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FIXING A 510(K) LOOPHOLE: IN SUPPORT OF THE SOUND DEVICES ACT OF 2012

by

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Abstract

The current medical device regulatory system contains a dangerous loophole. While the voluntary recall of a harmful medical device removes it from the market, new devices that claim they are substantially equivalent to the recalled device can still reach the market through the 510(k) premarket notification process. Devices that have gained regulatory clearance in this fashion have caused considerable harm and are much more likely to be recalled for safety reasons as well. The recently proposed Safety of Untested and New Devices Act of 2012 (the “SOUND Devices Act”) would fix this loophole. This paper describes the 510(k) clearance process and the recalled predicate loophole, summarizes the SOUND Devices Act’s proposed solution, and argues that Congress ought to enact the SOUND Devices Act.

I. Introduction

On January 31, 2012, U.S. Representative Edward Markey (D-MA) introduced a bill proposing the enactment of the Safety of Untested and New Devices Act of 2012 (the “SOUND Devices Act”).¹ The proposed legislation would amend the Federal Food, Drug, and Cosmetic Act to prevent the marketing of medical devices on the basis of substantial equivalence to predicate devices that have been recalled, corrected, or otherwise removed from the market for safety purposes.² Congressman Markey and his four co-sponsors claim that the SOUND Devices Act will plug a dangerous loophole in the 510(k) premarket notification process for medical devices to enter the market.³

As the 510(k) clearance process has become the most common regulatory pathway to market for medical devices,⁴ any new legislation affecting this process can have profound consequences for both the manufacturers who market new medical devices and the consumers who ultimately use them. This paper describes the SOUND Devices Act and argues that Congress ought to pass it. Faulty medical device products cleared on the basis of flawed

¹ See H.R. 3847, 112th Cong. (2012).

² Id.

³ See Office of Congressman Edward J. Markey, DEFECTIVE DEVICES, DESTROYED LIVES: LOOPHOLE LEAVES PATIENTS UNPROTECTED FROM FLAWED MEDICAL DEVICES 3 (March 22, 2012) [hereinafter *Markey Report*].

⁴ COMMITTEE ON THE PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS, INSTITUTE OF MEDICINE, MEDICAL DEVICES AND THE PUBLIC’S HEALTHY: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 85 (2011) [hereinafter *IOM 510(k) Report*].

predicates have caused substantial harm to consumers in a number of cases, but the FDA currently lacks authority to address this problem, whether directly or using its other regulatory tools. Furthermore, failing to close this loophole would undermine the policies underlying the 510(k) clearance process and render medical device regulatory review less effective as a whole. Part II of this paper summarizes the framework of modern medical device regulation and the 510(k) clearance process. Part III describes the loophole that allows new medical devices to be cleared on the basis of predicates that have proved to be unsafe. Part IV details the SOUND Devices Act's proposed solution to close this loophole. And Part V analyzes the solution, concluding that Congress ought to act swiftly to enact the SOUND Devices Act.

II. Medical Devices and the 510(k) Clearance Process

Although medical devices have existed since ancient times and have been misbranded since at least the mid-1700's, the U.S. public and legislature largely ignored the regulation of medical devices before the New Deal era, focusing instead on regulating food, drugs, and cosmetics.⁵ Medical devices came within the FDA's jurisdiction for the first time in 1938, when the newly passed Federal Food, Drug, and Cosmetic Act (the "FD&C Act") included medical devices in its basic misbranding and adulteration provisions.⁶ But these provisions only granted the FDA authority to regulate devices after they were placed on the market.⁷ The FD&C Act

⁵ See Peter Barton Hutt, A History of Government Regulation of Adulteration and Misbranding of Medical Devices, 44 FOOD DRUG COSM. L.J. 99, 99–100 (1989).

⁶ Peter Barton Hutt, Richard A. Merrill, and Lewis A. Grossman, FOOD AND DRUG LAW: CASES AND MATERIALS (3RD ED.) 968–69 (Foundation Press 2007).

⁷ Rodney R. Munsey, Trends and Events in FDA Regulation of Medical Devices Over the Last

created a system of premarket notification for new drugs, which became a premarket approval requirement after the Drug Amendments of 1962,⁸ but no comparable premarket regulatory scheme existed for medical devices until Congress established the modern medical device regulatory framework by passing the Medical Devices Amendments (the “MDA”) in 1976.

The MDA established the 510(k) clearance process as a by-product of the three-tiered medical device regulatory framework it created to balance competing considerations of ensuring product safety and fostering further innovation. This regulatory framework grew out of a Study Group formed by the Department of Health, Education, and Welfare at the behest of President Nixon and commonly referred to as the “Cooper Committee” after Dr. Theodore Cooper, the group’s chairman.⁹ The Cooper Committee envisioned the purpose of medical device legislation as not only avoiding hazards from unsafe medical devices but also promoting innovation in the development of new devices.¹⁰ Responding to the Committee’s call for regulatory requirements calibrated to the risks presented by different devices,¹¹ the MDA established a three-tiered

Fifty Years, 50 FOOD & DRUG L.J. 163 (1995).

⁸ See Hutt, et al., *supra* note 6 at 577.

⁹ Benjamin A. Goldberger, The Evolution of Substantial Equivalence in FDA’s Premarket Review of Medical Devices, 56 FOOD & DRUG L.J. 317, 320 (2001); Robert B. Leflar, Public Accountability and Medical Device Regulation, 2 HARV. J. L. & TECH. 1, 6–7 (1989) (“The concepts embodied in the Cooper Committee Report ultimately formed much of the basis for the 1976 Medical Device Amendments.”); Hutt, *supra* note 5 at 112 (“The final provisions of the 1976 Amendments are remarkably faithful to the Cooper Committee Report.”).

¹⁰ Theodore Cooper, Device Legislation, 26 FOOD DRUG COSM. L.J. 165, 172 (1971).

¹¹ Richard A. Merrill, The Architecture of Government Regulation of Medical Products, 82 VA.

classification system for medical device regulation, distinct from the single pathway of premarket approval for all new drugs.¹² After 1976, medical devices were organized according to three Classes. Class I comprises of those devices for which general controls such as misbranding and adulteration prohibitions and GMP regulations suffice to reasonably assure safety and effectiveness. Class II devices require both general controls and product performance standards to reasonably assure the same. Meanwhile, only a premarket approval (“PMA”) process similar to new drug approval can ensure the safety and effectiveness of Class III devices.¹³

Section 510(k) was created as part of the MDA’s attempt to address medical devices that were on the market prior to its enactment and new medical devices introduced later consistently within this framework. After observing the FDA’s difficulties implementing the Drug Amendments for pre-1962 drugs, Congress devised a scheme to phase the new requirements in.¹⁴ The MDA directed the FDA to designate an appropriate Class to all pre-1976 medical devices according to the recommendations of independent advisory panels. By virtue of their classification, pre-1976 devices placed in Classes I or II were not subject to premarket approval,

L. REV. 1753, 1807 (1996) (citing STUDY GROUP ON MEDICAL DEVICES, DEPARTMENT OF HEALTH, EDUCATION AND WELFARE, MEDICAL DEVICES: A LEGISLATIVE PLAN 11 (1970)).

¹² *See id.* at 1807.

¹³ Munsey, *supra* note 7 at 165–66.

¹⁴ *See* Merrill, *supra* note 11 at 1810 (“FDA’s difficulties in applying the effectiveness requirement to pre-1962 drugs led Congress to embrace the principle that new devices should not be disadvantaged by the inevitably gradual implementation of the law.”).

and in the interest of avoiding market disruption for existing Class III devices,¹⁵ pre-1976 products designated as Class III were also not subject to premarket approval unless and until the FDA issued an order requesting the submission of a PMA. Meanwhile, every new medical device introduced post-1976 is placed in Class III and subject to full premarket approval regulation, unless it is reclassified into Class I or II or, significantly, it is demonstrated to be “substantially equivalent” to a pre-1976 device that is not subject to premarket approval, referred to as a predicate.¹⁶ The clearance of devices that are substantially equivalent to devices already on the market was introduced to prevent the unfairness that can result from allowing pre-1976 devices to remain on the market while subjecting their substantially equivalent counterparts to the full force of post-MDA regulation before they can be marketed.¹⁷ As a practical matter the FDA has also allowed using as a predicate a device that was itself cleared through 510(k) by

¹⁵ See Leflar, *supra* note 9 at 8 (noting that the different treatment of pre-1976 and post-1976 Class III devices “was probably designed to avoid market disruptions by freeing those with an existing stake in the lightly regulated preenactment status quo from the application of various new regulatory strictures for a temporary grace period.”).

¹⁶ Munsey, *supra* note 7 at 165–66; *see also* IOM 510(k) report, *supra* note 4, at 32 (“[I]f a new device were ‘substantially equivalent’ to a preamendment device, it could enter the market on the same terms and conditions as the preamendment device.”). Under the regulatory structure established in 1976, a valid predicate can be any pre-1976 Class I or Class II device, or it can be any pre-1976 Class III device for which the FDA has not yet imposed a PMA requirement. Hutt, *et al.*, *supra* note 6 at 991. Note that the current structure extends this to any legally marketed device. *See infra* notes 18–19 and accompanying text.

¹⁷ Goldberger, *supra* note 9 at 321.

comparison to another predicate device.¹⁸ This practice of “piggybacking” was specifically authorized in 1990, when Congress effectively extended the set of allowed predicates beyond pre-1976 devices to include any “legally marketed device.”¹⁹ Thus, under current medical device regulation, a new device can be cleared for the market if it is shown to be substantially equivalent to a legally marketed predicate device.

The MDA added section 510(k) to the FD&C Act to establish a premarket notification system for new devices to ensure that a new device cannot be marketed unless it has an approved PMA, it has been reclassified into Class I or II, or it is substantially equivalent to a predicate device.²⁰ Section 510(k) itself simply requires device manufacturers to notify FDA 90 days in advance of marketing any new device, but FDA has exercised its rule-making authority to require that manufacturers claiming substantial equivalence to a predicate device include in their premarket notifications data demonstrating the basis for substantial equivalence.²¹ Since section 510(k) effectively acts as the gatekeeper between devices touted as substantially equivalent to predicate devices and the market, the substantial equivalence path to FDA clearance has become known as the 510(k) clearance process. Importantly, a determination that a device is

¹⁸ Hutt, et al., *supra* note 6 at 998–99.

¹⁹ 21 U.S.C. § 360c(i)(1)(A)(ii); *see also* 21 C.F.R. 807.92(a)(3) (1994) (“A legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed [pre-1976], or a device which has been reclassified from Class III to Class II or I . . . or a device which has been found to be *substantially equivalent through the 510(k) premarket notification process.*”) (emphasis added).

²⁰ H.R. REP. 94-853 at 37 (1976); Goldberger, *supra* note 9 at 321; Merrill, *supra* note 11 at 1810.

²¹ Leflar, *supra* note 9 at 29.

substantially equivalent to a predicate device does not connote FDA approval of the device's safety and effectiveness.²² However, for all intents and purposes, 510(k) clearance continues to act as an FDA-condoned “green light”²³ for marketing a new device that applies for a small number of Class I devices, most Class II devices, and some Class III devices.²⁴

The 510(k) process has come to dominate the path to market for new medical devices. Largely due to resource constraints at the FDA, the agency and industry alike have favored 510(k) as the primary way to bring devices to market.²⁵ The relative ease of clearing 510(k)

²² 21 C.F.R. § 807.97 (revised April 1, 2011) (noting that clearance of a device through the 510(k) premarket notification process “does not in any way denote official approval of the device.”); *see also* Medtronic, Inc. v. Lohr, 518 U.S. 470, 493 (1996) (“[T]he 510(k) process is focused on *equivalence*, not safety.”).

²³ Leflar, *supra* note 9 at 28.

²⁴ Since 1976, Congress has exempted most Class I devices from the 510(k) premarket notification requirement and authorized FDA to exempt Class II devices where appropriate. Hutt, *et al.*, *supra* note 6 at 992. Furthermore, the FDA has still not issued orders requiring PMA's for all pre-1976 Class III devices. *See* IOM 510(k) Report, *supra* note 4 at 33. *See also* U.S. GOV'T ACCOUNTABILITY OFFICE, MEDICAL DEVICES: FDA SHOULD TAKE STEPS TO ENSURE THAT HIGH-RISK DEVICE TYPES ARE APPROVED THROUGH THE MOST STRINGENT PREMARKET REVIEW PROCESS, Report 09-190 to Sen. Edward M. Kennedy, Rep. Henry A. Waxman, Sen. Charles E. Grassley, and Rep. John D. Dingell, 17 (Jan. 2009) [hereinafter *GAO Devices Report*] (showing that 1,265 Class I, 10,670 Class II, and 228 Class III devices were cleared through 510(k) during 2003–2007).

²⁵ *See* Robert Adler, The 1976 Medical Device Amendments: A Step in the Right Direction

premarket notifications as compared to reviewing PMA applications or reclassifying devices to Class I or II has applied internal pressure on the agency to find much more often than not that new devices are substantially equivalent to predicate devices.²⁶ As a result, only 1–4% of 510(k) submissions each year between 1976 and 2009 were found to be not substantially equivalent.²⁷ Apart from a higher probability of success, other considerations have also caused manufacturers to prefer 510(k) clearance. FDA condoned and in 1990 specifically authorized the practice of allowing new devices to “piggyback” by demonstrating substantial equivalence to a predicate that also entered the market on a showing of substantial equivalence.²⁸ Furthermore, resource pressures delayed FDA’s plans to issue orders for PMA’s for pre-1976 Class III devices and establish performance standards for Class II devices.²⁹ Between 1976 and 1990, more than 98 percent of FDA-regulated medical devices were cleared through 510(k) premarket notification, and in the year 2005, almost 99 percent of devices were cleared through the 510(k) process.³⁰ Whether by design or not, 510(k) clearance is now the default path to market for almost all new medical devices.

Needs Another Step in the Right Direction, 43 FOOD DRUG COSM. L.J. 511, 516 (1988).

²⁶ IOM 510(k) Report, *supra* note 4 at 33.

²⁷ *Id.* at 33.

²⁸ *See supra* notes 18–19 and accompanying text.

²⁹ IOM 510(k) Report, *supra* note 4 at 33. As of April 2011, efforts to promulgate regulations requiring submission of PMA applications for Class III devices were still not finished. IOM 510(k) Report, *supra* note 4 at 34.

³⁰ James M. Flaherty, Jr., Defending Substantial Equivalence: An Argument for the Continuing Validity of the 510(k) Premarket Notification Process, 63 FOOD & DRUG L.J. 901, 902 (2008).

III. The Recalled predicate loophole

1. The current 510(k) process clears new devices that are substantially equivalent to recalled predicate devices.

As the law currently stands, the FDA must allow any medical device that demonstrates substantial equivalence to a predicate device to reach the market, even if the predicate device was voluntarily recalled for safety reasons and the new device repeats the same flaws. This unfortunate loophole in the medical device regulatory framework arises from a conflict between the standards for 510(k) clearance and the FDA's institutional role as the guarantor of the safety and effectiveness of medical devices.

As mentioned above,³¹ 510(k) clearance has become the most common way for medical devices to reach patients, but the 510(k) clearance process is considered an evaluation only of a device's substantial equivalence to a predicate, not of a product's safety and effectiveness. Congress added language to the FD&C Act in 1990 that ostensibly enabled some level of safety and effectiveness review to enter the substantial equivalence inquiry.³² The statute currently requires that, where a new device has "different technological characteristics" from the predicate with which it claims substantial equivalence, it must demonstrate that the new device is "as safe and effective" as the predicate and "does not raise different questions of safety and efficacy."³³ However, the statutory scope of such an evaluation is very narrow,³⁴ and it does not address the

³¹ See *supra* notes 22–30 and accompanying text.

³² See IOM 510(k) Report, *supra* note 4 at 253–54.

³³ 21 U.S.C. § 360c(i)(2) (2006).

³⁴ IOM 510(k) Report, *supra* note 4 at 254 ("Arguably, [introducing the requirements for devices that had different technological characteristics] from their predicates represented an effort by

underlying problem of clearing a new device based on a flawed predicate because the “technological characteristics” can include design flaws.³⁵ A device that recreates the design flaws of a predicate can thus reach the market, regardless of how unsafe those flaws might be. This also creates a perverse situation where a new device that inherits a design flaw from its predicate can avoid safety and effectiveness evaluation while one that changes the device to fix that flaw may have introduced “different technological characteristics” and undergo a more extensive premarket notification process. Furthermore, according to both the FDA and Congress, a finding of substantial equivalence in no way indicates that a device has passed any sort of safety and effectiveness review.³⁶ The FDA has gone so far as to issue a regulation stating that “[a]ny representation that creates an impression of official approval of a device because of complying with the [510(k)] premarket notification regulations is misleading and constitutes misbranding.”³⁷ And the Congressional Research Service has found that, even if the FDA wanted to include safety in its 510(k) clearance evaluations, the FD&C Act would prohibit

Congress and the FDA to redesign the 510(k) system to include an evaluation of safety and effectiveness of all new devices. Nevertheless, the statutory scope of such an evaluation was very limited.”).

³⁵ Markey Report, *supra* note 3 at 5 (citing Communications between FDA staff and Representative Markey staff, March 7, 2012).

³⁶ *See* H.R. REP. No. 101-808 at 27 (1990) (“A determination by the FDA that a device is substantially equivalent to another device is a final agency action under the substantial equivalent provisions, but it does not preclude further agency action regarding safety and effectiveness.”).

³⁷ 21 C.F.R. § 807.97 (revised April 1, 2011).

it from doing so.³⁸ In effect, when a device demonstrates it is substantially equivalent to a predicate device, “FDA cannot deny clearance based on an independent determination of the safety and effectiveness of the device under review.”³⁹

As a backstop, the FD&C Act prohibits using as a predicate any device that has been the subject of a mandatory removal order,⁴⁰ but the vast majority of recalls are voluntary. Section 518(e), added in 1990,⁴¹ directs the FDA to order manufacturers, importers, distributors, and retailers to cease the manufacture and distribution of a device if it finds there is a “reasonable probability that [it] would cause serious, adverse health consequences or death.”⁴² Following such an order, the FDA must provide the affected parties an opportunity for an informal hearing on the merits of the order and the need for a recall, after which the FDA may amend its order to require a recall from everyone except individuals and certain device user facilities within its discretion.⁴³ However, the FDA very rarely exercises its mandatory recall authority because most manufacturers, upon discovering that a device presents a serious risk, agree to a voluntary recall. A recent Government Accountability Office report on medical device recalls counted

³⁸ Memorandum from Vanessa Burrows, Legislative Attorney, Congressional Research Service, to Rep. Edward Markey, The FDA’s Authority with Regard to Substantial Equivalence Determinations (March 16, 2012) [*hereinafter* CRS Memorandum on Substantial Equivalence].

³⁹ Markey Report, *supra* note 3 at 5 (citing Communications between FDA staff and Representative Markey staff, March 7, 2012).

⁴⁰ 21 U.S.C. § 360c(i)(2) (2006).

⁴¹ IOM 510(k) Report, *supra* note 4 at 57; Hutt, *supra* note 6 at 1059.

⁴² 21 U.S.C. § 360h(e)(1) (2006).

⁴³ 21 U.S.C. § 360h(e)(2) (2006).

3,510 voluntary recalls between January 1, 2005 and December 31, 2009 but noted that during that period the FDA did not issue a single mandatory recall order.⁴⁴ The invocation of the recall order is rare enough that the FDA does not formally track such orders and can only estimate that it has used its authority to force device recalls at least three times in the last two decades.⁴⁵ Under current law, all of the 3,510 devices recalled from 2005 through 2009 can act as valid predicates for new devices, even if those devices repeat the flaws that led to the recalls in the first place.

2. Harmful products have reached the market through the recalled predicate loophole.

Out of all the predicates cited by the 510(k) submissions received by the FDA in 2009, 29 percent were devices that were not registered and listed in either 2009 or 2010, suggesting that these were predicates that had been removed from the market.⁴⁶ According to the FDA, each year the agency clears an average of 28 devices that demonstrate substantial equivalence to a predicate known to be recalled, and such devices are five times more likely to be recalled with a

⁴⁴ U.S. GOV'T ACCOUNTABILITY OFFICE, MEDICAL DEVICES: FDA SHOULD ENHANCE ITS OVERSIGHT OF RECALLS, Report 11-468 to Sen. Charles E. Grassley and Sen. Herb Kohl, 3, n.5, 14 (June 2011).

⁴⁵ IOM 510(k) Report, *supra* note 4 at 57 (citing Desjardins, P.R., FDA response to information inquiry from the IOM Committee on the Public Health Effectiveness of the 510(k) Clearance Process (Jan. 7, 2011)).

⁴⁶ CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMIN., 510(K) WORKING GROUP PRELIMINARY REPORT AND RECOMMENDATIONS 57 (August 2010) [*hereinafter* CDRH Preliminary Report].

design flaw than other devices.⁴⁷ The following two examples highlight the harm that these devices can produce and the danger caused by the regulatory loophole that allows them to reach patients.

Transvaginal mesh implants—hammock-shaped slings inserted to treat urinary incontinence and to repair pelvic organ prolapse—have contributed to severe injuries and even death long after the recall of early versions of the device, rendering it a potent example of the recalled predicate loophole. In 1997, the FDA cleared the ProteGen sling, manufactured by Boston Scientific Corporation, for marketing based on a showing that it was substantially equivalent to mesh devices already on the market.⁴⁸ The product was a colossal failure from a safety standpoint, as it proved to erode extremely quickly within 8 months of implantation, causing bleeding ulcers and infections, and Boston Scientific voluntarily recalled the ProteGen sling in January 1999.⁴⁹ Unfortunately, the withdrawal of this product did not deter manufacturers from referring to it as a predicate device in subsequent 510(k) premarket

⁴⁷ See DELOITTE CENTER FOR HEALTH SOLUTIONS, HEALTH CARE REFORM MEMO: MARCH 26, 2012, http://www.deloitte.com/view/en_US/us/Insights/Browse-by-Content-Type/Newsletters/health-care-reform-memo/efdeadabede46310VgnVCM3000001c56f00aRCRD.htm (citing Brett Norman, Today in Politico Pro, March 23, 2012, <http://dyn.politico.com/members/forums/thread.cfm?catid=16&subcatid=57&threadid=6550012> (quoting FDA spokesperson Karen Riley)).

⁴⁸ L. Lewis Wall, The Perils of Commercially Driven Surgical Innovation, AM. J. OBSTET. GYNECOL., 202:30.e1–4, 30.e2 (2010); Markey Report, *supra* note 3 at 8.

⁴⁹ Wall, *supra* note 48 at 30.e2.

notification clearances. Most notably, Mentor Corporation introduced a vaginal mesh product called ObTape in 2003, and it cleared the FDA 510(k) process on the basis of substantial equivalence to two products, one of which had as its 510(k) predicate the ProteGen sling.⁵⁰ Soon after ObTape's introduction, however, concerns about its safety arose. Literature studying ObTape-related complications has reported erosion of the mesh, abscess formation, erosion of vaginal tissue, and infection after ObTape insertion,⁵¹ resulting in 266 reports of adverse events to the FDA as of 2009.⁵² The device was removed from the market in March 2006,⁵³ and its legacy contributed to the FDA's release of a public safety warning to health care providers and patients about the risks of transvaginal mesh devices.⁵⁴ However, under the current regulatory

⁵⁰ Roni Caryn Rabin, *Women Sue Over Device to Stop Urine Leaks*, N.Y. TIMES, May 5, 2009, at D5, available at <http://www.nytimes.com/2009/05/05/health/05tape.html> (last visited April 7, 2012).

⁵¹ See Roxana Geoffrion, et al., Closing the Chapter on Obtape: A Case Report of Delayed Thigh Abscess and a Literature Review, J. OBSTET. GYNAECOL. CAN., 30(2): 143–147 (Feb. 2008).

⁵² Rabin, *supra* note 50. Ten deaths have also occurred in patients who have undergone transvaginal mesh procedures, five of which were linked to the mesh insertion procedure, one linked to complications from mesh removal, and four linked to post-operative complications not related to the mesh. OBSTETRICS AND GYNECOLOGY DEVICES ADVISORY COMMITTEE, FOOD AND DRUG ADMIN., SURGICAL MESH FOR TREATMENT OF WOMEN WITH PELVIC ORGAN PROLAPSE AND STRESS URINARY INCONTINENCE 14, 29 (Sept. 8–9, 2011).

⁵³ Geoffrion, et al., *supra* note 51 at 146.

⁵⁴ FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse (July 13, 2011),

regime, not only did nothing keep ObTape from reaching the market based on a predicate lineage that included previously recalled products, but manufacturers can continue basing future 510(k) submissions on substantial equivalence to ObTape and market new devices with the same design flaws.

Another type of medical device produced by Boston Scientific, the Resolution and Resolution II endoscopic clips, provides a stark example of a manufacturer's ability to market a flawed device, recall it when problems arise, and then quickly gain clearance for a follow-on device that repeats the flaws of its own recently recalled device. Endoscopic clips are metallic clips used for closing surfaces inside the body to stop gastrointestinal bleeding, close perforations, secure catheters or stents, and serve as markers for other therapies.⁵⁵ Boston Scientific recalled its Resolution clip in June 2009 in part because the clip sometimes would not deploy and, when it did deploy, sometimes would not release from tissue properly.⁵⁶ This created a risk that attempting to withdraw the delivery system would cause harm to the tissue that the clip had attached to.⁵⁷ Despite these problems with the Resolution clip, Boston Scientific

<http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm262435.htm> (last visited April 7, 2012) [hereinafter *FDA Updated Transvaginal Mesh Warning*].

⁵⁵ See AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY, TECHNOLOGY STATUS EVALUATION REPORT, ENDOSCOPIC CLIP APPLICATION DEVICES, GASTROINTESTINAL ENDOSCOPY, VOL. 63, NO. 6, 746–750, 746 (2006).

⁵⁶ FDA Enforcement Report for October 7, 2009, <http://www.fda.gov/Safety/Recalls/EnforcementReports/ucm185718.htm> (last visited April 7, 2012).

⁵⁷ See Markey Report, *supra* note 3 at 11.

received FDA clearance to market a second clip—called the Resolution II—based on a determination that it was substantially equivalent to the Resolution clip in December 2010, only a year and a half after Boston Scientific started gathering the first clip back from distributors.⁵⁸ While it cleared the device on substantial equivalence grounds, the FDA sought to address its lingering safety concerns by requesting stronger warnings in the Resolution II’s label.⁵⁹ Regrettably, those concerns were prescient, as the Resolution II was also removed from the market in short order in August 2011, citing problems very similar to those responsible for the recall of the Resolution clip.⁶⁰ The Resolution II’s delivery system sometimes failed to withdraw once the clip had deployed, creating the same risk that withdrawing the delivery system would damage tissue.⁶¹ Under the current legal regime, Boston Scientific could produce a substantially equivalent “Resolution III” clip with the same flaws and the FDA would have to grant 510(k) clearance. This loophole effectively allows device manufacturers to test new iterations of flawed devices not in a controlled clinical environment but on the unsuspecting public by releasing each new version to the market through the 510(k) process, voluntarily recalling the product if it proves harmful, and releasing the next version a short time thereafter under the rubric of 510(k)

⁵⁸ See Letter from FDA to Elena Nieves, Sr. Regulatory Affairs Specialist, Boston Scientific Corporation (Dec. 22, 2010).

⁵⁹ See Markey Report, *supra* note 3 at 11.

⁶⁰ *Id.*; FDA Enforcement Report for November 2, 2011, <http://www.fda.gov/Safety/Recalls/EnforcementReports/ucm278309.htm> (last visited April 7, 2012).

⁶¹ *Id.*

substantial equivalence, without having spent the time to do substantial further testing.⁶²

IV. The SOUND Devices Act's Proposed Solution

The SOUND Devices Act consists of four legislative proposals aimed at not only closing this loophole in the medical device regulatory framework but also establishing a robust system for manufacturers, the FDA, and the public to share information regarding the safety records of predicate devices. Specifically, the bill proposes (1) giving the FDA the authority to reject a device based on a recalled predicate; (2) requiring companies to submit information to the FDA about the market status of predicate devices; (3) instructing the FDA to create a public database of devices' eligibility to act as predicates; and (4) authorizing the FDA to review the effect that new device recalls have on devices in the same predicate lineage.⁶³

The most direct way in which the SOUND Devices Act would plug the recalled predicate loophole is by amending the FD&C Act to bolster the FDA's authority to reject claims of substantial equivalence to predicate devices that have proven to have serious safety issues. The bill would preserve and repeat the current prohibition against basing a substantial equivalence determination on a predicate that has been subject to a mandatory recall or has been determined to be misbranded or adulterated by judicial order.⁶⁴ But it would also add language to section

⁶² Cf. Deborah Cohen, Hip Implants: How Safe is Metal on Metal?, *BRITISH MED. J.*, 344:e1349, 22 (March 3, 2012) (“[A 510(k) clearance] is one very large uncontrolled experiment exposing millions of patients to an unknown risk.”) (quoting Michael Carome, deputy director of Public Citizen's Health Research Group).

⁶³ See Markey Report, *supra* note 3 at 7.

⁶⁴ Compare H.R. 3847, 112th Cong. § 2(b) (2012) with 21 U.S.C. § 360c(i)(2) (2006).

513(i) of the FD&C Act that gives the FDA authority to reject a claim that a new device is substantially equivalent to a predicate if the predicate or any other device in the predicate lineage was removed from the market and the removal was “due, in whole or in part, to an intrinsic flaw in technology or design that adversely affects safety” (which includes voluntary recalls).⁶⁵ This provision seeks to plug the recalled predicate loophole by granting the FDA discretionary authority to reject devices based on voluntarily recalled predicates, but it does not require the FDA to do so. The aim of this approach is to maintain the FDA’s flexibility in its implementation of this authority,⁶⁶ allowing it to introduce the requirement without overly disrupting the device industry.

In order to facilitate the FDA’s evaluation of the safety records of predicate devices, the bill’s second proposal would require a manufacturer seeking 510(k) clearance for a new device to furnish information about the market status of devices in its predicate lineage and the connections between any flaws in the predicates and the safety of the new device. In particular, the proposed provision would require the manufacturer to disclose, for each predicate device: (1) whether it has been corrected or removed from the market, (2) the basis for any correction or removal, including whether it was due to an “intrinsic flaw” that “adversely affects safety,” and (3) why the new device does not share such a flaw.⁶⁷ This provision would require

⁶⁵ H.R. 3847, 112th Cong. § 2(b) (2012). The proposed provision would also allow the FDA to reject a new device if (1) the FDA is in the midst of instituting regulatory action against a device in its predicate lineage or (2) the manufacturer of the device failed to submit information informing the FDA that a device in its predicate lineage had been recalled. *Id.*

⁶⁶ Markey Report, *supra* note 3 at 7.

⁶⁷ H.R. 3847, 112th Cong. § 2(a) (2012).

manufacturers to contemplate the safety of the predicate devices on which they base new products and force them to include information about those safety records in their 510(k) submissions, which they do not currently have to do.⁶⁸ In conjunction with the authority that the bill would grant the FDA to reject new devices that are based on harmful predicates, such a requirement would prevent situations like that of Oscor Inc.'s Adelante catheter introducer device. When the Adelante device was introduced to the market in 2007 on the basis of substantial equivalence to two earlier catheter products, Oscor failed to mention in its 510(k) submission that those products had been recalled in 2004 and 2005.⁶⁹ Then in 2008, Oscor recalled the Adelante device after discovering that it caused safety problems similar to those that led to the recall of its predicate devices.⁷⁰ Under the SOUND Devices Act, Oscor would have had to divulge the market status of the predicate devices to the FDA, which could have then exercised its authority to keep the device off the market because its predicates had been subject to recalls.

The third proposal the SOUND Devices Act makes is to instruct the FDA to create and maintain an up-to-date database that provides a common pool of information for the FDA, the public, and industry about medical devices' market status and eligibility as predicates. The

⁶⁸ See FDA, CONTENT OF A 510(K), March 15, 2012,

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm> (last visited April 7, 2012).

⁶⁹ See Markey Report, *supra* note 3 at 12.

⁷⁰ See *id.*; FDA Enforcement Report for November 5, 2008,

<http://www.fda.gov/Safety/Recalls/EnforcementReports/2008/ucm120530.htm> (last visited April 7, 2012).

proposed legislation would require the FDA to update this database when it makes a determination regarding the eligibility of a device to act as a predicate, and it would require the FDA to make such a determination when the agency issues a recall order for a device, the manufacturer reports a device recall, or the FDA “otherwise learns of a correction or removal of a device.”⁷¹ The database would ultimately include records of all device recalls and their effects on predicate eligibility, since the FD&C Act as it currently stands requires device manufacturers to report voluntary recalls to the FDA.⁷² Furthermore, the database would also include details regarding the causes for those recalls, because the SOUND Devices Act would instruct the FDA to include in the database “information . . . about the reason for the [recall]” and institute heightened reporting requirements that obligate manufacturers to submit addenda accompanying their voluntary recall reports that describe “the root cause assessment of each device defect leading to the [recall].”⁷³ In addition to providing the public with reliable information about device recalls, the purpose of this database would be to create a central resource on predicate eligibility so manufacturers can meet their obligations to avoid recalled predicates and furnish the FDA with market status information for the predicate lineages of their new products.⁷⁴

Finally, when new devices are recalled, the SOUND Devices Act would authorize the FDA to proactively review the effect that those recalls have on other devices in their lineages. The bill accomplishes this by allowing the FDA to order the manufacturers of devices in the same lineage as a newly recalled device to submit a report within 30 days stating whether their

⁷¹ H.R. 3847, 112th Cong., § 2(c) (2012).

⁷² 21 U.S.C. § 360i(g)(1) (2006).

⁷³ See H.R. 3847, 112th Cong., § 2(c)–(d)(1) (2012).

⁷⁴ See Markey Report, *supra* note 3 at 7.

devices share any intrinsic flaws with the recalled device and, if not, explain why.⁷⁵ This provision makes sure that the FDA can head off any flaws in recalled devices that are repeated in their substantially equivalent progeny, even if they have already been marketed.⁷⁶ For example, if Device A is a predicate device for both Device B, which is already on the market, and Device C, a new device in development, a recall of Device A should not trigger scrutiny of Device C's 510(k) clearance while ignoring the implications for Device B's safety. This rule allows the FDA to scrutinize both devices in light of the recall of a common predicate.

V. Analysis

Significant opposition has gathered in the medical device industry against the proposals embodied by the SOUND Devices Act and similar regulatory recommendations made by a working group at the FDA's Center for Devices and Radiological Health ("CDRH").⁷⁷ This Part will respond to opponents' arguments and demonstrate that Congress ought to pass the SOUND Devices Act because (1) the bill would enable the 510(k) clearance process to better address issues of device safety, (2) failing to adopt its proposals would undermine the noninferiority policy underlying the 510(k) clearance process, and (3) without legislative reform the FDA currently lacks the authority and tools to deal with the recalled predicate loophole.

⁷⁵ H.R. 3847, 112th Cong., § 2(d)(2) (2012).

⁷⁶ *Id.*

⁷⁷ See CDRH Preliminary Report at 55–57 (finding that “CDRH’s current [510(k)] practice allows for the use of some types of predicates that may not be appropriate” and noting that “a [510(k)] submitter is permitted to cite as a predicate a device that has been recalled by the manufacturer due to safety concerns.”).

1. If the SOUND Devices Act were enacted, the 510(k) clearance process would better address the safety of medical devices.

The SOUND Devices Act would improve the ability of the 510(k) clearance process to address the safety of new medical devices. Industry voices have argued that increasing the FDA's scrutiny of devices' eligibility to act as predicates will hinder innovation by increasing costs and delays in the marketing of new devices. Comments from industry representatives predicted that disallowing the use of certain devices would shrink the pool of available predicates, leading to a more difficult pathway for devices and increasing the time and cost associated with 510(k) clearance.⁷⁸ However, while the increased regulatory requirements authorized by the SOUND Devices Act may make the 510(k) clearance process more difficult and more costly, the extent of this effect is consistent with and justified by the safety interest that underlies FDA oversight of medical devices.

The proposed legislation would limit the pool of available predicates and thereby create a greater barrier for some new devices, but it would only eliminate predicates of limited value and allow the FDA to reject devices that are more likely to be harmful than others. As some industry members have conceded, banning certain substandard devices from predicate eligibility may improve the safety and effectiveness of new devices.⁷⁹ The benefit to public safety of

⁷⁸ FDA, 510(K) AND SCIENCE REPORT RECOMMENDATIONS: SUMMARY AND OVERVIEW OF COMMENTS AND NEXT STEPS 13, <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM239449.pdf> (last visited April 7, 2012) [*hereinafter* FDA Working Group Report].

⁷⁹ *Id.*

determining that a device is ineligible to act as a predicate is nowhere clearer than where a device was voluntarily recalled and thereby deemed “substandard” by its manufacturer. Out of over 2,400 medical devices that the FDA clears through the 510(k) process each year,⁸⁰ an average of only 28 list recalled devices as predicates in their submissions.⁸¹ Granting the FDA the authority to reject devices that claim substantial equivalence to recalled predicates would thus affect barely more than one percent of submissions each year. Meanwhile, these 28 devices are five times more likely to be recalled like their predicates were,⁸² potentially causing severe harm and widespread health complications for patients in the meantime. The added benefit to public health and safety of removing devices predicated on recalled products is thus disproportionate to the cost to the industry in terms of the number of devices that are affected, and prohibiting recalled devices from acting as predicates would likely improve the safety of new devices.

In addition to this specific cost-benefit analysis, the SOUND Devices Act would bring the 510(k) clearance pathway closer in line with the overarching goal of medical device regulation to ensure the safety and effectiveness of products for the consumer. Many courts and commentators have viewed 510(k) premarket notification negatively, largely due to a belief that the 510(k) process provides little in the way of assuring that devices utilizing this path to market are safe and effective.⁸³ In a recent report, the Institute of Medicine criticized the 510(k) process as “neither making safe and effective devices available to patients nor promoting innovation in

⁸⁰ See GAO Device Report, *supra* note 24 at 6.

⁸¹ See *supra* note 47 and accompanying text.

⁸² *Id.*

⁸³ Flaherty, *supra* note 30 at 902–03.

the medical-device industry” and suggested that the FDA abandon it in favor of a new pathway that is more closely tied to independent judgments of safety and effectiveness.⁸⁴ Commentators have complained that the 510(k) process encourages manufacturers to look to recasting past devices rather than truly innovating,⁸⁵ that this leads to inefficient resource allocation with respect to both product development and testing products for safety and effectiveness,⁸⁶ and that substantial equivalence determinations therefore provide little protection to the public.⁸⁷ Contrary to Congress’s intentions in drafting the MDA in 1976, the 510(k) exception has swallowed the rule of premarket approval of device safety and effectiveness,⁸⁸ causing medical

⁸⁴ IOM 510(k) Report, *supra* note 4 at 4, 7–8.

⁸⁵ *See* Goldberger, *supra* note 9 at 330 (“FDA encourages incremental changes to medical devices that would not preclude a finding of substantial equivalence rather than breakthrough changes that would bring radically new technologies to the marketplace through the PMA process.”)

⁸⁶ *Id.* at 330; Michael VanBuren, Closing the Loopholes in the Regulation of Medical Devices: The Need for Congress to Reevaluate Medical Device Regulation, 17 HEALTH MATRIX 443, 456 (2007) (“[The 510(k) process] encourages manufacturers to focus device testing on demonstrating substantial equivalence [which] does not have much value outside of the 510(k) process.”).

⁸⁷ Adler, *supra* note 25 at 516.

⁸⁸ *See* James S. Benson, Robert C. Eccleston, and Mark Barnett, The FDA’s Regulation of Medical Devices: A Decade of Change, 43 FOOD DRUG COSM. L.J. 495, 500 (1988) (“Congress never intended the 510(k) authority to act as a surrogate for [PMA] approval”); Jonathan Kahan, Premarket Approval versus Premarket Notification: Different Routes to the Same Market, 39

device regulation to drift away from the central paradigm of food and drug regulation. While the SOUND Devices Act will not cure the 510(k) pathway of all its ailments, it would insert into the substantial equivalence determination some independent evaluation of the safety of new devices by considering their predicates' safety records. The bill is thus a proposal to nudge the 510(k) process in the direction of a regime that focuses on device safety and effectiveness.

Furthermore, while there may be legitimate concerns about the effect that higher costs and delays in the 510(k) clearance process may have on medical device innovation, perpetuating a dangerous loophole is not the appropriate way to deal with those issues. The recent CDRH Medical Device Innovation Initiative proposed a number of ways to support greater innovation in ways that do not directly compromise public health and safety.⁸⁹ These include facilitating the development of pioneering technologies, strengthening the scientific and regulatory research infrastructure, and increasing CDRH's preparedness to respond to transformative innovations and scientific breakthroughs.⁹⁰ Moreover, it is a misnomer to characterize the object of medical device regulation as promoting innovation through the introduction of new products per se; rather, its goal should be to facilitate innovation by permitting the timely entry of new devices that it expects will improve public health.⁹¹ As noted by the FDA 510(k) Working Group, a

FOOD DRUG COSM. L.J. 510 (1984) ("[The] short, almost secondary [510(k)] provisions, have, in many ways, eclipsed the detailed statutory provisions [that Congress] so painstakingly drafted.").

⁸⁹ FDA, CDRH Innovation Initiative White Paper,

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/ucm242067.htm> (February 2011).

⁹⁰ *Id.*

⁹¹ IOM 510(k) Report, *supra* note 4 at 7.

proper study of how the FDA facilitates innovation should go beyond measures of “time to market” and the number of devices on the market and focus instead on an understanding of the broader relationship between regulation, innovation, and public health.⁹² Thus, any argument against the SOUND Devices Act that refers only to the phenomena of increased costs and delays or fewer available devices and predicates does not properly address concerns about innovation in the medical device industry.

2. Failing to close the recalled predicate loophole would undermine the noninferiority principle underlying the 510(k) process.

Failing to address the recalled predicate loophole would ultimately undermine the noninferiority principle that underlies the use of substantial equivalence as the basis for the 510(k) clearance of medical devices. As discussed above, the policy that motivated the creation of 510(k) substantial equivalence was a desire for parity in the MDA’s treatment of pre-1976 and post-1976 medical devices.⁹³ However, a basic principle of “noninferiority” also underlies 510(k) clearance, since the process is based on the premise that the safety and effectiveness of any new device cleared on the basis of substantial equivalence is at least equal to that of a legally marketed predicate device.⁹⁴ This principle is reflected in statutory and regulatory language that

⁹² *Id.* at 12.

⁹³ *See supra* notes 14–19 and accompanying text.

⁹⁴ *See* IOM 510(k) Report, *supra* note 4 (describing the standard of “noninferiority”: “the new device had to be ‘as safe and effective’ as the reference device and did ‘not raise different questions of safety and effectiveness’ from the reference device”); *cf.* Merrill, *supra* note 11 at 811 (“[The 510(k) process is] the primary means by which FDA attempts to ensure the safety and effectiveness of the majority of marketed devices.”).

requires new devices whose technological characteristics differ from their predicates to be “as safe and effective” as the latter.⁹⁵ In theory, noninferiority can establish a reasonable minimum standard for the safety of a new device by presuming that introducing a new medical device that is as safe and effective as a legally marketed medical device should not have an overall negative effect on public safety.⁹⁶ But by allowing a new device to reach the market based on substantial equivalence to a device that is proven to be harmful, the recalled predicate loophole flies in the face of this presumption and threatens the legitimacy of the 510(k) clearance process. A predicate that has been recalled has proved to have a negative effect on public health and safety, and allowing the clearance of a device that is merely no less safe than such a predicate erodes the premise that substantial equivalence reasonably assures public safety will not be harmed by the introduction of a new medical device. To the contrary, the current regime would hypothetically even allow devices that are expected to be harmful to reach the market because a device that is equally safe (and thus equally harmful) to a recalled predicate can be cleared under 510(k). By empowering the FDA to eliminate this possibility, the SOUND Devices Act’s proposal to plug the recalled predicate loophole would bring the 510(k) clearance process back in line with the

⁹⁵ 21 U.S.C. § 360c(i)(1)(A)(ii); 21 C.F.R. § 807.100(b)(2)(ii).

⁹⁶ *Cf.* H.R. Rep. No. 893, 94th Cong., 2d Sess. (1976) (legislative history of the MDA noting that substantial equivalence “should be construed narrowly where necessary to assure the safety and effectiveness of a device but not so narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness”). This language suggests that Congress construed 510(k) substantial equivalence as including a premise that new devices cleared through this process will not present new issues of safety and effectiveness beyond those already presented by legally marketed products.

principle that substantial equivalence determinations provide some assurance that newly cleared devices are not harmful to public health and safety.

The tension between the recalled predicate loophole and the principle of noninferiority is further exacerbated by the phenomenon of “predicate creep” that plagues the 510(k) clearance process. The SOUND Devices Act’s proposals would prevent this phenomenon from proliferating the harmful effects of a device recall. Given the approved practice of “piggybacking” a device’s substantial equivalence on predicates that were themselves cleared based on substantial equivalence to a third device,⁹⁷ incremental device changes may, over a number of iterations, result in a device that is significantly different from the original, in a phenomenon referred to as “predicate creep.”⁹⁸ When each iteration of a device claims to be merely at least as safe and effective as its predicate, this phenomenon can lead to a “difference in effectiveness between [the latest and earliest iterations that] may approach clinical significance.”⁹⁹ Therefore, if one device in this chain of predicates proves to be harmful enough to merit its withdrawal from the market, it raises significant implications for the safety and effectiveness of other devices in the chain. Through the mechanics of “predicate creep,” a flaw introduced in one predicate may propagate and even amplify in later iterations, further exacerbating the erosion of the principle that noninferiority reasonably assures safety and

⁹⁷ See *supra* notes 18–19 and accompanying text.

⁹⁸ Strengthening the Center for Devices and Radiological Health’s 510(k) Review Process; Public Meeting; Request for Comments, 75 Fed. Reg. 4402, 4404 (Jan. 27, 2010) [*hereinafter* CDRH Request for Comments]. This phenomenon has also been termed “equivalence creep.” Leflar, *supra* note 9 at 51.

⁹⁹ CDRH Request for Comments, *supra* note 98 at 4404.

effectiveness, as discussed above. The SOUND Devices Act’s proposals would address this problem by providing that the recall of a predicate triggers scrutiny of not only new devices but also devices that are already on the market and claim substantial equivalence to that predicate.¹⁰⁰ By addressing all devices in the affected predicate lineage, this proposal would mitigate the effects of “predicate creep” and ensure that determinations of substantial equivalence lead to the introduction of products that are not expected to be harmful to public health and safety.

3. **Legislative reform is necessary to fix the recalled predicate loophole.**

The FDA currently lacks the authority to adequately address the safety and effectiveness of devices based on predicates that have been recalled for safety reasons, necessitating a statutory intervention such as the SOUND Devices Act. Medical device industry representatives have argued that proposed legislation to increase FDA authority is unnecessary because “FDA already has abundant authority to carry out its mandate” to ensure the safety and effectiveness of medical devices.¹⁰¹ However, the Congressional Research Service has concluded that the FD&C Act does not currently authorize the FDA to deny a 510(k) clearance because it is based on substantial equivalence to a predicate device that has been recalled voluntarily.¹⁰² If a new

¹⁰⁰ See *supra* Part IV.

¹⁰¹ See Markey Report, *supra* note 3 at 6 (citing Communications between Advanced Medical Technology Association (Advamed) staff and Rep. Markey staff, March 6, 2010); Alex Nussbaum, Medical Device Loophole Needs Closing by Congress, FDA Device Chief Says, BLOOMBERG, Feb. 28, 2011, <http://www.bloomberg.com/news/2012-02-28/fda-device-chief-says-approval-loophole-needs-closing.html> (last visited April 7, 2012).

¹⁰² CRS Memorandum on Substantial Equivalence, *supra* note 38 at 2–3 (“[I]t would not appear that the FDA would be able to deny a § 510(k) clearance based on a predicate device that has

device has the same intended use and technological characteristics as a faulty predicate, the FDA has no authority to deny clearance on the basis of substantial equivalence.¹⁰³ If a new device has the same intended use but different technological characteristics, the FDA must clear the device so long as it is “as safe and effective” as the faulty device and raises no “different questions of safety and effectiveness,”¹⁰⁴ seemingly ensuring that new devices can repeat their predicates’ faults. Furthermore, the current statute is very specific about the requirement that the FDA may only review information related to substantial equivalence, to the exclusion of independent questions of safety.¹⁰⁵ The FD&C Act instructs that the FDA “shall only request information that is necessary to making substantial equivalence determinations” and must do so in the “least burdensome” way to the manufacturer.¹⁰⁶

The FDA’s continued clearance of new devices that the agency knows are based on flawed predicates highlights the agency’s inability to address the recalled predicate loophole without legislative action. As noted above,¹⁰⁷ the FDA acknowledges that devices predicated on recalled devices are five times more likely to be recalled themselves, but it continues to clear an average of 28 such devices each year. Furthermore, the agency’s current set of regulatory tools

been [voluntarily] recalled for safety or other reasons.”).

¹⁰³ See 21 U.S.C. § 360c(i)(1)(A)(i); 21 C.F.R. § 807.100(b)(2)(i).

¹⁰⁴ 21 U.S.C. § 360c(i)(1)(A)(ii); 21 C.F.R. § 807.100(b)(2)(ii).

¹⁰⁵ See Goldberger, *supra* note 9 at 328 (“Information not related directly to substantial equivalence, such as information about the absolute safety and effectiveness of a device, may not be requested.”).

¹⁰⁶ 21 U.S.C. § 360c(i)(D).

¹⁰⁷ See *supra* note 47 and accompanying text.

is inadequate to address the safety concerns that may accompany new devices that are substantially equivalent to flawed predicates. For example, the FDA has issued public health notifications describing “serious complications” associated with the use of transvaginal mesh devices,¹⁰⁸ but it lacks the authority to keep new transvaginal mesh devices that, like Mentor’s Obtape sling,¹⁰⁹ are substantially equivalent to previously recalled devices off the market. As a result, at least 13 new transvaginal mesh devices have been introduced since the first FDA public health warning in October 2008,¹¹⁰ despite 2,874 reports of injuries, deaths, and malfunctions between 2008 and 2010.¹¹¹ FDA’s power to enforce labeling requirements has also not been effective in preventing devices based on flawed predicates from causing harm. As discussed above,¹¹² Boston Scientific’s Resolution II endoscopic clip reached the market based on substantial equivalence to the recalled Resolution clip, and to mitigate foreseeable issues with the

¹⁰⁸ See, e.g., FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence, <http://www.fda.gov/medicaldevices/safety/alertsandnotices/publichealthnotifications/ucm061976.htm> (issued October 20, 2008).

¹⁰⁹ See *supra* notes 48–54 and accompanying text.

¹¹⁰ This number was compiled by comparing the list at Hissey Kientz LLP, List of Transvaginal Surgical Mesh Products and Manufacturers, <http://www.jdsupra.com/post/documentViewer.aspx?fid=2f9712f6-2ff4-4759-86b1-267c1b8e91e7> (March 30, 2012) with the FDA 510(k) Premarket Notification database.

¹¹¹ FDA Updated Transvaginal Mesh Warning, *supra* note 54.

¹¹² See *supra* notes 55–62 and accompanying text.

product, the FDA required a stronger warning on the device's label.¹¹³ However, the Resolution II was still ultimately recalled on the basis of a flaw it repeated from the Resolution clip.¹¹⁴ If the SOUND Devices Act were passed, Boston Scientific would have had to submit information during the Resolution II's 510(k) process that revealed the presence of the same flaw that led to the Resolution's recall, and the FDA would have had the power to reject the device on that basis. The FDA's want for regulatory power to remedy this type of situation has led Jeffrey Shuren, director of the CDRH, to express the agency's support for a legislative fix to the loophole.¹¹⁵

It is also relevant to note that industry comments have been self-contradictory with respect to the need for legislation to fix the recalled predicate loophole. Industry comments in opposition to the SOUND Devices Act, a piece of proposed legislation, claim that no such legislation is necessary. However, industry comments in response to a recommendation by the FDA's 510(k) Working Group that the CDRH consider developing regulatory guidance on when an unsafe device should no longer be available as a predicate noted that such a recommendation would require a statutory amendment to be implemented.¹¹⁶ Industry opinion on the appropriate form of reform appears to change depending on whether the reform it opposes is in the form of a legislative bill or regulatory guidance. This undermines the credibility of complaints that legislation is unnecessary.

¹¹³ See Markey Report, *supra* note 3 at 11.

¹¹⁴ *Id.*

¹¹⁵ Nussbaum, *supra* note 101.

¹¹⁶ FDA Working Group Report, *supra* note 78 at 13.

VI. Conclusion

Tremendous external pressure has mounted against suggestions for medical device regulatory reform recently.¹¹⁷ But as discussed above, the current regulatory system is not viable without fixing the recalled predicate loophole in the 510(k) clearance process. The SOUND Devices Act would grant the FDA the authority to scrutinize both new devices and devices already on the market that have recalled products in their predicate lineages, and it would establish new reporting requirements and a public database so that the FDA, manufacturers, and consumers can access information regarding the market status and safety records of predicate devices. Whether Congress wants to maintain the current 510(k) regime or ultimately discard it in favor of a better regulatory pathway,¹¹⁸ enacting this reform would enable the medical device regulatory system to better address safety and effectiveness concerns, plug a loophole that undermines the principles underlying the 510(k) process, and address a problem that requires a legislative solution. Congress should resist pressures from industry and other groups and pass the SOUND Devices Act in the interest of consumer protection.

¹¹⁷ Barry Meier, Study of Medical Device Rules Is Attacked, Unseen, N.Y. TIMES, July 28, 2011, at A1, *available at* www.nytimes.com/2011/07/28/health/28institute.html (last visited April 9, 2012) (describing the medical device industry’s “waging [of] an extraordinary campaign” against the IOM 510(k) Report’s recommendations for reform).

¹¹⁸ See IOM 510(k) Report, *supra* note 4 at 4, 7–8.