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ARTICLE

ATTACK OF THE CLONES:
AN EXAMINATION AND CRITIQUE OF FDA'S MEDICAL DEVICE REGULATORY SCHEME

William Chanes Martinez *

ABSTRACT

In the 43 years since the enactment of the Medical Device Regulation Act of 1976 (MDRA), the United States has devolved into a public health crisis emergency regarding medical device safety. Over the last decade, faulty or flawed medical devices have injured 1.7 million and killed nearly 83,000 people nationwide. This paper will argue that the country's current medical device safety crisis is directly tied to the United States Food and Drug Administration's (FDA) inadequate regulation of those products, the agency's inadequate pre-market approval (PMA) process, corporate abuse of the FDA 510(k) pathway, and the FDA's failure to engage in post market surveillance and enforcement that ensures the safety of the

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medical devices that it approves/clears. This paper reviews the major medical device regulatory oversight reforms that scholars have proposed over the last several decades and provides its own novel recommendations. Due to the recent enactment of the 21st Century Cures Act and the current Administration's pro-deregulation posture, our medical device safety crisis is likely to continue to worsen unless reforms are enacted that demand that the FDA live up to its mission of protecting and advancing the public health.

Introduction

At eight months old, Bella Aguilar began experiencing the symptoms of epilepsy.[1] Bella's parents gave their child six different medications and even considered corrective brain surgery to mitigate her condition.[2] When Bella's doctor recommended Vagus Nerve Stimulation (VNS) therapy, however, her life changed.[3]

VNS Therapy is delivered through a medical device implanted under the chest skin via a wire that is wound around the vagus nerve in the neck.[4] The device sends mild pulses to the vagus nerve at regular intervals throughout the day to prevent seizures.[5] Today, Bella "is thriving in everything from academics to sports."[6] Just 13 years old, Bella takes college-level courses, is a four-sport athlete, and mentors special needs children.[7]

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[1] *Girl Once Known as "Miracle Baby" Meets Medical Device Team Who Saved Her Life*, ABC13 HOUSTON, https://abc13.com/5628462/ (last visited Nov. 3, 2019) [hereinafter ABC13 Houston].
[2] *Id.*
[3] *Id.*
[4] LivaNova, *How It Works*, VNS THERAPY (Oct. 20, 2019, 1:50 PM), https://us.livanova.cyberonics.com/learn-more/how-it-works; Patricia O. Shafer and Patricia M. Dean, *Vagus Nerve Stimulation (VNS)*, EPILEPSY FOUND. (Oct. 20, 2019, 1:50 PM), https://www.epilepsy.com/learn/treating-seizures-and-epilepsy/devices/vagus-nerve-stimulation-vns.
[5] *Id.*
[6] ABC13 Houston, *supra* note 1.
[7] *Id.*

Bella's story is a testament to the modern-day miracles that are medical devices. These devices impact the lives of literally millions of Americans every day. The United States is the largest medical device market in the world, constituting 40 percent of worldwide device revenue and sales, which amounted to $156 billion in 2017.[8] By 2023, the U.S. medical device market is projected to grow to $208 billion in annual sales and revenue.[9] About 32 million Americans—or about 1 in 10—have an implanted medical device like Bella.[10]

Yet, not everyone who has been prescribed a medical device ends up as fortunate as Bella. United States Food and Drug Administration (FDA) data reveals that more than 80,000 deaths and 1.7 million injuries have been linked to medical devices in the past decade.[11] For example, in 2006, Stephen Tower, an orthopedic surgeon, required a hip replacement.[12] He requested that his surgeon provide him a metal-on-metal hip, the ASR XL, which is manufactured by Johnson & Johnson.[13] After his hip replacement procedure, Dr. Tower suffered a series of complications and was forced to undergo a

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[8] International Trade Administration (ITA), *Medical Technology Spotlight*, SELECT USA (Oct. 20, 2019, 1:56 PM), https://www.selectusa.gov/medical-technology-industry-united-states.

[9] *Id.*

[10] Jeanne Lenzer, *Can Your Hip Replacement Kill You?*, N.Y. TIMES (Oct. 20, 2019, 1:59 PM), https://www.nytimes.com/2018/01/13/opinion/sunday/can-your-hip-replacement-kill-you.html.

[11] Sasha Chavkin, *The Implant Files Sparked Reform Around the World. Here's Why We're Still Reporting.*, INT'L CONSORTIUM OF INVESTIGATIVE JOURNALISTS (Nov. 5, 2020, 12:30 PM), https://www.icij.org/investigations/implant-files/the-implant-files-sparked-reform-from-around-the-world-heres-why-were-still-reporting/.

[12] Lenzer, *supra* note 10.

[13] *Id.*

follow-up surgery to remove the ASR XL hip implant.[14] During the implant removal surgery, Dr. Tower's surgeon discovered that his hip was black and appeared to be full of dirty oil.[15] The ASR XL hip implant had leaked cobalt into Dr. Tower's hip joint, which destroyed his hip muscles, tendons, ligaments, as well as injured his heart and brain.[16]

At the time of Dr. Tower's hip implant surgery, the FDA designated metal-on-metal hips, like the ASR XL, as Class II medical devices under the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA).[17] Class II devices receive far less FDA pre-market scrutiny under the FDCA's regulatory scheme than Class III devices.[18] Under FDA's 510(k) pre-market medical device "clearance" process, the vast majority of Class II devices make it to market so long as they are "substantially equivalent to a predicate device" that FDA has already cleared or approved for sale.[19] Under the 510(k) process, FDA rarely inspects device manufacturing facilities or

[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] 21 U.S.C. §§ 301-399d (2018).
[18] *See Metal-on-Metal Hip Implants: The FDA's Activities*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/metal-metal-hip-implants/metal-metal-hip-implants-fdas-activities (last visited Oct. 20, 2019) [hereinafter FDA Activities]; *Class 2 Device Recall DEPUY ASR XL ACETABULAR CUP SYSTEM*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?id=96142 (last visited Oct. 20, 2019).
[19] Diana Zuckerman et al., *Lack of Publicly Available Scientific Evidence on the Safety and Effectiveness of Implanted Medical Devices*, JAMA INTERN MED. (Oct. 20, 2019, 2:18 PM), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1910556.

requires device manufacturers to conduct clinical trials before it clears a device for market distribution.[20]

In January 2013, FDA reclassified metal-on-metal hips as Class III devices, which required metal-on-metal hip implant manufacturers to immediately stop marketing their devices.[21] The reclassification further demanded that such manufacturers submit pre-market approval (PMA) applications to FDA before placing their metal hip implant devices back on the market.[22] The FDA PMA process requires a device manufacturer to present sufficient valid scientific evidence to the FDA to reasonably assure the agency that the device is safe and effective for its intended use.[23]

Johnson & Johnson recalled the ASR XL metal-on-metal hip implant in 2010, but it continued to sell a similar metal hip implant, the Pinnacle, until 2013.[24] In May 2019, Johnson & Johnson agreed to a $1 billion settlement to resolve thousands of lawsuits that alleged that the company's Pinnacle metal-on-metal hip implant devices were defective.[25] More than 6,000 patients filed claims against Johnson & Johnson contending that defects in their Pinnacle implants left them unable to walk and in pain.[26] The lawsuits further argued that

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[20] *Id.*; *see* INST. OF MED., *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years* (2011) [hereinafter IOM].
[21] FDA Activities, *supra* note 18.
[22] FDA Activities, *supra* note 18.
[23] FDA Activities, *supra* note 18.
[24] Barry Meier, *Maker Drops Hip Device, Then Warns of Failures*, N.Y. TIMES (Mar. 9, 2010), https://www.nytimes.com/2010/03/10/business/10device.html.
[25] Jef Feeley, *J&J Pays About $1 Billion to Resolve Pinnacle-Hip Suits*, BLOOMBERG (Oct. 20, 2019, 2:30 PM), https://www.bloomberg.com/news/articles/2019-05-07/j-j-said-to-pay-about-1-billion-to-resolve-pinnacle-hip-suits.
[26] *Id.*

Johnson & Johnson had purposely misled the public about the implants' health risks and durability.[27]

Even when the FDA subjects a medical device to pre-market clinical trials, the agency sometimes ignores the risks those studies detect.[28] In 1997, Cyberonics filed a pre-market application seeking FDA approval of its VNS therapy medical device.[29] After completing clinical trials, an FDA adviser raised concerns about the high death rate associated with the device.[30] The FDA nonetheless approved VNS for market distribution with the condition that Cyberonics conduct post-market safety studies on the device.[31] FDA also failed to require Cyberonics to inform patients about the device's mortality risks.[32]

Cyberonics submitted five post-market studies to the FDA demonstrating the device was safe.[33] The company did not, however, submit device-related death data to the FDA.[34] This is because the FDA did not require Cyberonics to count such deaths in its post-market studies.[35]

In 2006, Cyberonics filed an application that sought FDA approval to use the VNS Therapy device to treat depression.[36] FDA convened an external third party

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[27] *Id.*
[28] Lenzer, *supra* note 10.
[29] *Id.*
[30] *Id.*
[31] *Id.*
[32] *Id.*
[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] Gardiner Harris, *Device Won Approval Though F.D.A. Staff Objected*, N.Y. TIMES (Oct. 20, 2019, 2:34 PM), https://www.nytimes.com/2006/02/17/politics/device-won-approval-though-fda-staff-objected.html; *see also Top FDA Official Approves Medical Device Despite Lack of Efficacy*, UNION OF CONCERNED SCIENTISTS (Oct. 20, 2019, 2:34 PM),

committee to evaluate Cyberonics' application and that committee determined that the device had not proved effective in treating depression during clinical trials.[37] During one such trial, Cyberonics implanted the device in 235 depressed patients and activated the machines in half of them.[38] After three months, the two groups were equally depressed and the trial had failed.[39]

In a second trial, Cyberonics activated the VNS devices in all 235 study subjects and determined that 30 percent showed significant improvement after six or more months.[40] Without a control group, however, it was impossible to determine if the device had actually improved depression in patients.[41] The external committee unanimously recommended that FDA deny the Cybertronics application.[42] The FDA, however, ignored the committee's recommendation and approved the VNS Therapy device to treat depression.[43]

The Cyberonics and Johnson & Johnson controversies are examples of how the FDA enables device manufacturers to treat the American public like guinea pigs. As John Oliver, the host of the late-night comedy show *Last Week Tonight* put it, "[N]obody wants to be treated like a guinea pig unless it means you get your own hanging water bottle that you can suck on from your bed. Which actually sounds completely delightful . . . ."[44]

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https://www.ucsusa.org/resources/top-fda-official-approves-medical-device-despite-lack-efficacy [hereinafter UCS].

[37] *Id.*

[38] *Id.*

[39] *Id.*

[40] *Id.*

[41] *Id.*

[42] UCS, *supra* note 36.

[43] Harris, *supra* note 36.

[44] LastWeekTonight, *Medical Devices: Last Week Tonight with John Oliver (HBO)*, YOUTUBE (June 3, 2019), https://www.youtube.com/watch?v=-tIdzNlExrw.

The United States is in the midst of a faulty medical device public health crisis. The crisis is directly tied to the FDA's lax regulation of medical devices, the agency's inadequate pre-market approval (PMA) process, corporate abuse of the 510(k) pathway, and the FDA's failure to engage in post-market surveillance and enforcement that ensures the safety of the medical devices that it approves/clears. This paper proposes various reforms designed to mitigate these problems.

This paper proceeds in four parts. Part I discusses the current regulatory structure that applies to medical devices and provides a history of FDA's regulatory authority before and after the enactment of the Medical Device Amendments (MDA) of 1976.[45] Part II highlights examples of the country's current medical device public health crisis. Part III provides an overview of a number of proposals to reform FDA's oversight of medical devices. Part IV concludes with a number of novel recommendations that, if adopted, would ensure the FDA lives up to its mission to protect and advance the public health.

I. FDA's Current Regulatory Structure for Medical Devices

This Part of the paper provides a broad overview of FDA's current regulatory structure applicable to medical devices. It begins with a brief history of American medical device regulation. It then details the FDA's medical device classification system. This Part concludes by examining the FDA's medical device marketing application scheme and evaluating the agency's post-market medical device requirements.

A. Historical Development of Medical of Medical Device Regulation

[45] 21 U.S.C. § 360(c)-(k) (2018).

i. Pre-1976

Prior to the twentieth century, the federal government had no authority to regulate drugs and medical devices, and drug and medical device manufacturers had no obligation to ensure the safety or efficacy of their products.[46] The FDA's oversight of food and drugs commenced in 1906 when President Theodore Roosevelt signed into law the Pure Food and Drugs Act (PFDA).[47] The new statute gave the precursor to today's FDA the power to regulate drugs, but not medical devices.[48]

Specifically, the PFDA criminalized the manufacture of "misbranded drugs."[49] The statute defined a "misbranded drug" as one bearing false or misleading statements regarding its identity, strength, quality, purity, or ingredients.[50] The Supreme Court limited FDA's regulatory power under the Act by construing this provision as not aimed at false curative or therapeutic statements."[51] Therefore, manufacturers were liable for false claims about a drug's ingredients but not for false statements about its therapeutic effects.[52]

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[46] Kyle Lennox, Note, *Substantially Unequivalent: Reforming FDA Regulation of Medical Devices*, 2014 U. Ill. L. Rev. 1363, 1370 (2014).
[47] Pure Food and Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed 1938).
[48] *Id.*; *see A History of Medical Device Regulation & Oversight in the United States*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states (last visited Oct. 17, 2019).
[49] Pure Food and Drug Act, § 1, 34. Stat. at 768.
[50] Pure Food and Drug Act, § § 7-8, 34. Stat. at 769-70.
[51] *See* United States v. Johnson, 221 U.S. 488, 497 (1911).
[52] Spenser F. Powell, *Changing Our Minds: Reforming the FDA Medical Device Reclassification Process*, 73 FOOD & DRUG L.J. 177, 182 (2018).

The Elixir Sulfanilamide disaster in the late 1930s provoked federal legislative reform.[53] In 1937, a new liquid form of sulfanilamide, a drug that "had been used safely for some time in tablet and powder form" in treating streptococcal infections, killed more than 100 people.[54] The manufacturer of Elixir Sulfanilamide was unaware that one of the chemicals it used to liquify the drug was a deadly poison.[55] The PFDA did not require manufacturers to conduct pre-market pharmacological efficacy and safety studies or submit to other pre-market approval processes.[56]

Congress passed the Food, Drug, and Cosmetic Act of 1938 (FDCA) in response to the sulfanilamide crisis and in an attempt to address these gaps in the PFDA.[57] The FDCA was the first federal statute that required pre-market drug safety testing.[58] The statute prohibited drug manufacturers from introducing any "new drug" into the market without first submitting an application to the FDA containing evidence demonstrating that the drug was safe for use.[59] The FDCA technically granted FDA the authority to regulate medical devices but limited that oversight "to ensuring that devices were not adulterated or misbranded."[60]

Over the next four decades, medical devices were largely unregulated in the United States.[61] In 1962,

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[53] Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, FDA CONSUMER MAG. (June 1981), https://www.fda.gov/files/about%20fda/published/The-Sulfanilamide-Disaster.pdf.

[54] *Id.*

[55] *Id.*

[56] *Id.*

[57] 21 U.S.C. §§ 301–399f (2018).

[58] *Id.*

[59] 21 U.S.C. § 505(a)-(b) (2018).

[60] Burgunda V. Sweet et al., *Review of the Processes for FDA Oversight of Drugs, Medical Devices, and Combination Products*, 17 J. MANAGED CARE PHARMACY 40, 40 (2011).

[61] *See* Powell, *supra* note 52, at 185.

Congress amended the FDCA to permit the FDA to regulate certain devices, like contact lenses, by classifying them as "drugs."[62] The majority of medical devices, however, remained unregulated prior to market entry.[63] The FDA attempted to supplement this gap with service announcements warning the public about unsafe medical devices that were on the market.[64] Congress finally granted FDA regulatory control over medical devices by passing the Medical Device Amendments of 1976 (MDA).[65]

ii. Post-1976

Much like the FDCA, Congress passed the MDA in response to a public health controversy.[66] In 1970, A.H. Robins Company began marketing the Dalkon Shield.[67]

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[62] 21 U.S.C. § 301 et seq.; *see also* United States v. An Article of Drug . . . Bacto-Unidisk . . ., 394 U.S. 784, 798 (1969) (affirming regulation of devices under the 1962 Amendments because Congress intended the term "drug" to have a meaning "broader than any strict medical definition").

[63] 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, 904 (2008).

[64] LastWeekTonight, *supra* note 40 (explaining that "there are some [devices] as phony as a $3 bill, like this Zehra applicator, for example, which has claimed to cure arthritis with z rays. There are no z rays.").

[65] Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976) (hereinafter MDA).

[66] Congressional debate over the MDA focused heavily on the harm caused by the Dalkon Shield controversy. *See also, e.g.*, S. REP. NO. 94-33, at 1 (1975) ("[M]any of the deaths and much of the illness attributed to this device could have been prevented if medical device legislation . . . had been in effect when the Dalkon shield was developed.").

[67] Carol Krismann, *Dalkon Shield*, ENCYCLOPEDIA BRITANNICA, https://www.britannica.com/science/Dalkon-Shield (last visite d Nov. 10, 2019).

A contraceptive intrauterine device, the Dalkon Shield was purported to be safer than other birth control alternatives.[68] Yet, the device was responsible for a high number of inflammatory pelvic infections, uterine perforations, and spontaneous septic abortions, as well as at least four deaths.[69]

The Dalkon Shield crisis prompted the enactment of the MDA, which granted the FDA pre-market regulatory authority over medical devices.[70] The statute defines a "device" as:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man . . . [or] intended to affect the structure or any function of the body . . .[71]

As discussed below, the MDA created a three-tiered classification system for medical devices.[72] Furthermore, the MDA established two ways that manufacturers can seek market approval for a device: the Pre-market Approval Process (PMA) and the Pre-market Notification Process (commonly known as the 510(k) pathway).[73]

Following the MDA, Congress passed the Safe Medical Devices Act of 1990 (SMDA).[74] Among other things, the SMDA extended to the FDA the authority to

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[68] *Id.*
[69] *Id.*
[70] 21 U.S.C. § 360(c)–(k) (1976).
[71] 21 U.S.C. § 321(h) (1976).
[72] Powell, *supra* note 52, at 184.
[73] *See* 21 U.S.C. § 360c(a) (1976) (describing the three classifications and corresponding levels of review).
[74] Safe Medical Devices Act of 1990, Pub. L. No. 101-629, § 2(a), 104 Stat. 4511, 4512 (codified as amended in scattered sections of 21 U.S.C.).

seek civil penalties, order device recalls, and temporarily suspend PMA applications for medical devices.[75] Furthermore, the SMDA requires "device user facilities," like hospitals, and device manufacturers to report to the FDA information that suggests that a device has caused or contributed to a patient's death or injury.[76] Lastly, with regard to the 510(k) pathway, the statute requires manufacturers to demonstrate "substantial equivalence" to a predicate device, that is, "that a proposed device has the same intended use and technological characteristics as a device already in the market," in order to be cleared for sale and distribution.[77]

In an attempt to better calibrate the balance between patient safety and the market demand for innovative new products, Congress passed a trio of laws: the FDA Modernization Act of 1997 (FDAMA), the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), and the FDA Safety and Innovation Act of 2012 (FDASIA).[78] The FDAMA sought to streamline the medical device approval process by exempting most Class I devices from the 510(k) pre-market notification process.[79] The FDAMA also granted the FDA the authority to exempt Class II devices from that process when it is unnecessary to ensure safety and effectiveness.[80]

The MDUDMA authorized the FDA to require user fees from device manufacturers to fund pre-market and post-market review.[81] To ensure the timely review of

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[75] *Id.*; *see* DAVID G. ADAMS, ET AL., FOOD AND DRUG LAW AND REGULATION 554 (3d ed. 2015).
[76] 21 U.S.C. § 360i(b)(1)(A)-(B) (2012).
[77] Powell, *supra* note 52, at 185.
[78] Adams, *supra* note 75, at 554–55.
[79] 21 U.S.C. §§ 301, *et seq.* (2018).
[80] *Id.*; Notice: Medical Devices; Exemptions from Premarket Notification; Class II Devices, 63 Fed. Reg. 3142, 3143 (Jan. 21, 1998).
[81] Adams, *supra* note 75, at 554.

pre-market applications, the MDUDMA tied a portion of the FDA's budget to a performance goal requirement for the review of those submissions.[82] Finally, the FDASIA reauthorized the FDA's authority to collect device applicant or "user" fees and permitted the FDA to reclassify devices by administrative order rather than by regulation.[83]

The 2016 21st Century Cures Act (Cures Act) is the most recent law that governs the manufacture and marketing of medical devices.[84] The Cures Act was designed to expedite the FDA pre-market approval and clearance process.[85] It empowered the FDA to permit a manufacturer to demonstrate medical device safety and effectiveness by the least burdensome appropriate means necessary.[86] "Necessary" means the minimum required information that would support an FDA determination that a medical device application provides a reasonable assurance of the device's safety and effectiveness.[87] The Cures Act also eased regulatory requirements for safety and effectives for certain Class I and Class II medical devices.[88]

A. FDA's Medical Device Classification System

The FDA organizes medical devices into three classes (e.g., Class I, II, III) based on the safety concerns associated with the device and the level of control needed

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[82] *Id.*
[83] *Id.*
[84] *21st Century Cures Act*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/21st-century-cures-act (last visited Nov. 10, 2020).
[85] *Id.*
[86] 21 U.S.C. § 360e (2018).
[87] *Id.*
[88] *Id.*

to provide the FDA with reasonable assurances of the device's safety and effectiveness.[89] The following subsections of this paper explain the particulars that pertain to FDA's medical device classification system.

i. Class I: General Controls

Class I devices are medical devices that present relatively few risks to human health or safety.[90] The FDA subjects Class I devices to the lowest level of regulatory oversight because those devices: (1) are not purported to be for use in supporting or sustaining human life or for a use that is of substantial importance in preventing impairment of human health; and (2) do not present a potential, unreasonable risk of illness or injury.[91] As a result, a manufacturer's demonstration of compliance with FDA general controls is sufficient to reasonably assure the agency that the device is safe and effective.[92]

General controls are "the basic provisions . . . that provide the FDA with the means of regulating devices to ensure their safety and effectiveness."[93] They include the FDA's requirements for facility registration, product listing, maintenance of records, labeling, and adherence to good manufacturing practices (GMPs), among other things.[94] Examples of Class I devices include elastic bandages, examination gloves, and certain hand-held

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[89] 21 U.S.C. § 360c(a)(1) (2012); *see* Powell, *supra* note 52, at 186.

[90] Steve Kanovsky et al., *The Medical Device Approval Process*, *in* A PRACTICAL GUIDE TO FDA'S FOOD AND DRUG LAW AND REGULATION 211–13 (Kenneth R. Pina & Wayne L. Pines eds., 6th ed. 2017).

[91] 21 U.S.C. § 360c(a)(1)(A) (2012).

[92] 21 C.F.R. § 860.3(c)(1) (2016) (defining Class I devices).

[93] *General Controls for Medical Devices*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/regulatory-controls/general-controls-medical-devices#introduction (last visited Nov. 10, 2020).

[94] Kanovsky, *supra* note 90, at 213.

surgical instruments.[95] The FDAMA exempts Class I devices from the FDA's pre-market notification requirements (510(k) pathway), except those "that are intended for a use that is of substantial importance in preventing the impairment of human health or that present an unreasonable risk of injury or illness" such as blood bank supplies, cannulas, and cardiovascular surgical instruments.[96]

ii. Class II: Special Controls

Class II devices are medical devices for which "general controls alone are insufficient to ensure their safety and effectiveness."[97] In addition to general controls, therefore, Class II devices are subject to device-specific special controls.[98] Special controls include, among other things, performance standards, pre-market data demands, post-market surveillance, special labelling requirements, and patient registries.[99] Class II devices include contact lenses, infusion pumps, powered wheelchairs, and computed tomography (CT) scanners.[100]

The FDA requires the majority of Class II devices to satisfy its 510(k) pre-market notification process.[101] That process requires the manufacturer to notify FDA of its intent to market a device that is "substantially equivalent" to another device that FDA already has cleared or approved for the market.[102] The FDA may, however, exempt a Class II device from pre-market

[95] *Id.*
[96] Kanovsky, *supra* note 90, at 214.
[97] *Id.*
[98] *Id.*
[99] 21 U.S.C. § 360c(a)(1)(B) (2018).
[100] Powell, *supra* note 52, at 187.
[101] Bonnie Scott, *Oversight Overhaul: Eliminating the Premarket Review of Medical Devices and Implementing a Provider-Centered Postmarket Surveillance Strategy*, 66 FOOD & DRUG L.J. 377, 378 (2011).
[102] Kanovsky, *supra* note 90, at 227.

notification on its own initiative or in response to a petition from a device manufacturer.[103]

The FDA relies heavily on 510(k) substantial-equivalence review to ensure the safety and effectiveness of Class II devices.[104] "A study of FDA 510(k) submissions from 1996 to 2009 found that more than 80% of the 510(k)-cleared devices were classified as Class II" devices, while only about 10% and 2% were Class I and Class III devices, respectively.[105] Moreover, the FDA clears for marketing approximately 90% of the Class I and II 510(k) pre-market notifications that it receives.[106] This is concerning given that critics of the 510(k) process contend that it is insufficient to ensure that new medical devices are safe and effective for market distribution.[107]

iii.Class III: Pre- Market Approval

Class III medical devices are devices that present the highest potential risk to the public and, therefore, are subject to the most stringent regulatory controls.[108] In addition to general and special controls, Class III devices typically must receive pre-market approval by the FDA to ensure their safety and effectiveness.[109] Class III devices are those that are either: (1) intended "for a use

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[103] *Id.*

[104] IOM, *supra* note 20, at 85.

[105] *Id.*

[106] U.S. GOV'T ACCOUNTABILITY OFF., GAO-09-190, MEDICAL DEVICES: FDA SHOULD TAKE STEPS TO ENSURE THAT HIGH-RISK DEVICE TYPES ARE APPROVED THROUGH THE MOST STRINGENT PREMARKET REVIEW PROCESS (2009).

[107] Powell, *supra* note 52, at 188; *see, e.g.*, Jonas Zajac Hines et al., *Left to Their Own Devices: Breakdowns in United States Medical Device Premarket Review*, 7 Pub. Libr. Sci. Med. 1, 6 (2010) (arguing that FDA should strengthen premarket device review by, *inter alia*, "insisting on higher scientific standards" and "tightening the interpretation of 'same intended use'").

[108] 21 U.S.C. § 360c(a)(1)(C) (2018).

[109] Kanovsky, *supra* note 90, at 214-15.

in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health;" or (2) "[present] a potential unreasonable risk of illness or injury."[110] Further, medical "[d]evices that were not available on the market before the enactment of the Medical Device Amendments . . . (generally referred to as postamendments devices), are automatically classified" as Class III devices, regardless of their risks.[111] Examples of Class III devices include pacemakers, breast and cochlear implants, and certain surgical meshes.[112]

C. Medical Device Marketing Applications

FDA has designated two major ways medical devices may enter the market: the Pre-Market Approval Process (PMA) or the Pre-Market Notifications Process (commonly known as the 510(k) pathway).[113] First, the PMA is the most stringent type of FDA device marketing application.[114] The applicant must support its PMA application with valid scientific evidence that demonstrates the safety and efficacy of the device for its intended use.[115] Second, device manufactures utilizing the 510(k) pathway rely on "substantial equivalence" to assure the FDA that its device is safe and effective, which is much less stringent than PMA.[116]

i. Pre- Market Approval Process

[110] 21 U.S.C. § 360c(a)(1)(C).
[111] *Reclassification*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/cdrh-transparency/reclassification (last visited Oct. 20, 2019).
[112] *Id.*
[113] Kanovsky, *supra* note 90, at 234.
[114] *Id.* at 235.
[115] *Id.*
[116] 21 U.S.C. § 360(k) (2018); Kanovsky, *supra* note 90, at 227.

The PMA is the most stringent type of FDA device marketing application.[117] PMA applications typically include extensive clinical trial results, bench trials, laboratory studies, animal studies, and references to all standards relevant to a device's safety and efficacy.[118] PMA applications also "must contain a complete description of the device and its components; a detailed description of the methods, facilities, and controls used to manufacture the device; the proposed labeling and advertising literature; and any training materials."[119]

Upon receipt of a PMA application, the FDA review process proceeds in four steps: (1) administrative review of the application; (2) substantive review of the application; (3) advisory committee review of the application, where applicable; and (4) FDA's final decision.[120] In other words, upon receipt of the PMA, the FDA "performs an administrative and limited scientific review to determine if the application is ready for filing."[121] If the PMA meets those criteria, the FDA moves on to conduct a substantive review of the submitted clinical data and scientific evidence.[122] The FDA attempts to complete its substantive review within 180 days.[123]

Upon completion of its substantive review, the FDA has the discretion to convene a third-party advisory committee, which consists of a panel of external clinicians, to evaluate the PMA application.[124] The

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[117] Kanovsky, *supra* note 90, at 235.
[118] Thomas Reuters Westlaw, *FDA Medical Devices Regulations Practice Note ¶ 7-613-9907* (2019), (https://www.westlaw.com/7-6139907?transitionType=Default&contextData=(sc.Default)&VR=3.0&RS=cblt1.0&documentSection=co_anchor_a609486) [hereinafter *Practice Note*].
[119] Kanovsky, *supra* note 90, at 235.
[120] *Practice Note*, *supra* note 118.
[121] *Id.*
[122] 21 C.F.R. § 814.44 (2019).
[123] *Id.*
[124] Kanovsky, *supra* note 90, at 240.

committee must hold a public meeting to review the application.[125] There are times when FDA decides that a device application does not warrant an advisory committee review.[126] Specifically, FDA foregoes external committee review when the agency determines that it (1) understands without external evaluation the safety and effectiveness issues pertinent to the medical device under review and (2) is competent to address those issues.[127]

FDA discretion whether to submit a PMA application to external committee evaluation is of relatively new vintage. The MDA initially required FDA to convene an advisory panel to review all new Class III devices.[128] In 1990, however, Congress amended the MDA to give FDA broad discretion regarding PMA application referral to an external committee.[129] The FDA now may make such a referral on its own initiative or "upon the request of an applicant unless the [agency] finds that the information in the application . . . substantially duplicates information which has previously been reviewed by a panel."[130] In 2017, the FDA issued a guidance document reaffirming that advisory panels are unnecessary if the device under review presents issues already addressed by a previous panel.[131]

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[125] 21 C.F.R. § 814.44.

[126] *Practice Note*, *supra* note 118.

[127] *Id.*

[128] 21 U.S.C. § 360e(c)(3) ("Upon receipt of an application . . . , the Secretary shall refer such application to the appropriate panel . . . for study and for submission . . . of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation.").

[129] *Id.*

[130] 21 U.S.C. § 360e(c)(3).

[131] *Guidance for Industry and FDA Staff: Procedures for Meetings of the Medical Devices Advisory Committee*, U.S. FOOD & DRUG ADMIN. (Sept. 1, 2017), https://www.fda.gov/regulatory-information/search-fda-guidance-

Today, companies routinely include a rationale in their device PMA applications as to why a panel review is unnecessary.[132] If the FDA nonetheless convenes an advisory panel, the panel conducts its review and then submits a report to the FDA that includes its recommendation as to whether the application should be approved and the bases for its recommendation.[133] The FDA is not bound by the committee's recommendation or rationales.[134]

If the evaluation of a PMA is favorable, the FDA may issue either: (1) an approval order, which approves the device for market; or (2) an approvable letter, which conditionally approves the device so long as the applicant satisfies additional requirements or submits additional information.[135] If the evaluation is unfavorable, on the other hand, the FDA will either deny the application or issue a not approvable letter, which details why the agency denied the PMA and how the applicant can address outstanding issues.[136]

Once the FDA approves a PMA, a device manufacturer is required to submit a PMA supplement application before making any change affecting the safety or effectiveness of the device.[137] The FDA's regulatory scheme defers to device manufacturers to make the initial determination whether a proposed change would affect the safety or effectiveness of the

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documents/procedures-meetings-medical-devices-advisory-committee.

[132] *PMA Advisory Panels: Do their Votes Matter?*, FOOD & DRUG LAW INST. (2019), https://www.fdli.org/2019/05/pma-advisory-panels-do-their-votes-matter/ (last visited Nov 10, 2019) [hereinafter FDLI Report].

[133] *Id.*

[134] Kanovsky, *supra* note 90, at 240.

[135] 21 C.F.R. § 814.44(d)-(f); Kanovsky, *supra* note 90, at 240-41.

[136] Kanovsky, *supra* note 90, at 240-41.

[137] *Id.* at 243.

device.[138] While the FDA has enumerated the types of changes that could trigger a PMA supplement, the agency does not define what constitutes a change that affects safety or effectiveness.[139]

PMA supplements typically do not require device manufacturers to submit the same, detailed information required for initial PMA applications.[140] Instead, supplement applications are limited to information necessary to assure FDA that the proposed device change does not compromise the safety or efficacy of the existing approved device.[141] Device manufacturers are not required to submit a PMA supplement if: (1) the change does not affect the device's safety or effectiveness, and (2) the change is reported to the FDA in a post-approval annual report as a condition of approval of the existing device (e.g., an editorial change in labeling).[142]

In 1998, the FDA discontinued publication of PMA medical device approvals in the Federal Register.[143] The

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[138] 21 C.F.R. § 814.39(a) (year) ("While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device: (1) New indications for use of the device. (2) Labeling changes. (3) The use of a different facility or establishment to manufacture, process, or package the device. (4) Changes in sterilization procedures. (5) Changes in packaging. (6) Changes in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device.").

[139] *Id.*

[140] *Id.*

[141] *Id.*

[142] *PMA Supplements and Amendments*, U.S. FOOD & DRUG ADMIN. (Oct. 20, 2019, 5:48 PM), https://www.fda.gov/medical-devices/premarket-approval-pma/pma-supplements-and-amendments#overview.

[143] Center for Devices and Radiological Health, *PMA Approvals*, U.S. FOOD & DRUG ADMIN. (Oct. 20, 2019, 3:17 PM),

FDA now notifies the public of a PMA or supplement approval decision by posting that information on the FDA's Devices Approved website page, along with a summary of the safety and effectiveness data upon which the agency based those approvals.[144] However, the FDA's website fails to include all relevant device safety and efficacy information. For example, Cybertronics' initial PMA for its VNS Therapy device, which is discussed above, does not contain information on the device's safety and effectiveness.[145] Furthermore, out of the first 100 of 227 PMA supplements Cybertronics filed for this one device, only one supplement contained a summary of the device's safety and effectiveness.[146]

Because of the amount of information that device manufacturers are required to submit to the FDA in PMA applications and throughout the review process, it takes FDA a significantly longer amount of time to review PMAs than it does 510(k) applications.[147] FDA's average review time for a 510(k) application is 20 hours while the agency spends approximately 1200 hours on a PMA review.[148]

Furthermore, the PMA process is vastly more expensive for manufacturers than the 510(k) process.[149] A 2010 survey of over two hundred medical technology companies in the United States found that the cost of obtaining PMA approval was nearly $100 million, with $75 million spent on FDA-related activities (and

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http://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals.

[144] *Id.*

[145] *VNS THERAPY SYSTEM PMA*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970003 (last visited Nov 10, 2019).

[146] *Id.* (need specific supplement)

[147] Powell, *supra* note 52, at 188.

[148] *See* Medtronic, Inc. v. Lohr, 518 U.S. 470, 478–79 (1996).

[149] Powell, *supra* note 52, at 201.

excluding any marketing costs).[150] The average cost to manufacturers to obtain 510(k) clearance was $31 million, with $24 million spent on FDA-related activities.[151] In Fiscal Year 2021, the standard fee for a PMA is $365,657, in comparison to $12,432 for 510(k) clearance.[152] As such, device manufactures are strongly incentivized to pursue the 510(k) pathway. Given FDA's high rate of 510(k) approvals, device manufacturers, historically, have been successful in avoiding PMA.[153]

ii. 510(k) Pathway

When Congress first created the 510(k) pathway, there was only one means by which device manufacturers could seek clearance under this avenue.[154] In order to qualify for the 510(k) pathway, a device had to be deemed "substantially equivalent" to another device that FDA had already cleared for market.[155] The FDA, however, developed the "The New 510(k) Paradigm," which offers device manufacturers three alternative approaches for seeking 510(k) clearance, to streamline the evaluation of 510(k)s in 1998.[156]

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[150] *Id.* n.203.

[151] *Id.*

[152] Center for Devices and Radiological Health, *Medical Device User Fee Amendments (MDUFA)*, U.S. FOOD & DRUG ADMIN. (Oct. 1, 2020) http://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa.

[153] U.S. GOV'T ACCT. OFF., MEDICAL DEVICES: FDA SHOULD TAKE STEPS TO ENSURE THAT HIGH-RISK DEVICE TYPES ARE APPROVED THROUGH THE MOST STRINGENT PREMARKET REVIEW PROCESS, GAO-09-190, 17 (Jan. 2009), http://www.gao.gov/assets/290/284882.pdf.

[154] Kanovsky, *supra* note 90, at 227.

[155] 21 U.S.C. § 360(k); Kanovsky, *supra* note 90, at 227.

[156] Kanovsky, *supra* note 90, at 231.

Today, a device manufacturer may choose either the Traditional[157] or Special[158] pathway to seek clearance for their device under 510(k).[159] While not frequently used, a device manufacture may also submit an Abbreviated 510(k) application.[160] If FDA determines that the device is not a substantial equivalent, the device manufacturer may, among other things, submit a second 510(k) application with new data or submit a PMA.[161] Lastly, the 510(k) Third Party Review Program allows device manufacturers an alternative review process, in which accredited Third Party Review Organizations are allowed to review certain low-to-moderate risk medical devices before they submit the device manufacturer's application to the FDA for a final decision.[162]

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[157] *How to Prepare a Traditional 510(k)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/premarket-notification-510k/how-prepare-traditional-510k (last visited Oct. 20, 2019).

[158] *How to Prepare A Special 510(k)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/premarket-notification-510k/how-prepare-special-510k? (last visited Oct. 20, 2019).

[159] *510(k) Submission Programs*, U.S. FOOD & DRUG ADMIN. https://www.fda.gov/medical-devices/premarket-notification-510k/510k-submission-programs (last visited Oct. 20, 2019).

[160] *How to Prepare an Abbreviated 510(k)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/premarket-notification-510k/how-prepare-abbreviated-510k (last visited Oct. 20, 2019); John Speer & Michael Dures, *How To Use The Abbreviated FDA 510(K) Pathway To Your Advantage*, GREENLIGHT GURU, https://www.greenlight.guru/blog/how-to-use-the-abbreviated-fda-510k-pathway-to-your-advantage (last visited Dec. 5, 2019) ("The abbreviated 510(k), which is what we're talking about today, is only used about 2% of the time. So, a very, very, small number of the overall 510(k)'s are brought to the market as an abbreviate 510(k) . . . .).

[161] Kanovsky, *supra* note 90, at 233; Practical Note, *supra* note 118.

[162] *510(k) Third Party Review Program*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/medical-devices/premarket-subm

1. Traditional 510(k)

The Traditional 510(k) process requires a manufacturer to submit a pre-market notification application to FDA and receive agency clearance before it can commercially distribute certain new medical devices, including most Class II devices.[163] The burden is on the device manufacturer to show that the new medical device is substantially equivalent to a predicate device, that is, a device that is already legally marketed.[164] Initially, the MDA did not define "substantial equivalence," but the statute's legislative history indicates that the FDA should apply the term narrowly where necessary to assure the safety and efficacy of the new device.[165] A House committee report stated:

> The Committee believes that the term [substantially equivalent] 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. . . . [D]ifferences between new and marketed devices . . . [that] would have a bearing on . . . a new device's safety and effectiveness [would dictate that] such [new] devices should be automatically classified into class III.[166]

issions/510k-third-party-review-program (last visited Oct. 20, 2019) [hereinafter *Third Party Review*].

[163] *Id.*

[164] Kanovsky, *supra* note 90, at 231.

[165] IOM, *supra* note 20, at 223.

[166] *Id.*

FDA deems a new device as "substantially equivalent" to one or more predicate devices if the device has: (1) the same intended use as the predicate and (2) has either: (a) the same technological characteristics as the predicate or (b) different technological characteristics from the predicate that do not raise new questions of safety and effectiveness.[167] Initially, the FDA required device manufacturers to provide proof of the new device's equivalence to an actual pre-MDA device (i.e., one that was on the market prior to MDA).[168] The FDA now allows device manufacturers to rely on post-MDA Class I or II devices that are legally marketed or a legally marketed Class III device for which FDA has not yet called for a PMA application to satisfy its substantial equivalence criteria.[169] As a result, the predicate device on which a manufacturer relies in the 501(k) process no longer needs to be a pre-MDA device. It cannot, however, be a device that the FDA has recalled from the market or one that a court has ruled is misbranded or adulterated.[170]

Device manufacturers are required to use the Traditional 510(k) process under the following circumstances.[171] First, unless otherwise exempt, a device manufacturer must utilize the Traditional pathway if it seeks to introduce a medical device into the market for the first time.[172] Second, a Traditional 510(k) application is required when a manufacturer: (1) makes a change to a cleared device that could significantly affect the safety or efficacy of the device or (2) makes a major modification to the intended use of a previously cleared

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[167] Kanovsky, *supra* note 90, at 227; Practical Note, *supra* note 118.
[168] Kanovsky, *supra* note 90, at 228.
[169] 21 U.S.C. § 360c(I)(2); Kanovsky, *supra* note 90, at 228.
[170] Kanovsky, *supra* note 90, at 231.
[171] *Id.*
[172] 21 U.S.C. § 360(k); Kanovsky, *supra* note 90, at 227.

device.[173] FDA requires the manufacturer to submit its Tradition 510(k) notification at least 90 days prior to its intended introduction of the device into the market.[174]

"Preamendment devices" are exempt from the Traditional 510(k) rule.[175] A preamendment device is a medical device that was legally marketed in the U.S. prior to the passage of the MDA and that has not been significantly changed or modified since that time and for which FDA has not required a PMA application.[176] Preamendment devices are "grandfathered," and, therefore, are not subject to the Traditional 510(k) application process.[177]

2. Special 510(k) Submission

The Special 510(k) pathway is intended to facilitate the submission, review, and clearance of a proposed change to a manufacturer's existing device that is already approved for market distribution through 510(k) clearance.[178] A device manufacturer may use the Special 510(k) option if its proposed changes to the device do not affect the device's intended use or alter its fundamental scientific technology.[179] If the desired changes do alter the device's intended use or its

[173] 21 C.F.R. § 807.81(a)(3)(i-ii); Kanovsky, *supra* note 90, at 227.
[174] 21 U.S.C. § 360(k).
[175] *Premarket Notification 510(k)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k (last visited Oct. 20, 2019) [hereinafter *Premarket Notification*].
[176] Kanovsky, *supra* note 90, at 232.
[177] *Id.*
[178] *Id.*
[179] *The Special 510(k) Program*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program (last visited Oct. 20, 2019) [hereinafter *Special 510(k)*].

fundamental scientific technology, the manufacturer is required to submit a Traditional 510(k) application.[180]

The Special 510(k) pathway requires the device manufacturer to inform the FDA that the new device conforms to the design controls that attended to the previously cleared device, but it does not require the manufacturer to submit clinical data that ensures that the device's change does not affect its safety or effectiveness.[181] Design controls require device manufacturers to adhere to a set of procedures applicable to the design and development of the medical device.[182] These controls aim to ensure that device specifications achieve the device's intended use.[183]

According to the FDA, such design control procedures produce reliable results and, therefore, can form the basis for a substantial equivalence determination without compromising the statutory and regulatory criteria for substantial equivalence.[184] "As described by the FDA, 'a Special 510(k) provides an efficient pathway for manufacturers to provide the minimum required information necessary to establish substantial equivalence for a modified device.'"[185] In order to incentivize manufacturers to elect the Special 510(k) pathway, FDA has agreed to review such applications within 30 days.

3. 510(k) Third Party Review Program

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[180] *Premarket Notification*, *supra* note 175.
[181] *Id.*
[182] Practical Note, *supra* note 118.
[183] *Id.*
[184] *Id.*
[185] Wilson Sonsini Goodrich & Rosati, *FDA Finalizes Guidance on Special 510(k) Pathway*, JD SUPRA (Sep. 17, 2019), https://www.jd*supra*.com/legalnews/fda-finalizes-guidance-on-special-510-k-32005/ [hereinafter WSGR] (citing *How to Prepare A Special 510(k)*, *supra* note 158).

"The 510(k) Third Party Review Program provides medical device manufacturers with a voluntary alternative review process." Specifically, the program permits accredited Third Party Review Organizations (Third Parties) to review certain low-to-moderate risk medical devices in lieu of FDA review.[186] FDA maintains that this program streamlines the 510(k) process by allowing the agency to "focus its resources on higher risk devices, while still maintaining oversight of the review of lower risk devices...."[187]

Under this program, manufacturers may submit their 510(k) application directly to an accredited Third Party rather than FDA.[188] FDA requires Third Parties to use the same criteria as the FDA to review 510(k) submissions.[189] After the Third Party completes its review of the device, it sends a packet to the FDA, which includes the manufacturer's original 510(k) submission and the Third Party's recommendation whether the device is substantially equivalent to a predicate device.[190] "The FDA makes the final determination on the Third Party 510(k) submission."[191] Should the Third Party reviewer fail to appropriately apply the criteria applicable to a 510(k) submission, the FDA re-reviews all or part of the manufacturer's 510(k) submission.[192]

D. Post-Market Requirements

After the FDA approves or clears a device for market distribution, it has at its disposal a number of tools to assure that medical devices remain safe and

[186] *Id.*
[187] *Id.*
[188] *Id.*
[189] *Id.*
[190] *Id.*
[191] *Id.*
[192] *Id.*

effective.[193] First, the FDA may demand that device manufacturers conduct post-market studies to collect data on the safety and/or effectiveness of approved or cleared medical devices.[194] Second, the FDA has implemented a post-market Medical Device Reporting (MDR) system "for identifying, monitoring, and capturing adverse events involving medical devices."[195] Lastly, the FDA is authorized to recall or remove from the market medical devices that pose a danger to public health.[196]

i. Post Market Studies

The FDA has the authority to demand that device manufacturers conduct two different types of post-market studies.[197] The FDA requires a manufacturer perform the first type, the post-approval study, as a condition of PMA approval.[198] Because the FDA cannot identify all possible problems with a device during its PMA review, these studies seek to monitor approved devices through post-market clinical studies aimed at assessing the long-term safety or effectiveness of a device.[199]

The FDA requires that a manufacturer conduct the second type of post-market study, the Section 522 Post-market Surveillance Study, once a device is 510(k)

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[193] Bill Sutton, *Overview of Regulatory Requirements: Medical Devices – Transcript*, U.S. FOOD & DRUG ADMIN. (Nov. 2011), https://www.fda.gov/training-and-continuing-education/cdrh-learn/overview-regulatory-requirements-medical-devices-transcript.
[194] *Id.*
[195] *Id.*
[196] *Id.*
[197] *Id.*
[198] *Id.*
[199] *Id.*

cleared or PMA approved.[200] Section 522 Post-market Surveillance Studies are triggered by devices that: (1) are "reasonably likely to have a serious adverse health consequence;" (2) are "expected to have significant use in pediatric populations;" (3) are "intended to be implanted in the body for more than 1 year;" or (4) are "life-supporting device[s] [intended for] use outside of a user facility," such as hospitals, ambulatory surgical facilities, nursing homes, outpatient diagnostic facilities, or outpatient treatment facilities.[201]

ii. Adverse Reporting

The FDA has implemented a post-market Medical Device Reporting (MDR) system "for identifying, monitoring, and capturing adverse events involving medical devices."[202] An adverse event occurs when a device "may have caused or contributed to the death [or] serious injury" of a patient.[203] The FDA requires device manufacturers to file a MDR report with the agency within 30 days of notice that any device may have caused or contributed to a death or serious injury or has malfunctioned and would be likely to cause or contribute to a death or serious injury if a malfunction were to occur.[204] FDA does not mandate medical device

[200] *Id.*
[201] *Id.*
[202] *Id.*
[203] 21 C.F.R. § 803.20(c)(1) (2019) ("Any information, including professional, scientific, or medical facts, observations, or opinions, may reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. An MDR reportable event is a death, a serious injury, or, if you are a manufacturer or importer, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.").
[204] *Id.*; § 803.56.

distributors to report adverse events.[205] FDA does demand, however, that "device user facilities," which include hospitals, ambulatory surgical facilities, nursing homes, outpatient diagnostic facilities, and outpatient treatment facilities, file MDR reports *with the device manufacturer*.[206] A device user facility must file an MDR if it receives information of an adverse event from medical personnel who, in the course of their duties, became aware of reportable issues with a medical device.[207] FDA does not require user facilities to report device malfunctions directly to the agency but they can do so voluntarily.[208]

The American Medical Association's (AMA) *Code of Medical Ethics* requires physicians "to report suspected adverse events resulting from the use of a . . . medical device."[209] Under the AMA ethics rules, physicians have an ethical responsibility to "promptly report serious adverse events . . . to the appropriate regulatory agency."[210] The FDA, on the other hand,

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[205] *Medical Device Reporting (MDR): How to Report Medical Device Problems*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems#overview (last visited Oct. 20, 2019).

[206] Kanovsky, *supra* note 90, at 231.

[207] 21 U.S.C. § 360i(b)(1).

[208] 21 C.F.R. § 803.20(c)(2) ("If you are a user facility, importer, or manufacturer, you do not have to report an adverse event if you have information that would lead a person who is qualified to make a medical judgment reasonably to conclude that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur. Persons qualified to make a medical judgment include physicians, nurses, risk managers, and biomedical engineers.").

[209] *Code of Medical Ethics Opinion 8.8*, AM. MED. ASS'N, https://www.ama-assn.org/delivering-care/ethics/required-reporting-adverse-events (last visited Nov 30, 2019).

[210] *Id.*

exempts health professionals from reporting information that suggests that a device may have caused or contributed to a death or serious injury or has malfunctioned.[211]

Until recently, the FDA also permitted device manufacturers to request an MDR filing exemption pursuant to its Alternative Summary Reporting (ASR) system.[212] Under this program, manufacturers could submit quarterly summary reports of adverse events to the FDA instead of filing those reports within the required 30 days.[213] Unlike other MDRs that are publicly available in FDA's Manufacturer and User Facility Device Experience (MAUDE) database, the FDA did not disclose the events reported under the ASR system to the public.[214]

Since 2016, manufacturers have reported at least 1.1 million device-related adverse events under the ASR system instead of MAUDE.[215] While manufacturers did report certain device-related deaths in MAUDE, they submitted serious injury and malfunction reports related to approximately 100 medical devices exclusively to the

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[211] 21 U.S.C. § 360i(c)(1) ("Persons exempt. Subsection (a) shall not apply to-- (1) any practitioner who is licensed by law to prescribe or administer devices intended for use in humans and who manufactures or imports devices solely for use in the course of his professional practice.").

[212] Dr. Jeffrey E. Shuren, *Statement on Agency's Efforts to Increase Transparency in Medical Device Reporting*, U.S. FOOD & DRUG ADMIN. (June 21, 2019), https://www.fda.gov/news-events/press-announcements/statement-agencys-efforts-increase-transparency-medical-device-reporting.

[213] *Id.*

[214] Christina Jewett, *Hidden FDA Reports Detail Harm Caused by Scores of Medical Devices*, KAISER HEALTH NEWS (Mar. 7, 2019, 7:10 PM), https://khn.org/news/hidden-fda-database-medical-device-injuries-malfunctions/.

[215] *Id.*

ASR system.[216] A study of more than a decade's worth of MAUDE reports identified more than 1.7 million injuries and nearly 83,000 deaths linked to a problematic medical devices.[217] Given ASR's anonymity, there is no basis to determine the number of injuries or deaths that it captured over the years.[218]

The FDA recently replaced the ADR system with the Voluntary Malfunction Summary Reporting (VMSR) Program.[219] VMSR reports are publicly available in the MAUDE database.[220] The FDA also encourages—but does not require—device manufacturers to report certain device malfunctions in summary form on a quarterly basis to VMSR.[221] FDA notes, "reports of death or serious injury are not allowed to be submitted via the VMSR," however, the agency may still require individual reports of device malfunctions.[222]

iii. Recalls and Removals

The FDA is authorized to recall or remove from the market medical devices that pose a danger to public health.[223] Device manufactures, however, typically voluntarily initiate recalls of their own products.[224] When a device manufacturer learns that a medical device is defective and poses a risk to public health, they must take one of two steps: initiate corrective action or remove the

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[216] Ben Hallman, *FDA Releases Vast Trove of Hidden Medical Device Injury and Malfunction Reports*, ICIJ (June 24, 2019), https://www.icij.org/investigations/implant-files/fda-releases-vast-trove-of-hidden-medical-device-injury-and-malfunction-reports/.
[217] *Id.*
[218] *Id.*
[219] Shuren, *supra* note 212.
[220] *Id.*
[221] *Id.*
[222] *Id.*
[223] Kanovsky, *supra* note 90, at 231.
[224] *Id.*

product from the market.[225] Corrective actions attempt to address problems with a medical device in the place where it is used or sold,[226] while a removal action ensures the product may no longer be used or sold.[227] On rare occasion, when a device manufacturer fails to voluntarily recall a defective product associated with significant health problems or death, the FDA issues a recall.[228] Manufacturers are required to report all correction or removal actions to the FDA.[229]

II. The Problem

The manufacturing, distribution, and marketing of unsafe or ineffective medical devices is not a new phenomenon in the United States.[230] Yet, as technology advances, device manufacturers are hyper-incentivized to market new devices as quickly as possible—and before potential competitors—by any means necessary.[231] The

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[225] *What is a Medical Device Recall?* U.S. FOOD & DRUG ADMIN. (Sept. 26, 2018), https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall [hereinafter *FDA Recall*].

[226] *Id.*

[227] *Id.*

[228] 21 C.F.R. § 810.

[229] *FDA Recall*, *supra* note 224.

[230] *See* The Editorial Board, *80,000 Deaths. 2 Million Injuries. It's Time for a Reckoning on Medical Devices.*, N.Y. TIMES (May 4, 2019), https://www.nytimes.com/2019/05/04/opinion/sunday/medical-devices.html ("In the past decade, nearly two million injuries and more than 80,000 deaths have been linked to faulty medical devices, many approved with little to no clinical testing....").

[231] *Id.* ("It's not solely those laws that give medical device makers influence over regulators. The industry maintains a well-oiled revolving door with the F.D.A. – as The Associated Press has noted, the last four people to hold [the FDA Commissioner] position have gone on to lucrative industry gigs. Device makers also spent more than $300 million

following stories illustrate how the FDA's current regulatory system prioritizes innovation over safety, empowers device manufacturers to cut corners, and, therefore, endangers public health.

A. Case Study: Transvaginal Mesh

In the 1970s, gynecologic and urologic surgeons began to utilize surgical mesh to treat abdominal hernias.[232] In 1996, the FDA cleared Boston Scientific's ProtoGen Sling Device, a Class II transvaginal mesh device, via the 510(k) pathway to treat stress urinary incontinence.[233] Three years later, however, the FDA recalled ProtoGen mesh because of a number of complications involving the device, including its erosion of vaginal tissue.[234] The FDA nevertheless allowed device manufacturers to use ProtoGen mesh as a predicate device to clear subsequent transvaginal mesh devices that purported to treat pelvic organ prolapse (POP).[235]

POP occurs when the muscles that support the pelvic organs, like the uterus and vagina, weaken over time and cause the organs to bulge out of the vagina.[236] In recent years, doctors have used transvaginal mesh to treat POP.[237] Specifically, doctors have implanted transvaginal mesh into the vagina to create a "bladder

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lobbying Congress in the decade ending in 2017, according to the Center for Responsive Politics.").

[232] Carrie MacMillan, *Transvaginal Mesh: What Women Should Know*, YALE MED.: STORIES (June 19, 2019), https://www.yalemedicine.org/stories/transvaginal-mesh/.

[233] Powell, *supra* note 52, at 178.

[234] *Id.*

[235] *Id.* at 178–79.

[236] *What to Do About Pelvic Organ Prolapse*, HARV. MED. SCH. (July 2, 2020), https://www.health.harvard.edu/womens-health/what-to-do-about-pelvic-organ-prolapse.

[237] C. Gavin Shepherd, *Transvaginal Mesh Litigation: A New Opportunity to Resolve Mass Medical Device Failure Claims*, 80 TENN. L. REV. 477, 477–78 (2013).

sling" to help reinforce the weakened vaginal walls and reduce the rate of POP.[238]

From 2005 to 2011, "[the] FDA received over 4,000 reports of adverse events attributable to transvaginal mesh."[239] These devices caused thousands of women to suffer: "Patients reported that bowel, bladder, and blood vessel perforation, in addition to transvaginal mesh erosion, had led to extreme pain and an overall decrease in patient quality of life."[240] Gwyn Madsen, who was implanted with a Boston Scientific transvaginal mesh device, claimed that the device "felt like a cheese grater inside of [her]."[241] Disturbingly, researchers have identified at least 61 medical devices that the FDA cleared for market under the 510(k) pathway on the basis of their "substantial equivalence" to the ProteGen mesh device.[242] Worse yet, none of the manufacturers of those 61 devices submitted any clinical trial evidence in

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[238] *Id.*

[239] Powell, *supra* note 52, at 179; *see Daniel G. Schultz, FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence*, U.S. Food & Drug Admin. (Oct. 20, 2008), http://www.amiform.com/web/documents-risques-op-coelio-vagi/fda-notification-about-vaginal-mesh.pdf; *Update on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse: FDA Safety Communication*, U.S. Food & Drug Admin. (July 13, 2011), https://www.burgsimpson.com/wp-content/uploads/2018/03/FDA-safety-communication-pelvic-mesh.pdf.

[240] Shepherd, *supra* note 237, at 480.

[241] Scott Pelley, *Gynecological Mesh: The Medical Device That Has 100,000 Women Suing*, CBS NEWS (Apr. 17, 2019), https://www.cbsnews.com/news/boston-scientific-gynecological-mesh-the-medical-device-that-has-100000-women-suing-2019-04-17/.

[242] Carl J. Heneghan et al., *Trials of Transvaginal Mesh Devices for Pelvic Organ Prolapse: A Systematic Database Review of the U.S. FDA Approval Process*, 7 BMJ OPEN (2017), https://bmjopen.bmj.com/content/7/12/e017125.

support of the safety and efficacy of those devices prior to FDA approval.[243]

In 2016, the FDA reclassified transvaginal medical devices from Class II to Class III devices.[244] As part of that reclassification, the FDA required transvaginal mesh device manufacturers to submit and obtain PMA application approval to ensure that their devices were safe and effective.[245] In response, Boston Scientific submitted PMA applications seeking approval for two of its transvaginal devices, the Uphold LITE Vaginal Support System and the Xenform Soft Tissue Repair System.[246] In order to allow those mesh devices to stay on the market, the FDA demanded that Boston Scientific submit evidence demonstrating that the devices were more effective at treating POP than a surgery to relieve the condition without the use of mesh.[247] Boston Scientific failed to submit such data and,

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[243] *Id.*

[244] *FDA Strengthens Requirements for Surgical Mesh for the Transvaginal Repair of Pelvic Organ Prolapse to Address Safety Risks*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2016), http://www.fda.gov/news-events/press-announcements/fda-strengthens-requirements-surgical-mesh-transvaginal-repair-pelvic-organ-prolapse-address-safety.

[245] *Id.*

[246] *FDA Takes Action to Protect Women's Health, Orders Manufacturers of Surgical Mesh Intended for Transvaginal Repair of Pelvic Organ Prolapse to Stop Selling All Devices*, U.S. FOOD & DRUG ADMIN., (Apr. 16, 2019), http://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-womens-health-orders-manufacturers-surgical-mesh-intended-transvaginal [hereinafter *FDA Commissioner Report*]. Boston Scientific was one of two device manufacturers marketing transvaginal mesh to treat POP. Coloplast, the other manufacturer, also failed to demonstrate a reasonable assurance of safety and effectiveness for its devices. FDA, therefore, ordered Coloplast to stop selling its devices. *Id.*

[247] *Id.*

in 2019, the FDA ordered the manufacturer to stop selling the mesh.[248] In 2018 alone, Boston Scientific paid over $600 million in settlement funds to resolve thousands of lawsuits involving the harm caused by its transvaginal mesh products.[249]

B. Case Study II: Implantable Cardioverter-defibrillators

Implantable cardioverter-defibrillators (ICDs) are small battery-powered medical devices. ICDs are implanted under the skin and connected to the heart through wire "leads" to keep track of an individual's heart rate.[250] If the device detects an abnormal heart rhythm, it delivers an electric shock to the heart to restore a normal heartbeat.[251]

In 1993, the FDA approved Medtronic's PMA application for its Transvene ICD Lead System device.[252] A lead is a special wire that delivers energy from the ICD to the heart muscle.[253] In 2005, Medtronic submitted a

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[248] *Id.*

[249] *Boston Scientific Says 50K Mesh Settlements Almost Final*, LAW360 (Feb. 20, 2019), https://www.law360.com/articles/1130868/boston-scientific-says-50k-mesh-settlements-almost-final.

[250] *Implantable Cardioverter Defibrillator (ICD)*, AMER. HEART ASS'N, https://www.heart.org/en/health-topics/arrhythmia/prevention--treatment-of-arrhythmia/implantable-cardioverter-defibrillator-icd (last visited Nov 3, 2019).

[251] *Id.*

[252] U.S. Food & Drug Admin., *Medtronic(R) Transvene Lead System PMA*, PREMARKET APPROVAL DATABASE (2019), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P920015 (last visited Nov 3, 2019).

[253] *Pacemaker and ICD Lead Extraction*, JOHN HOPKINS MED., https://www.hopkinsmedicine.org/heart_vascular_institute/conditions_treatments/treatments/pacemaker_icd_lead_extraction.html (last visited Nov. 30, 2019).

PMA supplement to the FDA seeking approval of its Medtronic Sprint Fidelis ICD Lead device on the basis of the FDA's earlier approval of the Transvene ICD device.[254] The FDA approved the Sprint Fidelis ICD Lead device for market distribution within three months of Medtronic's request and without any clinical trial data.[255]

Over the ensuing three years, practitioners implanted 90% of Medtronic's ICD devices with the Sprint Fidelis ICD Lead.[256] Medtronic, however, recalled the Sprint Fidelis ICD Lead device in October 2007—after it had been on the market for 38 months and used in 268,000 worldwide implantations—because of its propensity to fracture.[257] Medtronic cited to five Fidelis Lead-related deaths during its device recall and explained that fractures in the device's leads could cause an ICD to fail to deliver a lifesaving shock or to even shock the heart for no reason.[258] In 2010, Medtronic agreed to pay $268 million to settle lawsuits involving the Fidelis Lead device.[259]

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[254] *Medtronic Sprint Fidelis Leads Models 6949, 6948, 6931, 6930*, U.S. FOOD & DRUG ADMIN. (2019), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P920015S032 (last visited Nov. 3, 2019) [hereinafter Fidelis PMA Supplement].

[255] *Id.*; *see* William H. Maisel, *Semper Fidelis – Consumer Protection for Patients with Implanted Medical Devices*, 358 NEW ENG. J. MED. 985, 985–87 (2008).

[256] *Id.*

[257] *Id.*

[258] Barry Meier, *Medtronic Links 13 Deaths to Faulty Heart Device*, N.Y. TIMES (Mar. 13, 2009), https://www.nytimes.com/2009/03/14/business/14device.html; *see Physician Advisory Letter* (Oct. 15, 2007), MEDTRONIC, https://www.medtronic.com/us-en/healthcare-professionals/products/product-performance/sprint-fidelis-physician-10-15-2007.html.

[259] *Medtronic to Settle Sprint Fidelis Defibrillator Suits*, N.Y. TIMES (Oct. 14, 2010), https://www.nytimes.com/2010/10/15/business/15device.html.

One study discovered that, from 1979-2012, FDA approved 77 original and 5,829 supplement PMA applications for cardiac implantable electronic devices, including ICDs.[260] It further found that 79% of the 77 original PMA applications FDA approved during the same period were the subject of at least one supplemental application.[261] Thirty-seven percent of those FDA-approved supplements involved a change to the device's design.[262] Moreover, in the vast majority of cases, the FDA failed to demand any new clinical data related to ICD device design changes prior to approval.[263] Specifically, FDA only required new clinical data to support the changed device's safety and effectiveness in 23% of the supplemental applications it approved from 2010-2012.[264] Much like the role the 510(k) pathway played in the transvaginal mesh debacle, the PMA supplement pathway permitted FDA to approve and deem safe many "change-design" ICDs without any production or evaluation of new clinical data.[265]

III. Proposed Reforms

This Part of the paper highlights a number of proposed reforms to FDA's current regulatory structure for medical devices. First, this Part will discuss a number of reforms the FDA, and other commentators, have proposed regarding the medical device approval and clearance process. This Part then will examine

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[260] Benjamin N. Rome, Daniel B. Kramer & Aaron S. Kesselheim, *FDA Approval of Cardiac Implantable Electronic Devices via Original and Supplement Premarket Approval Pathways, 1979-2012*, 311 JAMA 385–391 (2014) [hereinafter Rome].
[261] *Id.* at 387.
[262] *Id.* at 388.
[263] *Id.*
[264] *Id.* at 385.
[265] *Id.* at 389.

additional, prevailing proposed reforms to FDA's medical device pre-market review process.

A. Reforming 510(k) Pathway

In November 2018, the FDA released a report detailing the improvements it has made to the 510(k) program.[266] First, the agency implemented a refuse-to-accept policy that applies to 510(k) submissions that fail to satisfy the agency's quality threshold for review.[267] Simply stated, if a device manufacturer submits a 510(k) application that fails to include one of the requisite items for approval consideration, FDA now refuses to accept that application for review.[268]

Second, FDA issued new guidance concerning the Special 510(k) Program in 2019.[269] As the agency explained, the program had been "limited to review of changes that did not affect the device's intended use nor alter the device's fundamental scientific technology."[270] The FDA, however, has shifted its focus to assessing "whether the method(s) [a manufacturer uses] to evaluate the change(s) are well-established, and whether the results can be sufficiently reviewed in a summary or risk analysis format."[271] Under the new guidance, the FDA empowers device manufactures to self-regulate and determine if additional testing is necessary to evaluate a change that otherwise requires a Traditional 510(k)

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[266] *FDA Has Taken Steps to Strengthen The 510(k) Program*, U.S. FOOD & DRUG ADMIN. (Nov. 2018), https://www.fda.gov/media/118500/download [hereinafter *FDA 510(k) Report*].
[267] *Id.* at 5.
[268] *Id.*
[269] *The Special 510(k) Program – Guidance for Industry and Food and Drug Administration Staff*, U.S. FOOD & DRUG ADMIN. (Sept. 13, 2019), https://www.fda.gov/media/116418/download [hereinafter *Special 510(k) Guidance*].
[270] *Id.* at 5.
[271] *Id.* at 5–6.

submission.[272] If the manufacturer determines that additional testing is not necessary, it must submit to the FDA a Special 510(k) application that includes a clear rationale supporting that conclusion.[273]

Third, the FDA is in the process of eliminating the use of the 510(k) pathways for Class III devices.[274] The FDA reports that it refused to clear any Class III device via a 510(k) pathway in Fiscal Year 2018.[275] The FDA also is in the process of disincentivizing manufacturer reliance on a 510(k) cleared device as a predicate for 510(k) pathway approval of a subsequent device when the predicate device has raised safety concerns.[276] Since 1976, the FDA has eliminated the use of 1,758 devices as predicates in the 510(k) pathway process.[277] The FDA has eliminated 1,477 (84%) of those predicates since 2012.[278]

There are commentators that view the FDA's 510(k) pathway processes as adequate as they currently stand.[279] James M. Flaherty, for example, has characterized the 510(k) pathway as an appropriate mechanism for reviewing medium-risk devices because it achieves a worthy balance between protecting the public health through pre-market review and promoting innovation and the timely introduction of new devices into the market.[280] He also argues that, while the 510(k) pathway process is not as rigorous as PMA review, it succeeds in ensuring the safety and effectiveness of certain medical devices through its use of the substantial

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[272] *Id.* at 10.
[273] *Id.*
[274] FDA 510(k) Report, *supra* note 266, at 7.
[275] *Id.*
[276] *Id.* at 8.
[277] *Id.*
[278] *Id.*
[279] 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, 926–27 (2008).
[280] *Id.*

equivalence standard.[281] For support, Mr. Hall points to an independent study, which evaluated 2005-2009 510(k) pathway medical device submissions using FDA recall data.[282] That study found that: (1) over 99.5% of those 510(k) submissions did not result in a Class I safety recall; (2) over 99.7% did not result in a Class I recall for any reason relevant to the 510(k) pre-market system; and (3) approximately 55% of all Class I recalls during the study's timeframe involved problems or issues that arose after market and, therefore, are not attributable to pre-market approval systems or requirements.[283]

Other commentators, however, have recommended that the FDA eliminate the 510(k) pathway.[284] At the FDA's request, for example, the Institute of Medicine (IOM) examined the 510(k) process and recommended a number of reforms in 2011.[285] Among other things, the IOM report concluded that FDA should eliminate the 510(k) process for at least two reasons.[286] First, the 510(k) process fails to adequately evaluate the safety and effectiveness of medical devices because its substitutes an independent and objective evaluation of a device with the substantial equivalence to predicate devices standard.[287] Second, the FDA's finite resources

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[281] *Id.* at 926.
[282] *Id.*
[283] *A Delicate Balance: FDA and the Reform of the Medical Device Approval Process: Hearing Before the Special Committee on Aging*, 112th Cong. 81–107 (2011) (statement of Ralph Hall, Distinguished Professor, University of Minnesota Law School); *see also Recalls Background and Definitions*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/safety/industry-guidance-recalls/recalls-background-and-definitions (last visited Nov 3, 2019) ("Class I recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.").
[284] IOM, *supra* note 20, at 4.
[285] *Id.* at 1, 7–8.
[286] *Id.* at 5–6.
[287] *Id.*

would be better invested in the development of integrated pre-market and post-market regulatory frameworks that provide a reasonable assurance of safety and effectiveness throughout the device's life cycle rather than in the current 501(k) process.[288]

B. Pre-market Approval Reforms

Critics have proposed a number of solutions aimed at addressing the problems that plague the FDA's current pre-market approval process.[289] First, they have argued that the FDA should completely rewrite its pre-market medical device regulations.[290] These commentators base that conclusion on an independent assessment of the FDA process that was conducted pursuant to the MDUFA.[291] They concede, however, that the FDA is highly unlikely to completely rewrite its medical device regulations.[292]

Second, certain reformers maintain that the FDA ought to privatize its pre-market approval processes and delegate all pre-market approval determinations to third parties reviewers.[293] Proponents of this reform argue that

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[288] IOM, *supra* note 20, at 8.

[289] Stephanie P. Fekete, *Litigating Medical Device Premarket Classification Decisions for Small Businesses: Have the Courts Given the FDA Too Much Deference? The Case for Taking the Focus Off of Efficacy*, 65 CATH. U.L. REV. 605, 626 (2016).

[290] *Id.*; Christa Altenstetter, *US Perspectives on the EU Medical Devices Approval System, and Lessons Learned from the United States*, 4 Eur. J. of Risk Reg. 443, 447 (2013).

[291] Fekete, *supra* 289, at 623, 626; *MDUFA II/III Evaluation–Priority Recommendations*, U.S. FOOD & DRUG ADMIN. (Dec. 11, 2013), http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGDeviceR/Overview/MDUFAIII/UCM378202.pdf.

[292] Fekete, *supra* 289, at 627.

[293] *Id.* at 628; *see also* Elizabeth C. Price, *Teaching the Elephant to Dance: Privatizing the FDA Review Process*, 51 FOOD & DRUG L.J. 651, 653–54 (1996).

the privatization of pre-market medical device review would permit FDA to allocate its finite resources to other agency functions while ensuring that devices are safe and effective.[294] They view the FDA's current regulatory structure for medical devices as "perpetuating the FDA monopoly, with its resulting delays, inefficiency, and suboptimal allocation of scarce societal resources [and] an anachronistic vestige of a big government is better government mentality."[295] Under the guise of innovation, these reformers seek to inject a healthy dose of competition into FDA product review with the aim of speeding up the approval and clearance of potentially life-saving products.[296] However, as discussed below, prioritizing speed over patient safety is likely to simply exacerbate the current problems with the FDA's medical device regulatory system.

IV. Recommendations

History instructs that it takes major public health crises — like the Elixir Sulfanilamide disaster or the Dalkon Shield controversy — to provoke Congress to allocate additional authority to the FDA to regulate medical products.[297] The same history teaches that medical product manufacturers always push back on those regulatory reforms and, unfortunately, the agency tends to bend to corporate will by easing regulatory reforms over time.[298]

As noted above, Congress intended the 510(k) pathway to apply to a very narrow group of medical devices when it created that pathway as an alternative to full PMA review.[299] In the name of innovation, however,

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[294] *Id.* at 666.
[295] Price, *supra* note 293, at 652–653.
[296] *Id.* at 676.
[297] *See* Ballentine, *supra* note 53; Krismann, *supra* note 67.
[298] The Editorial Board, *supra* note 230.
[299] IOM, *supra* note 20, at 223.

the 510(k) pathway has evolved from a narrow exception to PMA review to the general rule that permits the vast majority of devices to be marketed without clinical trials.[300]

The FDA's ASR adverse event reporting system provides another relevant data point.[301] In this context, the FDA created a reporting system that permitted device manufacturers to hide from public disclosure of adverse events related to medical devices.[302] The FDA claims the ASR Program allowed the agency to review reports of well-known, well-understood adverse events more efficiently and, thereby, focus its resources on identifying and taking action on new safety signals and less understood risks.[303] The ASR system, however, shielded at least 1.1 million medical device-related adverse incidents from public view.[304] While FDA finally has discontinued the ASR reporting program, the agency continues to refuse to mandate that manufacturers report malfunctioning medical devices incidents.[305]

It further warrants mention that FDA compliance and enforcement actions have plummeted since President Donald J. Trump's inauguration.[306] A study found that enforcement actions from the FDA Center for Devices and Radiological Health, which is responsible for regulating medical devices, have dropped by more than two-thirds since 2016.[307] This is particularly troubling given that there have been more than 1.7 million

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[300] *Id.*
[301] Shuren, *supra* note 212.
[302] *Id.*
[303] *Id.*
[304] Jewett, *supra* note 214.
[305] Shuren, *supra* note 212.
[306] Charles Piller, *Exclusive: FDA enforcement actions plummet under Trump*, SCIENCE (Jul. 2, 2019, 8:00 AM), https://www.sciencemag.org/news/2019/07/exclusive-fda-enforcement-actions-plummet-under-trump.
[307] *Id.*

documented injuries and nearly 83,000 deaths linked to a problematic medical devices over the last decade.[308] The bottom line is that we are in the throes of a medical device public health crisis. Time after time, Congress and the FDA have put the interests of medical device manufacturers ahead of those of the American public and, by so doing, have abdicated their collective responsibility to protect the public health.[309] As the history of medical product regulation makes clear, it is beyond time the American public calls out for meaningful reforms.

A. Third Party Review Boards

As explained above, FDA currently allows device manufacturers to submit medical device applications to an external third party under the 510(k) Third Party Review Program.[310] The FDA, on the other hand, rarely elects to send PMA medical device applications to external third parties for review.[311] As such, this paper advocates that FDA develop and implement an objective standard that triggers a third-party review for both 510(k) and PMA applications—in lieu of the current process that simply permits manufacturers to self-select and FDA to elect to refuse external review without any articulable criteria.

FDA's rationale for refusing to require a third-party review for most devices is similar to its 510(k)'s substantial equivalence theory reasoning and goes as follows:[312] so long as the FDA believes that it understands the issues relating to the safety and effectiveness of a predicate device and has developed the ability to address

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[308] Hallman, *supra* note 216.
[309] *What We Do*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/about-fda/what-we-do (last visited Nov 10, 2019).
[310] *Third Party Review, supra* note 162.
[311] FDLI Report, *supra* note 132.
[312] *Id.*

those issues, future PMA applications for similar devices need not be brought before an external panel.[313] Given their heighten risk to human health, however, this Paper argues that FDA ought to require that new Class II and III devices undergo pre-market third-party review without exception. Under this proposal, the FDA remains free to accept or reject a third-party panel's recommendation regarding a PMA or 510(k) application so long as the agency provides a public rationale for that decision.[314]

As pointed out earlier, the FDA no longer publishes its rationale for accepting or rejecting PMA or 510(k) device applications in the Federal Register.[315] This paper, therefore, further recommends that the FDA reinstate the requirement that it publish all medical device approvals—and their supporting rationales—in the Federal Register. Such action will permit the public to understand why the FDA approved a medical device notwithstanding a third-party panel recommendation to keep the product off of the market. This proposed reform also will provide device manufacturers the bases for the FDA's decisions on their applications. Should the FDA fail to give a thorough description of those bases on an application it denies, the affected manufacturer could sue the FDA for violating its own regulations under traditional principles of administrative law.

B. Adverse Reporting

The FDA's current definition of an "adverse device-related event" that triggers an agency report is vague and demands clarification. Current FDA regulation requires certain entities to report "any information, including professional, scientific, or medical facts, observations, or opinions, [that] may reasonably

[313] Kanovsky, *supra* note 90, at 240.
[314] FDLI Report, *supra* note 132.
[315] Kanovsky, *supra* note 90, at 240.

suggest that a device has caused or may have caused or contributed to an MDR reportable event."[316] It is unclear, however, what constitutes a "reasonable suggestion" under the current regulation and it does not appear that the FDA has ever held a manufacturer liable for ignoring such a suggestion. For example, is the rule triggered where one patient who has received an implant reports severe post-surgical discomfort to the device manufacturer? Or is the rule triggered when a provider who uses a medical device routinely in surgery informs a device manufacturer or user facility that ten patients have reported severe post-surgical discomfort? It is difficult to answer these questions with authority under the current regulatory scheme. As a result, this Paper contends that the FDA should convene health professionals to clearly define what constitutes a "reasonable suggestion." For example, if a post-surgical patient who has serious complications that appear related to the device and the provider has ruled out all possible causes is enough to reasonably suggest that an issue has arisen with the device, then this could constitute a "reasonable suggestion."

This paper also recommends that the FDA extend mandatory, medical device-related, adverse event reporting to all state-licensed medical professionals that employ medical devices in their practice. Currently, "any practitioner who is licensed by law to prescribe or administer devices intended for use in humans and who manufactures or imports devices solely for use in the course of his professional practice" is exempt from the mandatory reporting of medical device-related adverse events to the FDA.[317] Physicians, physical therapists, psychologists, and other health professionals work directly with patients. As a result, they are often the first to know if a medical device appears to be malfunctioning or causing other complications that could lead to an

[316] 21 C.F.R. § 803.20(c)(1).
[317] 21 U.S.C. § 360i(c).

adverse event. Congress should amend the FDCA to include a mandatory device-related adverse event reporting requirement for health professionals consistent AMA's *Code of Medical Ethics*.

This new mandatory reporter rule, however, ought to reflect the reality that different health professionals use different classes of medical devices in their respective practices and that those devices present varying levels of risks to patients. For example, given the low risk that Class I devices pose to human health, there is no need for Congress to impose a mandatory reporting requirement on health care providers related to that categories of devices. Given the heightened risk to human health that attend to Class II devices, on the other hand, Congress should require mandatory health professional reporting related to those products so long as the use of said devices constitutes 25% or more of the professional's practice. Finally, because Class III devices pose the highest risk to human health, Congress should require all health professionals to report any adverse event relating to those medical devices to the agency.

Under current FDA regulations, if a user facility or manufacturer receives information from someone who is "qualified to make a medical judgment" and that individual reasonably concludes that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur neither is required to report that information to FDA.[318] This rule, however, ignores the conflict of interest that arises when mandatory reporters are permitted to rely on the determination of individuals that they choose and, often, compensate to determine whether to make a report. This paper proposes that FDA amend its regulations to eliminate this conflict of interest-riddled loophole and require user facilities and device manufacturers to report to FDA any suspicion, at a minimum regarding Class III

[318] 21 U.S.C. § 360i(a).

devices, that their medical device has malfunctioned or caused or contributed to an adverse event.

Finally, this paper recommends that FDA eliminate the Voluntary Malfunction Summary Reporting (VMSR) program. As detailed above, VMSR encourages manufacturers to voluntarily report certain device malfunctions to the FDA in summary form on a quarterly basis.[319] While the FDA requires device manufacturers to report device-related deaths or serious injuries to the agency within 30 days, this program leaves it to the manufacturer's discretion whether to report device malfunctions.[320]

Device malfunctions serve as a significant indication that the device is defective and could harm human health. One need not look any further than Boston Scientific's ICDs Lead Device as a recent example. As a result, FDA should require device manufacturers to submit device malfunction reports to the agency as soon as possible to ensure the safety and effectiveness of the device.

C. Supplements and Grandfathering

In 2007, Steve Jobs introduced the world to the very first iPhone.[321] The original iPhone was heralded as a technological revolution but it lacked even basic picture messaging and video creation capabilities.[322] The recently-released iPhone 11, by contrast, includes a three-camera system with a new ultrawide-angle lens

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[319] Shuren, *supra* note 212
[320] *Id.*
[321] Rob Price, *The first iPhone went on sale 10 years ago today — here's how Steve Jobs announced it*, BUSINESS INSIDER (June 29, 2017, 5:01 AM), https://www.businessinsider.com/watch-steve-jobs-first-iphone-10-years-ago-legendary-keynote-macworld-sale-2017-6.
[322] *Id.*

that has the ability to take high quality video.[323] The iPhone's video imagining capability provides a simple demonstration of how quickly and dramatically technology can evolve in just a dozen years.

FDA's 510(k) pathway processes, however, entirely ignore this reality. As illustrated above, the FDA allows device manufacturers to avoid a thorough review of new medical devices by relying on predicate devices that the FDA cleared for market as far back as 1975 and without conducting clinical trials on those new devices.[324] Worse yet, the FDA in no manner restricts the number of PMA supplements a device manufacturer is entitled to submit that similarly relies on dated device technology so long as the manufacturer follows current FDA rules.

This paper argues that the FDA should it amend its rules to preclude device manufacturers from relying on predicate devices that are more than 10 years old in 510(k) and PMA supplement applications. The FDA also should require device manufacturers to submit clinical data that demonstrates the safety and effectiveness of any proposed "major change" to a medical device prior to approval. This paper recommends that the FDA defines a "major change" as any change in a device that increases its danger to human health.

V. Conclusion

Medical devices are modern day miracles that continue to impact the lives of millions of Americans. The U.S. Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of those devices. In the 43 years since the enactment of the MDA, a number of national

[323] Nilay Patel, *Apple iPhone 11 review: the phone most people should buy*, THE VERGE (Sept. 17, 2019, 6:00 AM), https://www.theverge.com/2019/9/17/20869456/apple-iphone-11-review-camera-price-budget-battery-screen-size-features.
[324] 21 U.S.C. § 360(k).

public health emergencies have motivated Congress to expand the FDA's authority to regulate medical devices. Device manufactures, however, have always decried additional regulation and, too often, the FDA has succumbed to manufacturer interests. The 510(k) pathways, the PMA Supplement pathway, and the ASR reporting system are all examples of how the FDA has developed expedient, industry-favorable review processes at the expense of public health and safety.

Over the last decade, faulty or flawed medical devices have injured 1.7 million and killed nearly 83,000 people nationwide. The country's current medical device safety crisis is directly tied to the FDA's regulation of those products. The FDA must restore the public trust by implementing transparent and effective regulatory reforms to address this medical device safety crisis.

First, the FDA should reinstate the requirement that it publish all medical device approvals — and their supporting rationales — in the Federal Register. Furthermore, in the spirit of ensuring the public that the FDA is concerned primarily with patient safety, the FDA must extend mandatory, medical device related adverse event reporting to state-licensed medical professionals that employ certain medical devices in their practice. Finally and while the timely introduction of lifesaving medical products is admittedly a worthy objective, the FDA must amend its rules to preclude device manufacturers from relying on predicate devices that are more than 10 years old in new device 510(k) and PMA supplement applications and require device manufacturers to submit clinical data for major changes that affect device safety and effectiveness. These reforms will become all the more critical as technology advances and the pressure to deregulate continues.