup>83</sup>*Id.*

<sup>84</sup>Medical Device User Fee and Modernization Act §737(4)(D) *reprinted in Id.*

Thus, a manufacturer may submit a real-time supplement for minor changes to device design, labeling, or sterilization and packaging.

The existence of these different PMA supplements should further alleviate increased burdens due to the elimination of 510(k)'s. By judicious use of these supplements, manufacturers will not be forced to “reinvent the wheel” when the new device is truly substantially similar to a device legally on the market. The FDA will additionally benefit when manufacturers utilize these supplements because they will require less Agency review time as well.

## Tort Liability

Tort law has recognized that a finding of substantial equivalence does not indicate that the device is safe.<sup>85</sup> Manufacturers are shielded from tort liability when products go through the PMA process. However, there is no liability shield when devices are introduced to the market through the PMA process. Some say that the existence of a tort liability shield should encourage manufacturers file PMA's, but that is unrealistic because small manufacturers, such as those prevalent in the medical device field, live hand to mouth. Thus, they need to have their devices approved as quickly as possible. However, the needs of device manufacturers may not be in line with the best interests of the American public. On one hand, injured people should be able to recover from defective or injurious products, so a tort liability shield is a detriment. However, even better than giving private people a cause of action in tort would be to prevent these objects from making their way to the marketplace to begin with. Manufacturers can always file for bankruptcy if lawsuits become too numerous or too expensive. However, if they are prevented from putting their products on the market to begin with, that benefits all Americans.

## CONCLUSION

The first of three principle purposes of the Medical Device Amendments that Thomas Scarlett (FDA Chief Counsel) noted was "to assure that the control is commensurate with the hazard presented by a device."<sup>86</sup> Due to statutory changes over the past 25 years, the 510(k) largely circumvents this principle purpose by disallowing the FDA to look at anything but the stated intended use and differences between the new device

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<sup>85</sup>Medtronic v. Lohr, 518 U.S. 470 (1996).

<sup>86</sup>Food and Drug Law Institute's 27<sup>th</sup> Annual Educ. Conference, Washington DC (12/13/83), *reprinted in* Hutt et al., *supra* note 7, at 627.

and predicate device(s). In order to protect the public from unsafe devices, the FDA must look into safety and efficacy, and not focus on substantial equivalence. Since the FDA can tailor the PMA process to the level of hazard presented by utilizing supplemental PMA's and requiring only the least burdensome means to demonstrate safety and efficacy, the 510(k) should be eliminated for all Class III devices. After all, under the original statutory vision, the PMA was the way that most Class III devices were to be approved.

Current thinking in the FDA is moving in the opposite direction. In hopes of getting products to market more quickly, the FDA may utilize post-market surveillance. Thus, under pressure from the industry, the FDA essentially permits the manufacturers to conduct population-wide clinical trials so that devices can get to market faster. Although post-market surveillance can be used beneficially for many things, such as continuing to insure the safety of the American public, it should not be used as a safety net because the FDA is being pressured to approve devices too quickly. There is little evidence that the review times in fact have decreased,<sup>87</sup> but even if they had, it is hard to imagine why post-market surveillance is preferable to premarket review. If premarket review were truly less useful than post-market surveillance, the FDA ought to return to the pre-1976 regime where it was neither authorized nor expected to protect the American consumer from medical products before harm occurred.

However, because the 1976 Amendments were passed, clearly Congress had a regime in mind where a governmental body ensured the safety and effectiveness of medical products before they could cause substantial harm. In line with this vision, all Class III devices should be regulated using the same standard: a showing that the device is both safe and effective. After all, the perception of the American public, as well as the original statutory vision, is that the FDA's role is to weed out devices that are unsafe or ineffective, not devices that are not substantially equivalent to pre-1976 devices. Prior to the 1997 Amendments, one manufacturer stated, "in addition to making sure that it is safe and effective, it also gives a perceived value to

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<sup>87</sup>Merrill, *supra* note 1 at 1829.

the health care consumer that this product in fact does offer a safe and effective means for whatever purpose it was designed.”<sup>88</sup>

Thus, it seems that the premarket notification process has moved far beyond what it was intended to do. Moreover, the problem that it was meant to address has long since ameliorated.

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. 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.*<sup>89</sup>

While we may be concerned about new entrants into the device field, recent statutory changes have significantly changed the landscape for new devices. Device user fees and the interpretation of vague statutory language indicate that requiring PMA’s for all Class III devices may be warranted.

Not only does the elimination of the 510(k) for Class III devices have the benefit of focusing regulatory attention on something that matters, but it also eliminates several incidental problems as well. For example, there will be no fictitious line between devices created for one purpose and those created with a different intended use. Manufacturers would be less inclined to facetiously declare that their device’s intended use is something different because intended use is no longer as critical a question. Each indication would likely

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<sup>88</sup> *Regulating Innovation*, *supra* note 40, at 56 (1994) (statement of Brad A. Kohl, President of Medical Safety Technologies, Inc.).

take the same amount of time to get through FDA review, and thus manufacturers would be encouraged to be honest about the intended use in order to only go through the premarket approval process once. Additionally, manufacturers will be able to retain their proprietary information from their competitors without resulting in harm to the public. Since all Class III devices will be safe and effective, testing data garnered for FDA submissions will be irrelevant to the public.

Although PMA's may take marginally longer to review on average and may be more expensive for manufacturers, this private cost may be passed to the public once the device is on the market. Cost differentials may not be that great anyway, given that most manufacturers submit hybrid 510(k)'s with varying amounts of preclinical and clinical data. At any rate, the benefit to the public of a single regulatory scheme which focuses on the important question of whether the device is safe and effective far outweighs the incremental cost and inconvenience to manufacturers.

Thus the FDA ought to return to its statutory role, that is, to require manufacturers to show safety and efficacy. An inquiry, no matter how thorough, into substantial equivalence is an inefficient allocation of resources. Substantial equivalence has no relevance outside the FDA.<sup>90</sup>

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<sup>90</sup>Goldberger, *supra* note 10, at 330.