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21st Century Cures Act: The Problem with Preemption in Light of Deregulation

Megan C. Andersen

University of Michigan Law School

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21ST CENTURY CURES ACT: THE PROBLEM WITH PREEMPTION IN LIGHT OF DEREGULATION

Megan C. Andersen*

*The 21st Century Cures Act introduced innovative changes to the Food and Drug Administration's regulatory processes. In an effort to address the slow, costly, and burdensome approval process for high-risk devices, the Cures Act modernized clinical trial data by allowing reviewers to determine whether devices merit expedited review and to consider post-market surveillance data in the premarket approval process. These changes will get life-saving devices to the people who need them faster than ever before. But the tradeoff is a greater risk of injury to the patient. The 2008 Supreme Court decision *Riegel v. Medtronic, Inc.*, held that any device receiving premarket approval is federally preempted from state tort claims. This means injured patients of medical device malfunctions are barred from seeking remedy against the manufacturers. Thus, the Cures Act potentially puts patients at greater risk, but does nothing to provide those patients remedies for injury.*

*This Note argues that federal preemption for medical devices receiving premarket approval should be reconsidered. Because the regulatory framework for which *Riegel* was decided has now shifted, the Court should reevaluate its prior ruling. Additionally, Congress should amend the preemption clause in the Food, Drug, and Cosmetic Act to allow for state tort action. Finally, Congress should create a victim compensation fund, run by HHS, to allow victims to make no-fault injury claims and receive payments for their suffering.*

TABLE OF CONTENTS

INTRODUCTION.....	802
I. BACKGROUND.....	804
A. <i>The FDA and the Medical Device Regulatory Structure</i>	804
B. <i>Premarket Approval</i>	806
C. <i>Riegel v. Medtronic, Inc.</i>	807
II. THE 21ST CENTURY CURES ACT	809
A. §§ 3051 and 3058	810
B. <i>Potential Downsides of §§ 3051 and 3058</i>	811
III. WHAT THIS COULD MEAN FOR PATIENT SAFETY	814
A. <i>Implantable Cardioverter-Defibrillator Failures and Consequences</i>	814

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B. *The Problems with Post-Market Surveillance*..... 817

IV. SOLUTIONS AND ALTERNATIVE COMPENSATION

MECHANISMS 821

A. *Judicial Remedy*..... 821

B. *Statutory Amendment*..... 824

C. *Establishing a Victim Compensation Fund*..... 825

CONCLUSION 828

INTRODUCTION

The safety and effectiveness of medical devices has been a critical issue since 1976, when Congress enacted the Medical Device Amendments (MDA),¹ giving the Food and Drug Administration (FDA) power to regulate medical devices alongside pharmaceuticals and food products. Since then, the FDA has had the immense task of assessing the safety and effectiveness of innovative medical technology.

Ensuring that medical devices are safe and effective for the intended user is a difficult and burdensome process. It requires the FDA to request and review lengthy, complex, and costly scientific material provided by the manufacturer that demonstrates the efficacy of the device.² This process has led many critics to denounce the FDA for hurting innovation, preventing life-saving devices from reaching the market quickly, and creating a cost-prohibitive system.³ Recently, in an effort to assuage those mounting criticisms, Congress passed the 21st Century Cures Act (Cures Act): an amendment to the Food, Drug, and Cosmetic Act (FDCA).⁴ The Cures Act allows manufacturers to submit less rigorous data to the FDA for the approval of drugs and devices,⁵ thereby effectively deregulating the FDA.

The Cures Act does not change the requirement that manufacturers need to provide safety and efficacy evidence.⁶ It does, how-

1. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.); see George Horvath, *Trading Safety for Innovation and Access: An Empirical Evaluation of the FDA’s Premarket Approval Process*, 2017 BYU L. REV. 991, 993.

2. Horvath, *supra* note 1, at 993–94.

3. See, e.g., *id.* at 994, 1006.

4. 21st Century Cures Act, Pub L. No. 114-255, 130 Stat 1033 (2016) (codified in scattered sections of 21 U.S.C.).

5. Aaron S. Kesselheim & Jerry Avorn, *New “21st Century Cures” Legislation: Speed and Ease vs. Science*, 317 J. AM. MED. ASS’N 581, 581 (2017).

6. See 21st Century Cures Act, Pub. L. No. 114-255, § 3058(b)(5)(A)–(D), 130 Stat. 1033, 1129 (2016) (stating that “[n]othing in this paragraph alters the standards for premarket approval of a device.”). Note that the sections in the FDCA and Cures Act are numbered differently, even though they refer to the same language. This is because I refer to the

ever, implicitly encourage the FDA to emphasize speed over scientific rigor.⁷ This tacit understanding—that life-saving devices should no longer spend years awaiting approval—creates a question about safety. Specifically, will the assessment of high-risk medical devices under this new Cures Act standard remain rigorous enough to ensure patient safety?

In 2008, the Supreme Court held in *Riegel v. Medtronic, Inc.* that the federal government preempts tort claims with respect to medical devices that received FDA premarket approval (PMA).⁸ The Court looked at the PMA process and found that the FDA approves medical devices based on a rigorous standard of safety and effectiveness.⁹ Thus, because the FDA has already concluded the devices are safe and effective, claimants cannot assert tort claims predicated on device safety.¹⁰ The case led to injured patients with minimal recourse since their claims against device manufacturers are barred.

This ruling should be reconsidered. Both the Cures Act and the FDA demonstrate a trend toward deregulation. The lowered standards of the PMA process help expedite innovation, but they also risk patient safety. As the standards of rigor are being lowered at the FDA, so too should the device industry's shield against liability.

Part I of this Note discusses the background of the FDA and the regulatory scheme for medical devices. This Note first describes the goals of the FDA and how the agency regulates devices through the FDCA and the MDA. It then discusses the approval process for medical devices through both the premarket notification and premarket approval processes. This section ends with a short discussion of the Supreme Court case *Riegel v. Medtronic, Inc.* and the preemptive effect the case has upon tort liability related to faulty high-risk medical devices.

Part II discusses the changes which the Cures Act makes to the FDCA and the approval process for medical devices. This section analyzes two device amendments from both a textual and procedural perspective. Specifically, §§ 3051 and 3058 lay out how the Department of Health and Human Services (HHS) Secretary should take more “flexible” approaches in reviewing PMA applications. Combined, the sections highlight how the Cures Act both lowers the rigor of scientific data and makes it necessary to do only

Cures Act as public law, i.e., what Congress put together to present the Act as legislation. The FDCA is located in the United States Code, which has its own numbering system based on when the Act was codified.

7. Kesselheim & Avorn, *supra* note 5, at 582.

8. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008).

9. *Id.* at 317–18.

10. *Id.* at 330.

the minimum number of clinical trials, deferring safety and effectiveness tests until after the device is already on the market and used by patients.

Part III reviews past instances of device malfunctions and how failures in the regulatory system contributed to the problem. While the Cures Act is too recent to provide direct evidence of lax regulatory standards for device approval, Part III examines past cases to reveal a pattern of risk and injury to patients and consumers of medical devices. Post-market surveillance studies are particularly scrutinized, since the Cures Act prominently relies on post-market evaluation for device approval.

Part IV evaluates potential solutions to provide victims of faulty medical devices remedies. Judicial override and Congressional amendments are analyzed and rejected as impractical due to the structure of government and political will of Congress. However, the creation of a victim compensation fund is one promising remedial route. While this fund would still need to be enacted by Congress, it would delegate authority to HHS and the FDA to compensate medical device failure victims. This solution avoids clogging up the court system, while still providing compensation to victims of medical device malfunction.

Part VI concludes.

I. BACKGROUND

A. *The FDA and the Medical Device Regulatory Structure*

The FDA protects the public health by ensuring the safety, efficacy, and security of drugs, biological products and medical devices.¹¹ Congress passed the FDCA in 1938 to empower the FDA to exert more control over drugs and food.¹² Notably, the authority to regulate medical devices was missing from the FDCA. In 1976, Congress passed the MDA to establish a comprehensive scheme for the premarket and post-market regulation of devices.¹³

11. *What We Do*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/WhatWeDo/> (last updated Mar. 28, 2018).

12. *How Did the Federal Food, Drug, and Cosmetic Act Come About?*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/Transparency/Basics/ucm214416.htm> (last updated Aug 22, 2018).

13. Jeffrey K. Shapiro, *The Medical Device Amendments of 1976: The Statute That Went Awry*, FDAL BLOG (June 3, 2013), <http://www.fdalawblog.net/2013/06/the-medical-device-amendments-of-1976-the-statute-that-went-awry/>.

The MDA gave the FDA authority to regulate all types of medical devices and classify them into three categories based on their perceived risk.¹⁴ Class I devices pose almost no risk and are minimally regulated by “general controls.”¹⁵ Examples of Class I devices include band-aids and tongue depressors.¹⁶ Class II devices, like ultrasounds, are potentially more dangerous and are regulated using the premarket notification pathway.¹⁷ Class III devices are high-risk devices that either “presen[t] a potential unreasonable risk of illness or injury,” or are “purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health” and are regulated under the premarket approval (PMA) pathway.¹⁸ Many types of implants, like heart valves or breast implants, are regulated as Class III medical devices.¹⁹ Due to their perceived risk, devices regulated under the PMA process must provide evidence of reasonable assurance of their “safety and effectiveness.”²⁰

Low-risk devices, Class I, are exempt from premarket review, but most moderate- and high-risk devices, Class II and Class III respectively, must submit an application to the FDA before marketing to the public.²¹ All Class II and some Class III devices qualify for the abbreviated application process, called the premarket notification or 510(k), if they are predicated on an existing FDA-approved medical device.²² The manufacturers of such devices only need to show one of the following: (1) “substantial equivalence,” (2) that the device has the same technological characteristics and intended use as the predicate, or (3) that the device has the same intended use as the predicate and different technological characteristics that do not raise questions about its safety and effectiveness.²³

14. JUDITH A. JOHNSON, CONG. RESEARCH SERV., FDA REGULATION OF MEDICAL DEVICES 3 (2016).

15. Food, Drug & Cosmetic Act, 21 U.S.C. § 360c(a)(1)(A) (2018); JOHNSON, *supra* note 14, at 3, 5.

16. Elastic Bandage, 21 C.F.R. § 880.5075(b) (2018); Tongue Depressor, 21 C.F.R. § 880.6230(b) (2018).

17. 21 U.S.C. § 360c(a)(1)(B) (2018); JOHNSON, *supra* note 14.

18. 21 U.S.C. § 360c(a)(1)(C) (2018); JOHNSON, *supra* note 14.

19. JOHNSON, *supra* note 14, at 5 tbl.I.

20. *Id.*

21. JOHNSON, *supra* note 14, at 5–6.

22. See U.S. FOOD & DRUG ADMIN., THE 510(K) PROGRAM: EVALUATING SUBSTANTIAL EQUIVALENCE IN PREMARKET NOTIFICATIONS [510(K)]: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 3 (2014).

23. *Premarket Notification 510(k)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm#se> (last updated Sept. 27, 2018).

B. *Premarket Approval*

The PMA is the FDA's most stringent type of device regulatory review. The application requires the manufacturer to submit all available scientific knowledge concerning investigations; clinical and nonclinical data of the device's safety and effectiveness; detailed information regarding its design, components, ingredients, properties, and principles of operation; any applicable performance standards; and other information deemed relevant by the FDA.²⁴ In addition to these application requirements and agency review, the FDA may request additional data from the manufacturer or refer it to an outside panel of experts.²⁵ All of this information is necessary because PMA approval is based on the determination that the device is safe and effective for its intended use or uses.²⁶

Completing the PMA application is both time-consuming and expensive. According to a 2010 independent analysis, "the average total cost from concept to approval was approximately \$94 million" for PMAs, with \$75 million spent on clinical stages required by the FDA application process.²⁷ The same study showed that from first communication with the FDA, it took an average of fifty-four months for FDA reviewers to make a determination on the device.²⁸ Clearance rate, which factors in only the time the manufacturer first filed its application with the FDA to the determination of safety and effectiveness, is around 264 days;²⁹ this runs up against the FDA's guidelines, which state it should take only 180 days to review a PMA and make a determination.³⁰

Once the FDA makes a determination, the manufacturer cannot make changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness.³¹ While the PMA process is burdensome, FDA Commissioner Scott Gottlieb recently touted it as "the gold standard when

24. Richard E. Kaye, Annotation, *Federal Preemption of State Common-Law Products Liability Claims Pertaining to Medical Devices, Implants, and Other Health-Related Items*, 74 A.L.R. Fed. 2d 1, § 1.2 (2018).

25. See 21 U.S.C. § 360e(c)(1)(G) (2018); 21 C.F.R. § 814.44(a) (2018).

26. See 21 U.S.C. § 360c(a)(C) (2018).

27. JOSH MAKOWER ET AL., FDA IMPACT ON U.S. MEDICAL TECHNOLOGY INNOVATION: A SURVEY OF OVER 200 MEDICAL TECHNOLOGY COMPANIES 7 (2010).

28. *Id.* at 6.

29. *Premarket Approval (PMA)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarket-submissions/premarketapprovalpma/#overview> (last updated Sept. 27, 2018).

30. *Id.*

31. See 21 U.S.C. § 360e(d)(5)(A)(i) (2018).

it comes to device safety.”³² Of the thousands of medical devices approved by the FDA, very few turn out to be unsafe or ineffective.³³ Nonetheless, a study conducted by George Horvath found that “under a best-case scenario at least 4.6%–6% of PMA-approved devices will fail in such a way as to threaten death or serious and permanent harm.”³⁴ So, while clinical trials are the “gold standard” for the FDA to establish safety and effectiveness,³⁵ this is actually more true for drugs than devices.³⁶ Despite the rigorous and stringent standards and demands for evidence-based science, not all approved PMAs are backed by high-quality randomized controlled clinical trials.³⁷ Section III discusses the implications of patient safety due to the regulatory procedures.

C. Riegel v. Medtronic, Inc.

A prominent case of medical device failure occurred in 2008. Charles Riegel underwent coronary artery surgery and, during the angioplasty, the catheter ruptured causing extreme complications. The Riegels brought a lawsuit against Medtronic, the manufacturer of the catheter, alleging strict liability; breach of implied warranty; negligence of design, testing, inspection, distribution, and labeling; and negligent manufacturing, as well as other claims.³⁸ The Supreme Court denied the Riegels relief, holding that the MDA preempted the Riegel’s common-law tort claims,³⁹ leaving the Riegels without remedy from Medtronic.

32. Thomas M. Burton, *Do the FDA’s Regulations Governing Medical Devices Need to be Overhauled?*, WALL ST. J. (Mar. 23, 2015), <https://www.wsj.com/articles/do-the-fdas-regulations-of-medical-devices-need-to-be-overhauled-1427079649>.

33. *Id.*

34. Horvath, *supra* note 1, at 992.

35. Laura E. Bothwell et al., *Assessing the Gold Standard—Lessons from the History of RCTs*, 374 N. ENGL. J. MED. 2175, 2175 (2016).

36. See generally Annetine C. Gelijns, *Appendix A: Comparing the Development of Drugs, Devices, and Clinical Procedures*, in MODERN METHODS OF CLINICAL INVESTIGATION: MEDICAL INNOVATION AT THE CROSSROADS 147 (1990).

Most Phase II studies are double-blinded, randomized controlled clinical trials The well-designed randomized controlled trial (RCT) is generally regarded as the statistically most powerful method to determine efficacy Traditionally, most device evaluations lack randomized control groups. While this may in part be due to less sophistication in clinical research on the part of many device manufacturers, it may also result from inherent characteristics of device development that make the classical RCT more difficult to perform.

Id. at 157, 167–68.

37. Sanket S. Dhruva et al., *Strength of Study Evidence Examined by the FDA in Premarket Approval of Cardiovascular Devices*, 302 J. AM. MED. ASS’N 2679, 2683 (2009).

38. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 320–21 (2008).

39. *Id.* at 325.

Here, the Court first reviewed the relevant section, 360k, in the MDA. Section 360k provides an express preemption clause affirming that no state may establish requirements different, or in addition to, device safety or effectiveness requirements established by the MDA.⁴⁰ The Court found that the word “requirements” in the section includes a state’s common-law duties.⁴¹ The Court then reviewed the regulation promulgated by the FDA that specified state requirements are preempted “only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device. . . .”⁴² The Court interpreted the FDA’s “specific requirements applicable to a particular device” to mean the device review process.

The Court then reasoned that, because the premarket approval process is rigorous and specific to individual devices, preemption applies.⁴³ The Court compared the fact pattern here to the precedent case, *Medtronic, Inc. v. Lohr*, which analyzed preemption of the lower-risk approval process: the 510(k).⁴⁴ Under the 510(k) pathway, device manufacturers need only show “substantial equivalence” to an already FDA-approved device. In *Lohr*, the Court held that there was no preemption for 510(k) devices since the review was predicated on equivalence, and not safety and effectiveness.⁴⁵ In the case of the PMA, however, “it is in no sense an exemption from federal safety review—it *is* federal safety review.”⁴⁶ Thus, any tort claims of safety and effectiveness would contradict the reasonable assurance by the FDA that the device was in fact safe and effective.

Scholars argue that the *Riegel* decision represents a safe harbor for device manufacturers who obtain a PMA for their product, because the device manufacturer escapes tort liability, regardless of the harms caused and the number of people injured.⁴⁷ To a certain

40. 21 U.S.C. § 360k(a) (2018) (“Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement— (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.”).

41. *Riegel*, 552 U.S. at 324.

42. *Id.* at 322; see also 21 C.F.R. § 808.1(d) (2018).

43. See *Riegel*, 552 U.S. at 323–24.

44. *Id.*

45. *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

46. *Riegel*, 552 U.S. at 323.

47. See generally Demetria D. Frank-Jackson, *The Medical Device Federal Preemption Trilogy: Salvaging Due Process for Injured Patients*, 35 S. ILL. U. L.J. 453 (2011); John C.P. Goldberg & Benjamin C. Zipursky, *The Supreme Court’s Stealth Return to the Common Law of Torts*, 65 DEPAUL L. REV. 433 (2016); Lawrence O. Gostin, *The Deregulatory Effects of Preempting Tort*

extent, protecting device manufacturers makes sense because of the societal value of imperfect medical devices: if devices were perfectly safe, then nothing would be approved and society would not have access to innovative, life-saving technology.⁴⁸ However, the Cures Act weighs more heavily in favor of regulatory speed and innovation than safety and effectiveness. Section II evaluates the latest changes made to the regulatory system and assesses whether *Riegel* now represents an outdated position concerning the PMA process.

II. THE 21ST CENTURY CURES ACT

The Cures Act enacts innovative changes to the way the FDA regulates food, drugs, and medical devices. Congress passed this landmark legislation in 2016 with bipartisan support, with the goal of accelerating the discovery, development, and delivery of new cures and treatments.⁴⁹ The bill also had strong support from the pharmaceutical, biotechnology, and medical device industries because it purported to modernize the clinical trials systems and accelerate the development of new medical products.⁵⁰ The approval process for drugs and devices was “a relic of another era” and Congress was determined to enhance the system to keep pace with rapidly accelerating innovation.⁵¹

The Cures Act functions as an amendment: adding and changing provisions to the FDCA. The changes pertaining to medical devices are laid out in Subtitle F “Medical Device Innovations,” §§ 3051 to 3060.⁵² Two sections in particular have a significant impact on patient safety: §§ 3051 and 3058.

Litigation: FDA Regulation of Medical Devices Lawrence, 299 J. AM. MED. ASS'N 2313 (2008); George Horvath, *Recovery and Preemption: The Collision of the Medicare Secondary Payer Act and the Medical Device Amendments*, 103 CALIF. L. REV. 1353 (2015); Arlen W. Langvardt, *Generic Pharmaceuticals and the “Unfortunate Hand” Dealt to Harmed Consumers: The Emerging State Court Resistance*, 17 MINN. J.L. SCI. & TECH. 565 (2016).

48. See generally Gail A. Van Norman, *Drugs and Devices: Comparison of European and U.S. Approval Processes*, 1 J. AM. C. CARDIOLOGY BASIC TO TRANSLATIONAL SCI. 399 (2016) (outlining the ways in which regulators in Europe and the United States use approval processes to address the risks that medical devices may pose).

49. Pat Stricker, *The 21st Century Cures Act: A Model For Change*, CMSATODAY, <http://www.naylor-network.com/cmsatoday/articles/index-v3.asp?aid=415957&issueID=53656> (last visited Jan. 28, 2019)

50. Peggy Eastman, *21st Century Cures Act Aims to Speed Approvals of New Drugs & Devices*, 38 ONCOLOGY TIMES 18, 18 (2016).

51. Stricker, *supra* note 49.

52. 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033, 1034–35 (2016).

A. §§ 3051 and 3058

One important addition to the FDCA is § 3051, describing “breakthrough” devices. § 3051(a) provides, “[t]he purpose of this section is to encourage . . . and provide the Secretary with sufficient authority, to apply efficient and flexible approaches to expedite the development of . . . devices that represent breakthrough technologies.”⁵³ Section (a) grants the Secretary with discretion to facilitate new devices through the regulatory system. Section (b) then clarifies some of this power by detailing the structure the Secretary may use to expedite approval for select devices:

The Secretary shall establish a program to expedite the development of, and provide for the priority review for, devices . . . that represent breakthrough technologies . . . that offer significant advantages over existing approved or cleared alternatives . . . [or] the availability of which is in the best interest of patients.⁵⁴

Another substantial change to the FDA’s regulatory regime is § 3058’s amendment to the least burdensome device review standard. The FDA defines “least burdensome” as “a successful means of addressing a premarket issue that involves the most appropriate investment of time, effort, and resources on the part of industry and FDA.”⁵⁵ This type of review already exists in the FDCA, but the Cures Act tweaks this standard to allow for a more deregulatory effect.⁵⁶ In addition to requiring that the Secretary consider the least burdensome appropriate means in requesting information, the statute also requires that the Secretary consider “the role of postmarket information in . . . demonstrating a reasonable assurance of device safety and effectiveness.”⁵⁷

53. 21st Century Cures Act, Pub. L. No. 114-255, § 3051(a), 130 Stat. 1033, 1121 (2016).

54. *Id.* § 3051(b).

55. U.S. FOOD & DRUG ADMIN., THE LEAST BURDENSOME PROVISIONS OF THE FDA MODERNIZATION ACT OF 1997 1, 2 (2002).

56. 21 U.S.C. § 360c (2018).

57. 21st Century Cures Act, Pub. L. No. 114-255, § 3058(b)(5)(A)–(D), 130 Stat. 1033, 1129 (2016). The section provides in full:

(A) In requesting additional information with respect to an application under this section, the Secretary shall consider the least burdensome appropriate means necessary to demonstrate a reasonable assurance of device safety and effectiveness. . . . (C) For purposes of this paragraph, the Secretary shall consider the role of postmarket information in determining the least burdensome means of demonstrating a reasonable assurance of device safety and effectiveness. (D) Nothing in this paragraph alters the standards for premarket approval of a device.

Id.

B. *Potential Downsides of §§ 3051 and 3058*

§§ 3051 and 3058 go a long way toward increasing Congress's goal of modernizing the clinical approval process and speeding innovative technology from bench to bedside. § 3051 establishes a breakthrough device pathway that reinforces the existing priority review pathway, and § 3058 mandates that FDA reviewers consider the least burdensome means necessary for demonstrating a reasonable assurance of safety and effectiveness.⁵⁸ By design, these sections are somewhat malleable, allowing the Secretary of HHS to expedite any type of device he or she deems to be "in the best interests of patients."⁵⁹ Likewise, the ability to expedite devices that "offer significant advantages" over existing or cleared devices, or that are "in the best interest of patients," implies subjectivity in review standards that could accelerate approval.⁶⁰ Thus, approvals may hinge on reviewers' beliefs regarding the utility of the device and not on complete clinical data.⁶¹

The Cures Act specifically delegates authority to the Secretary of HHS to choose a select number of devices that will go through the flexible approval process, but leaves ambiguous the meaning of § 3051's standards. Guidance documents for the FDA outline criteria for breakthrough devices. The draft documents state that a sponsor must "demonstrate a *reasonable expectation* that the device could provide for more effective treatment or diagnosis of the disease or condition identified in the proposed indications for use."⁶² Demonstrating a "reasonable expectation" of success could mean providing "literature or preliminary data (bench, animal, or clinical)."⁶³ However, relying on applications primarily supported by bench or animal data could potentially lead to inconsistent review for certain types of devices because the devices have not yet been adequately tested in humans.⁶⁴ It is still unclear what this could

58. See *id.* §§ 3051, 3058.

59. *Id.* § 3051(b).

60. *Id.* § 3051(b)(2)(C)–(D).

61. See U.S. FOOD & DRUG ADMIN., BREAKTHROUGH DEVICES PROGRAM: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 9 (2017), <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664.pdf> (stating a complete set of clinical data is not required for approval).

62. *Id.* at 12 (emphasis added).

63. *Id.*

64. See Malcolm R. Macleod et al., *Good Laboratory Practice: Preventing Introduction of Bias at the Bench*, 29 J. CEREBRAL BLOOD FLOW & METABOLISM 221 (2009) (providing that bench data is susceptible to experimental bias and based off of researcher hypotheses); see also John P. Gibbs, et al., *Bedside to Bench: Integrating Quantitative Clinical Pharmacology and Reverse Translation to Optimize Drug Development*, 103 CLINICAL PHARMACOLOGY & THERAPEUTICS 196,

mean for patient safety and safety/effectiveness standards for Class III devices expedited through this pathway.

Section 3058 also includes unclear standards and creates discretionary and subjective criteria. In the FDA's draft guiding principles, "least burdensome" means "the minimum amount of information necessary to adequately address a regulatory question or issue through the most efficient manner at the right time (e.g., need to know versus nice to know)."⁶⁵ But under the Cures Act, post-market information takes on a leading role of demonstrating safety and effectiveness.⁶⁶ The FDA provides that post-market studies are only appropriate in certain circumstances, such as modifying labeling, assessing long-term performance, and confirming bench data.⁶⁷ Thus, a reviewer adhering to the least burdensome review standard could approve a device based on promising bench trial data and rely on post-market surveillance for confirmation of safety and effectiveness. But, it seems counterintuitive to mandate reviewers to rely on uncollected data to approve a device as safe and effective.

Benefit-risk determinations calculate the risk of clearing devices predicated on post-market data collection.⁶⁸ The FDA states that: "there is never 100% certainty when determining reasonable assurance of safety and effectiveness of a device. However, the degree of certainty of the benefits and risks of a device is a factor we consider when making benefit-risk determinations."⁶⁹ The Guidance for Benefit-Risk determination lists multiple factors, such as magnitude of benefits and severity of risks, but also lists patient perspective as an evaluation criterion.⁷⁰ These criteria indicate that the FDA would never approve an obviously risky device based solely on observational data. But despite the FDA's best efforts, discretionary

196 (2018) (emphasizing that bench data is valuable for refining target selection and validation, however, "mechanistic insights are needed for gaining full understanding.").

65. U.S. FOOD & DRUG ADMIN., THE LEAST BURDENSOME PROVISIONS 8 (2017), <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM588914.pdf>.

66. See 21st Century Cures Act, Pub. L. No. 114-255, § 3058(b)(5)(C), 130 Stat. 1033, 1129 (2016).

67. See U.S. FOOD & DRUG ADMIN., BALANCING PREMARKET AND POSTMARKET DATA COLLECTION FOR DEVICES SUBJECT TO PREMARKET APPROVAL: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 9–13 (2015).

68. *Id.* at 8.

69. *Id.* (quoting U.S. FOOD & DRUG ADMIN., FACTORS TO CONSIDER WHEN MAKING BENEFIT-RISK DETERMINATIONS IN MEDICAL DEVICE PREMARKET APPROVAL AND DE NOVO CLASSIFICATIONS 11 (2012)).

70. U.S. FOOD & DRUG ADMIN., FACTORS TO CONSIDER REGARDING BENEFIT-RISK IN MEDICAL DEVICE PRODUCT AVAILABILITY, COMPLIANCE, AND ENFORCEMENT DECISIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 9 (2016).

factors exist in many of the FDA review standards that reviewers can use when approving Class III medical devices.

Section 3058 of the Cures Act increases review subjectivity because reviewers are *required* to consider the “least burdensome means” principal to demonstrate a reasonable assurance of safety and effectiveness.⁷¹ However, while the FDA has development requirements to help guide device reviewers, it has yet to develop performance metrics to evaluate them.⁷² In 2002, the FDA stated that it planned to periodically assess the implementation of the least burdensome principles, but without performance metrics, use of least burdensome means is discretionary.⁷³ The Government Accountability Office (GAO) found that “until such measures are developed and used, FDA will not be able to evaluate whether it effectively and consistently applies a least burdensome approach in its medical device reviews.”⁷⁴ According to GAO, it appears that exercise of the “least burdensome means” is subject to the discretion of the reviewer.

Furthermore, while the drug approval process necessitates clinical trials, § 3058 makes it clear this “gold standard” is not the priority for devices.⁷⁵ Instead, proposals based off of the language of the Cures Act suggest “‘shorter or smaller clinical trials’ for devices and the request that the FDA develop criteria for relying on ‘evidence from clinical experience,’ including ‘observational studies, registries, and therapeutic use’ instead of randomized, controlled trials for approving new uses for existing drugs.”⁷⁶ Studies suggest that these approaches are not as rigorous or as valid as randomized trials in assessing efficacy.⁷⁷ While § 3058 specifically states that it will not alter the standards for PMAs,⁷⁸ it encourages less rigorous science and more discretion in decision-making in reality.

71. See 21st Century Cures Act, Pub. L. No. 114-255, § 3058(b)(5)(A), 130 Stat. 1033, 1129 (2016). Note that for purposes of statutory interpretation, “shall” is meant to refer to actions that are mandatory, whereas “may” is interpreted to mean optional.

72. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-18-140, FDA MEDICAL DEVICE REVIEWS: EVALUATION IS NEEDED TO ASSURE REQUESTS FOR ADDITIONAL INFORMATION FOLLOW A LEAST BURDENSOME APPROACH 23–26 (2017).

73. *Id.* at 26–27.

74. *Introduction to id.*

75. See *The FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm> (last updated Nov. 24, 2017); see also U.S. GOV’T ACCOUNTABILITY OFFICE, *supra* note 72, at 4.

76. Jerry Avorn & Aaron S. Kesselheim, *The 21st Century Cures Act—Will It Take Us Back in Time?*, 372 NEW ENG. J. MED. 2473, 2474 (2015).

77. *Id.*

78. 21st Century Cures Act, Pub. L. No. 114-255, § 3058(b)(5)(D), 130 Stat. 1033, 1129 (2016).

III. WHAT THIS COULD MEAN FOR PATIENT SAFETY

The Cures Act has only been in operation for a short period of time and the immediate effects of a more flexible and discretionary standard for medical devices cannot yet be directly assessed. Predictions can be made based on the past trends of medical device performance, however. This section analyzes several cases of device failures and anticipates how the Cures Act could potentially exacerbate this type of problem in the future. Specifically, it attempts to show how the failures in safety and efficacy review under the pre-Cures Act approval process are actually the methods of approval that the Cures Act favors. Because the Cures Act encourages practices that have led to device recalls, this Note predicts more incidents of device failure and more injury to patients will occur.

A. *Implantable Cardioverter-Defibrillator Failures and Consequences*

One of the most infamous failures of Class III devices was the Sprint Fidelis Lead wire fracture. Manufactured by Medtronic, the Sprint Fidelis Leads were specific models of cardiac electrodes, or thin wires that connected an implantable cardioverter-defibrillator (ICD) directly to a patient's heart.⁷⁹ The primary purpose of the leads was to prevent sudden cardiac death by sending shocks to the heart when sensing irregular heart rhythms.⁸⁰ In testing its wires, Medtronic relied on stress testing—tests meant to recreate the pressures of the body—rather than on clinical trials.⁸¹ And despite this, in June 2004, the FDA approved a PMA supplement for the Sprint Fidelis Leads.⁸²

Implantation of ICDs for prevention of sudden cardiac death is an accepted treatment strategy for high-risk patients.⁸³ Lead failure has been a known risk for several decades,⁸⁴ yet the benefits of ICDs are critical in preventing acute myocardial infarction, myo-

79. *Defective Medtronic Sprint Fidelis Leads Malfunctioning*, CLASS ACTION (Oct. 11, 2013), <https://www.classaction.org/medtronic-sprint-fidelis-lead>.

80. *Implantable Cardioverter Defibrillator*, AM. HEART ASS'N, <https://www.heart.org/en/health-topics/arrhythmia/prevention—treatment-of-arrhythmia/implantable-cardioverter-defibrillator-icd> (last visited Jan. 28, 2019).

81. Burton, *supra* note 32; see also *Medtronic Defibrillator Sprint Fidelis Lead Recall*, BEASLEY ALLEN (Oct. 23, 2007), <http://www.beasleyallen.com/news/medtronic-defibrillator-sprint-fidelis-lead-recall/>.

82. *In re Medtronic, Inc.*, 623 F.3d 1200, 1203 (8th Cir. 2010).

83. P.F.H.M. van Dessel, *The Sprint Fidelis Lead Fracture Story: Time to Come to Our Senses?*, 18 NETH. HEART J. 4, 4 (2010).

84. *Id.*

cardial ischemia, and electrolyte imbalance and drug toxicity.⁸⁵ The problem with Sprint Fidelis was that the leads were prone to fracture in a small number of patients, and about 2% of patients were estimated to experience lead fracture within 30 months.⁸⁶ The fractured leads could cause a defibrillator to fail to deliver a lifesaving shock or to fire for no reason. After five patients died due to lead failure, Medtronic pulled the models from the market.⁸⁷ By the time they acted, though, approximately 268,000 patients were implanted with the Sprint Fidelis Leads.⁸⁸

After Medtronic recalled their product, patients began considering having the faulty wires removed. Because the leads were implanted directly on or into the heart, though, surgery to remove the wires was incredibly dangerous and even fatal. By 2009, four patients had died from doctors' efforts to surgically remove the leads.⁸⁹

One reason why the Sprint Fidelis situation is often cited as an infamous failure of medical innovation and FDA regulation is because of the large number of patients who were implanted with the leads before its recall. Over 250,000 people were implanted with the Sprint Fidelis Leads and an estimated 150,000 people in the United States still have them today.⁹⁰ Sprint Fidelis represents the failure of the FDA to properly protect patients from faulty medical device innovation, and underscores the leniency of the PMA standards in practice. These leads were approved with evidence of stress tests, not through more rigorous clinical trials.⁹¹ This is exactly the type of "reasonable expectation"⁹² of success shown through bench, animal, or clinical evidence that the Cures Act encourages for modernized PMAs.

While this example reveals certain flaws of the FDA's regulation of Class III medical devices, it also shows that, overall, the FDA's regulation is effective. There is no recent comparable case to Sprint Fidelis in terms of scale and mortality, despite thousands of medical devices being approved in the interim. The fact that Sprint

85. See generally van Dessel, *supra* note 83; see also *Implantable Cardioverter Defibrillator*, *supra* note 80.

86. *Defective Medtronic Sprint Fidelis Leads Malfunctioning*, CLASS ACTION (Oct. 11, 2013), <https://www.classaction.org/medtronic-sprint-fidelis-lead>.

87. Barry Meier, *Removing Medtronic Heart Cables is Hard Choice*, N.Y. TIMES (Apr. 6, 2009), <https://www.nytimes.com/2009/04/07/business/07device.html>.

88. van Dessel, *supra* note 83.

89. Mikhael F. El-Chami et al., *Outcomes of Sprint Fidelis and Riata Lead Extraction: Data From 2 High-Volume Centers*, 12 HEART RHYTHM 1216, 1218 (2015).

90. Barry Meier, *Medtronic Links Device for Heart to 13 Deaths*, N.Y. TIMES (Mar. 13, 2009), <https://www.nytimes.com/2009/03/14/business/14device.html>.

91. *Medtronic Defibrillator Sprint Fidelis Lead Recall*, *supra* note 81.

92. *Id.*

Fidelis happened over a decade ago indicates that the FDA has a safer and more robust process for evaluating medical devices. When asked about failure prevention, FDA Commissioner Scott Gottlieb remarked,

[t]he failure of any defibrillator lead is tragic, but to portray the malfunction of Medtronic's lead as an example of a device failure that could have been avoided through a bigger clinical trial gives short shrift to the basic science and engineering challenges that permeate this type of problem, and how one tries to prevent it from occurring. Keep in mind that 99.8% of all medical devices have no serious adverse events associated with them.⁹³

Commissioner Gottlieb is right—medical devices are not like drugs. Most devices cannot be tested through rigorous double-blind controlled clinical trials like pharmaceuticals are.⁹⁴ And while sham medical device procedures do occur, they tend to cause “moral discomfort in clinician-investigators” who are “[t]rained to perform invasive interventions only for the medical benefit of patients” but find themselves administering fake procedures and creating false beliefs in patient-subjects.⁹⁵

In 2017, medical device maker St. Jude Medical failed to recall their defibrillators for faulty batteries. The lithium batteries in the ICD, implanted under the skin by the collarbone, were short-circuiting, causing two deaths and serious adverse effects in dozens of other patients.⁹⁶ The same thing that happened in early 2000s also happened a decade later. A device that patients relied on to live led to death and serious injury. This time, however, 400,000 people worldwide were affected.⁹⁷

One large similarity between the two device failures is that both Medtronic and St. Judes Medical not only ignored studies showing their defibrillators were malfunctioning, but they also failed to properly report these studies to the FDA. In the case of the Sprint Fidelis Leads, before Medtronic issued a recall, it had known about

93. Burton, *supra* note 32.

94. Rita F. Redberg, *Sham Controls in Medical Device Trials*, 371 NEW ENG. J. MED. 892, 892–83 (2014).

95. Franklin G. Miller & Ted J. Kaptchuk, *Sham Procedures and the Ethics of Clinical Trials*, 97 J. ROYAL SOC'Y MED. 576, 576 (2004).

96. Katie Thomas, *St. Jude Medical Played Down Defibrillator Failures for Years, F.D.A. Says*, N.Y. TIMES (Apr. 13, 2017), <https://www.nytimes.com/2017/04/13/health/st-jude-medical-defibrillator-abbot-fda.html>.

97. *Id.*

the fracturing problem for months.⁹⁸ Prior to the recall, there were over one hundred reports of lead fracturing and since then there have been over a thousand reports of fractures.⁹⁹ When the FDA conducted inspections of the leads, it revealed deficiencies of FDA Current Good Manufacturing Practices, citing “[f]ailure to establish and maintain adequate procedures for validating the device design; and [f]ailure to establish and maintain adequate procedures for implementing corrective and preventive action.”¹⁰⁰ The FDA previously issued two Warning Letters to Medtronic prior to the 2007 recall.¹⁰¹ Yet, despite these warnings and reports, Medtronic failed to act.¹⁰²

In the case of the St. Jude’s defibrillator, physicians at Duke University and the University of Illinois reported cases of battery problems with the devices in 2014 and 2015.¹⁰³ St. Jude fixed the problem for new defibrillators, but failed to recall the defective models and did not alert doctors or patients of the potential risk for malfunction.¹⁰⁴ These defibrillators were approved under the non-Cures Act rigorous standard, yet faulty manufacturing proliferated without recourse. The Cures Act could thus promote more device-failure incidents by favoring tests like Medtronic’s stress-test and by leaning more heavily on post-market surveillance studies with which companies may or may not comply.

B. *The Problems with Post-Market Surveillance*

The Cures Act may be less effective than envisioned and cause more harm to patients because of manufacturers’ and hospitals’ consistent and systematic underreporting of issues.¹⁰⁵ As seen in the

98. See Meier, *supra* note 90; *Medtronic Defibrillator Sprint Fidelis Lead Recall*, *supra* note 81.

99. *Medtronic Defibrillator Sprint Fidelis Lead Recall*, *supra* note 81.

100. U.S. FOOD & DRUG ADMIN., CENTER FOR DEVICES AND RADIOLOGICAL HEALTH 2–6 (2008), <https://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129810.pdf>.

101. *Id.*

102. See Tom Lamb, *Sprint Fidelis Lead Wire Defect Litigation Comes to an Apparent Disappointing End (Medtronic Wins)*, DRUG INJ. WATCH (Nov. 10, 2010), <https://www.druginjury.com/druginjurycom/2010/11/medtronic-sprint-fidelis-litigation-settlement-followed-by-federal-preemption-ruling-affirmed.html> (noting that Medtronic settled many of its cases, while many others were found to be preempted under *Riegel*).

103. Thomas, *supra* note 96.

104. *Id.*

105. See James R. Ward & P. John Clarkson, *An Analysis of Medical Device-Related Errors: Prevalence and Possible Solutions*, 28 J. MED. ENGINEERING & TECH. 1, 5 (2009) (describing underreporting rates for device-related medical errors ranging from ten to eighty percent); see also *A Delicate Balance: FDA and the Reform of the Medical Device Approval Process: Hearing Before the Spec. Comm. on Aging*, 112th Cong. 81, 88 (2011) (statement of Ralph D. Hall, Distinguished Professor and Practitioner, University of Minnesota Law School).

defibrillator's context, both Medtronic and St. Jude's knew there were issues with their products, yet, they both failed to act. This problem extends beyond manufacturers, though. Hospitals and consumers also fail to report medical device malfunctions.¹⁰⁶ This calls into question the Cures Act's reliance on the FDA reliably approving devices based on predictions of successful post-market surveillance.

The FDA provides mandatory reporting guidelines for manufacturers, importers, and Device User Facilities, but lacks compliance enforcement provisions. Manufacturers must report deaths, serious injuries and malfunctions to the FDA within 30 days of learning of the adverse event.¹⁰⁷ Hospitals and outpatient facilities must report suspected medical-device-related deaths to the manufacturer and the FDA, but can report serious injuries only to the manufacturer.¹⁰⁸ Doctors are not required to report adverse events to the FDA at all, and studies show that many do not bother.¹⁰⁹

Medical providers play a significant role in failing to report medical product issues to the FDA. One prominent example of multiple hospitals' failures to report issues is in the context of laparoscopic power morcellators: bladed power tools that gynecologists use to perform hysterectomies through small incisions.¹¹⁰ The device failure became publicized when it was discovered that the morcellators were spreading and worsening undetected cancers.¹¹¹ In response to the public outcry, the FDA investigated and

106. Efthimios Parasidis, *Patients over Politics: Addressing Legislative Failure in the Regulation of Medical Products*, 2011 WIS. L. REV. 929, 951, 953, 975.

107. *Mandatory Reporting Requirements: Manufacturers, Importers and Device User Facilities*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm> (last updated Sept. 27, 2018).

108. *Id.*
109. Anna A. Gagliardi et al., *Factors influencing the Reporting of Adverse Medical Device Events: Qualitative Interviews with Physicians about Higher Risk Implantable Devices*, BMJ QUALITY & SAFETY 1, Aug. 2 2017, at 1 (finding many physicians believe ADME reporting is unnecessary); Stephen Barlas, *FDA Flags Inconsistent Hospital Reporting of Medical Device Problems: Hazy Reporting Rules Beget Confusion*, 42 PHARMACY & THERAPEUTICS 97, 98 (2017) (describing hospital underreporting of devices causing death, serious injury or illness, or a malfunction); DEP'T OF HUMAN AND HEALTH SERVICES OFFICE OF INSPECTOR GENERAL, ADVERSE EVENT REPORTING FOR MEDICAL DEVICES (2009) (stating that the majority of adverse event reports were made by manufacturers and voluntary reporters make up a small percentage of the total reports made).

110. Jon Kamp & Jennifer Levitz, *FDA Presses Hospitals on Medical-Tool Problems*, WALL ST. J. (Dec. 2, 2016, 11:13 AM), <https://www.wsj.com/articles/fda-presses-hospitals-on-medical-device-problems-1480690803>. Morcellators are actually Class II medical devices that were approved under the 510(k). However, I use this example to show flaws in the post-market surveillance system, not the FDA's safety and efficacy review. *Laparoscopic Power Morcellators*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medicaldevices/productsandmedicalprocedures/surgeryandlifesupport/ucm584463.htm> (last updated Aug. 22, 2018).

111. Kamp & Levitz, *supra* note 110.

acknowledged that no one, including hospitals, filed reports until after the media publicized problems.¹¹² Some hospitals knew how to notify the FDA or device manufacturers, but did not submit the required reports for deaths or serious injuries, and in some cases, “did not have adequate procedures in place for reporting device-related death or serious injury events to FDA or to the manufacturers.”¹¹³ Based on the FDA’s inspection, a report found that hospitals are not alone in their limited, sometimes non-existent, reporting to the FDA or to manufacturers.¹¹⁴ The report further concluded that staff members were neither aware of, nor trained to comply with, reporting requirements.¹¹⁵

The FDA plays its own role in failing to follow-up on post-market studies.¹¹⁶ When the FDA began regulating medical devices in 1976 after the passage of the MDA, all existing medical devices on the market were grandfathered into the regulatory scheme.¹¹⁷ Those devices were allowed to remain on the market as long as they submitted evidence showing safety and effectiveness. Most companies never submitted that data, however, and the FDA did not follow up.¹¹⁸ The fact that the FDA set a precedent of not adhering to its own post-market guidelines, since the inception of the regulatory standard, casts doubt on how effective the new Cures Act emphasis on post-market surveillance will be.

A troubling example of recent post-market surveillance failure is the case of female contraception. Conceptus pioneered the use of a device called Essure: a permanent contraceptive that was developed in part to avoid the risks of tubal ligation surgery.¹¹⁹ The FDA fast-tracked the device because it offered “significant advantages over existing approved alternatives,” despite Conceptus not knowing the risks of long-term implantation.¹²⁰ When Conceptus eventually conducted follow-up studies, they were not registered at Clin-

112. *Id.*

113. Jeffrey Shuren, *FDA Is Working with Hospitals to Modernize Data Collection About Medical Devices*, FDA VOICE (Oct. 24, 2016), <https://www.healthdataanswers.net/fda-working-hospitals-modernize-data-collection-medical-devices/>.

114. *Id.*

115. *Id.*

116. Parasidis, *supra* note 106, at 951.

117. 21 U.S.C. § 360e(b)(1)(A)–(B) (2018).

118. *Fresh Air: Are Implanted Medical Devices Creating a “Danger Within Us”?*, NAT’L PUB. RADIO (Jan. 17, 2018), <https://www.npr.org/2018/01/17/578562873/are-implanted-medical-devices-creating-a-danger-within-us>.

119. Jennifer Block, *The Battle Over Essure*, WASH. POST (July 26, 2017), <http://www.washingtonpost.com/sf/style/2017/07/26/essure/>.

120. *Id.*

icalTrials.gov—though not legally required by the FDA—and their results were neither disseminated nor published.¹²¹

Over thirteen years later, the FDA has restricted the sale of Essure due to safety and effectiveness problems and the need for additional post-market studies.¹²² Large numbers of adverse events have been reported to the FDA through its Manufacturer and User Facility Device Experience (MAUDE) database, including incomplete procedures, tubal perforations, intractable pain and bleeding leading to hysterectomies, possible device-related deaths, and hundreds of unintended pregnancies.¹²³ The MAUDE database aggregates adverse events reports voluntarily submitted by users of an FDA approved product. As of June 2015, a total of 5,093 Essure complaints had been submitted to MAUDE, finally motivating the FDA enough to reevaluate the device.¹²⁴ Unfortunately, this number may only capture some of the issues Essure presents to women, as voluntary reporting typically underestimates adverse-events rates.¹²⁵

The FDA acknowledges that medical device mishaps are underreported.¹²⁶ This is the result of what Center for Devices and Radiological Health director, Jeffrey Shuren, calls “passive surveillance.”¹²⁷ The FDA relies on manufacturers, hospitals, and consumers to alert the agency of injuries, malfunctions, and other adverse events linked to medical devices. However, even with prompt reliable reporting, it can take “months or even years for the FDA to detect patterns of failure.”¹²⁸ With the limitations of underreporting, biases, and lack of causality¹²⁹, it is unsettling to think that the Cures Act is encouraging more post-market surveillance in device approvals when the reporting system lacks efficiency and efficacy.

The Cures Act’s effective streamlining of the medical device regulatory system relies in part on the efficacy of post-market surveillance. This reliance may be misplaced in light of the systematic underreporting of adverse events by patients, doctors, hospitals and manufacturers, though. There are serious gaps in the post-

121. Sanket S. Dhurva et al., *Revisiting Essure — Toward Safe and Effective Sterilization*, 373 NEW ENG. J. MED. e17(1), e17(1)–(2) (2015).

122. *Id.* at e17(1); *FDA Restricts Sale and Distribution of Essure to Protect Women and to Require That Patients Receive Risk Information*, U.S. FOOD & DRUG ADMIN. (Apr. 9, 2018), <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm604098.htm>.

123. Dhurva et al., *supra* note 121, at e17(1).

124. *Id.* at e17(2).

125. Parasidis, *supra* note 106, at 950–51.

126. Shelia Kaplan, *F.D.A. Deal Would Relax Rules on Reporting Medical Device Problems*, N.Y. TIMES (July 11, 2017), <https://www.nytimes.com/2017/07/11/health/fda-medical-device-problems-rules.html>.

127. Shuren, *supra* note 113; *see also* Parasidis, *supra* note 106, at 953.

128. Kaplan, *supra* note 126.

129. INST. OF MED., CHALLENGES FOR THE FDA: THE FUTURE OF DRUG SAFETY 5 (2007).

market surveillance system that will hinder the FDA's ability to reliably assess device safety and effectiveness. Unless the FDA acts to bolster their post-market regulation, patient safety under the Cures Act will be compromised. There are no studies yet which affirmatively show the connection between deregulation of the premarket approval process and harmful, risky medical devices; but, the scientific literature is full of past examples of PMA review failure to catch harmful devices both premarket and post-market before they seriously, and in some cases irreparably, harm patients.¹³⁰

IV. SOLUTIONS AND ALTERNATIVE COMPENSATION MECHANISMS

Reliance on post-market information to approve medical devices in an effort to streamline the regulatory process is not an inherently bad idea. In fact, it is an innovative proposition that can get life-saving medical devices to patients who desperately need them in a cost effective and timely way. It is likely that some, if not many, dangerous Class III medical devices will prematurely advance through the approval process and seriously harm patients, though. This is a risk that a bipartisan Congress and the medical community were willing to take. But, if Congress and medical device manufacturers are willing to risk patients' physical and mental wellbeing with devices whose safety and effectiveness have not established prior to patient use, they should also be willing to compensate those patients who are harmed.

A. *Judicial Remedy*

Because *Riegel v. Medtronic, Inc.* was decided on the basis of a regulatory framework that has since been legislatively altered, this Note argues the precedent should likewise be reevaluated. Unfortunately, judicial action to overrule the holding seems far from likely. While the Cures Act amended several sections of the FDCA,

130. See, e.g., Homa Alemzadeh, et al., *Adverse Events in Robotic Surgery: A Retrospective Study of 14 Years of FDA Data*, PLOS ONE, Oct. 2018, at 1 (analyzing failures in robotic surgery); John Amooore & Paula Ingram, *Learning From Adverse Incidents Involving Medical Devices*, NURSING STANDARD, Apr. 2003, at 41 (showing device malfunctions are multifactorial, but are due to malfunction of the device itself); Sheena Galhotra & Joseph Maurice, *Assessment of Obstetric and Gynecologic Food and Drug Administration Device Approvals and Recalls*, 25 J. MINIMALLY INVASIVE GYNECOLOGY 1281, 1281 (2018) (showing increased risk to patients by improper device risk classification and increased device malfunctions); Tomas Zaremba et al., *Risk of Device Malfunction in Cancer Patients With Implantable Cardiac Device Undergoing Radiotherapy: A Population-Based Cohort Study*, 38 PACING CLINICAL ELECTROPHYSIOLOGY 343 (2015) (detailing cardiac device failure).

it left § 360k(a), the express preemption clause cited by Justice Scalia in the *Riegel* opinion, intact. Thus, it would appear to be the legislative intent to leave *Riegel's* essential holding untouched and keep the preemption clause for PMAs. The plain statutory language of the text and legislative intent will most likely dissuade any judge from overruling the 2008 decision.

Despite the clear preemption foundation that *Riegel* was based upon, it would otherwise appear that the premise for the decision has changed. Justice Scalia emphasized the fact the PMA, unlike the 510k in *Lohr*, was a review of “safety and effectiveness;” that the PMA “is federal safety review”¹³¹ and thus consumers cannot make claims about safety. But can courts, Congress, patients, and the FDA really say the standard is still just as rigorous as in 2008 when post-market surveillance was a less powerful force in the regulatory process? The answer should be no.

The Cures Act § 3058 amendment states, “[n]othing in this paragraph alters the standards for premarket approval of a device.”¹³² The FDA, however, cannot guarantee this statement to be true—especially when the statute mandates new review processes and regulatory standards that need to be put in place.¹³³ Faulty devices passed through the rigorous pre-Cures Act PMA process, and faulty devices will continue to pass through the post-Cures Act PMA process—likely at an even higher rate. Especially because the Cures Act relies more heavily on post-market data that will not reveal safety or effectiveness until years after approval and patient use. In the preceding section, this Note highlighted just a few examples of device and post-market surveillance failures that severely injured and caused deaths in many patients.

One 2018 study indicates that under the Cures Act, “4.6%-6% of PMA-approved devices will fail in such a way as to threaten death or serious and permanent harm.”¹³⁴ And although as a society we are willing to exchange readily available innovative technology for less than 100% safety, the Cures Act “further tip[s] the balance away from ensuring device safety.”¹³⁵ The Cures Act allows more room for uncertainty in approving the safety of medical devices in order to expedite innovative technology. It is changing the standard on which *Riegel* was decided. Thus, *Riegel's* holding should be reconsidered.

131. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 320–21 (2008).

132. 21st Century Cures Act, Pub. L. No. 114-255, § 3058(b)(5)(A)–(D), 130 Stat. 1033, 1129 (2016).

133. See U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 72, at 19–28.

134. Horvath, *supra* note 1, at 992.

135. *Id.* at 991.

As the only dissenter in the *Riegel* decision, Justice Ginsburg assessed the fact that the MDA's purpose was "to provide for the safety and effectiveness of medical devices intended for human use" and yet that "Congress would, without comment, remove all means of judicial recourse for large numbers of consumers injured by defective medical devices."¹³⁶ Ginsburg made the point that the majority's interpretation of the statute seemed to work against Congress's original intent.

Justice Ginsburg also reviewed the history of the FDA's regulatory power. The FDCA has no explicit preemption clause for drugs and food additives, but the MDA imposed one in connection with the regulation of medical devices.¹³⁷ The purpose of this decision was not to ban tort claims regarding medical devices, but rather "to empower the FDA to exercise control over state premarket approval systems installed at a time when there was no preclearance at the federal level."¹³⁸ Prior to the MDA, states established their own regulatory systems of medical devices.¹³⁹ By enacting the preemption clause § 360k(a) and (b), Congress simply wanted to place all state systems under the controlling authority of the FDA—not to bar state tort claims.¹⁴⁰

The FDA itself further did not believe that at the time the MDA was enacted, all medical device manufacturers would be absolved of state tort liability. After the *Lohr* decision, Chief Counsel of the FDA, Margaret Porter, commented,

FDA's view is that FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection. FDA regulation of a device cannot anticipate and protect against all safety risks to individual consumers. Even the most thorough regulation of a product such as a critical medical device may fail to identify potential problems presented by the product. Regulation cannot protect against all possible injuries that might result from use of a device over time.

136. *Riegel*, 552 U.S. at 335–37 (Ginsburg, J., dissenting) (first quoting 90 Stat. 539 pmb1.; then quoting *Silkwood v. Kerr McGee Corp.*, 464 U.S. 238, 251 (1984)).

137. *Id.* at 340.

138. *Id.* at 341.

139. *Id.* at 343 n.14 (noting that "Congress featured California's regulatory system in its discussion of § 360k(a), but it also identified California's system as a prime candidate for an exemption from preemption under § 360k(b). . . . Congress sought not to terminate all state premarket approval systems, but rather to place those systems under the controlling authority of the FDA.").

140. *Id.*

Preemption of all such claims would result in the loss of a significant layer of consumer protection.¹⁴¹

The *Lohr* decision was predicated on the FDA standard of “equivalence,” though, and the *Riegel* decision was predicated on the standard of “safety and effectiveness.” While Justice Ginsburg made compelling arguments against the majority’s decision in *Riegel*, it seems unlikely that the Court would be motivated to deviate from the plain statutory language of the text and legislative intent of the Cures Act.

B. Statutory Amendment

An alternative to judicial action is for Congress to pass an amendment providing relief to victims of malfunctioning devices. After the Supreme Court came down with its decision in *Riegel* and more than 1,000 patient lawsuits involving the Sprint Fidelis tort claims were thrown out due to federal preemption, Democrats in Congress vowed to pass legislation that would override *Riegel*.¹⁴² Almost a decade later, though, such legislation remains to be an empty promise. With the recent passage of the Cures Act there appears to be a lack of political will in Congress to provide such relief. Had Congress wanted to override *Riegel*, passage of the Cures Act would have been the time to do it. Yet it did not. This implies that Congress is satisfied with preemption for medical devices.

A congressional amendment to the preemption provision of the Cures Act appears to be the best way to hold device manufacturers accountable for their products and to compensate victims from the harms posed by unsafe medical devices. In 2009, after the *Riegel* decision and after the Sprint Fidelis failure caught the media’s attention,¹⁴³ the Medical Device Safety Act of 2009 was introduced in the House.¹⁴⁴ The bill’s opponents in Congress argued that removing preemption would inhibit innovation and delay the use of life saving technologies.¹⁴⁵ Arguments against removing preemption

141. Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 FOOD DRUG L.J. 7, 11 (2004).

142. Meier, *supra* note 87.

143. See, e.g., *id.*

144. Medical Device Safety Act of 2009, H.R. 1346, 111th Cong. § 2(a) (2009) (proposing amendments to federal law that would clearly state that “[n]othing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State.”).

145. Michelle H. Lyu, *House Subcommittee Holds Hearing to Overturn Riegel: H.R. 1346, The “Medical Device Safety Act of 2009”*, REED SMITH LLP, May 13, 2009, <https://www.lexology.com/library/detail.aspx?g=e531c446-b39c-4fbf-b7a0-d94b18fc1e1d>.

also focused on the issue of clogging the court system and leaving safety and effectiveness concerns in the hands of inexperienced juries.¹⁴⁶ These opponents viewed preemption as a finely-struck balance between innovation and safety that they did not want to disturb.¹⁴⁷ This bill never passed the House.

Statutory override used to be a common occurrence. Between 1967 and 1990, Congress passed legislation that overrode 121 Supreme Court statutory interpretations.¹⁴⁸ A congressional override of *Riegel* would have the effect of “modify[ing] the consequences of the decision, such that the same case would have been decided in the same way but subsequent cases would be decided differently.”¹⁴⁹ However, due to “legislative paralysis brought on by congressional polarization,”¹⁵⁰ congressional overrides have come almost to a standstill. This political polarization ultimately gives the Supreme Court the last word. Therefore, barring another Sprint Fidelis-esque failure, it seems unlikely Congress will act to amend § 360k(a).

C. *Establishing a Victim Compensation Fund*

Another potential solution is for Congress to establish a medical device victim compensation fund modeled after the vaccine compensation program. Vaccines are similarly situated in respect to high-risk medical devices: they are rigorously regulated by the FDA and go through clinical testing to ensure safety, efficacy, purity, and potency of the product;¹⁵¹ the FDA even requires post-market surveillance to oversee specific questions about the vaccine’s safety and effectiveness while on the market.¹⁵² Vaccines save lives by preventing diseases, but like many types of medicines, some serious health problems can arise due to vaccine injections.¹⁵³ PMAs are approved on the same grounds of safety and effectiveness as vaccines; yet in the rare circumstances that patients are hurt, they are

146. *Id.*

147. *See generally* Horvath, *supra* note 1.

148. William N. Eskridge, *Overriding Supreme Court Statutory Interpretation Decisions*, 101 *YALE L.J.* 331, 334 (1991).

149. *Id.* at 332 n.1.

150. Adam Liptak, *In Congress’ Paralysis, a Mightier Supreme Court*, *N.Y. TIMES* (Aug. 20, 2012), <https://www.nytimes.com/2012/08/21/us/politics/supreme-court-gains-power-from-paralysis-of-congress.html>.

151. U.S. FOOD & DRUG ADMIN., *Vaccines*, <https://www.fda.gov/BiologicsBloodVaccines/Vaccines/default.htm> (last updated Feb. 2, 2018).

152. *Id.*

153. *National Vaccine Injury Compensation Program*, HEALTH RES. & SERVS. ADMIN. <https://www.hrsa.gov/vaccine-compensation/index.html> (last visited Jan. 29, 2019) (“In very rare cases, a vaccine can cause a serious problem, such as a severe allergic reaction.”).

banned from seeking tort remedy. In the rare circumstances that patients are hurt by a vaccine, they have a compensation route. This same route should be open for victims of medical device malfunctions.

The National Vaccine Injury Compensation Program (VICP) is a simple way to provide compensation for injured patients either through direct compensation or settlement. The VICP acts as a no-fault alternative to the traditional tort system.¹⁵⁴ In 1986, Congress enacted the VICP as part of the Public Health Service Act, removing the mounting vaccine-related litigation from the judiciary into the executive branch.¹⁵⁵ A number of administrative agencies manage VICP: HHS hosts it, conducts medical reviews of petitions, and makes Court-ordered compensation payments; the Department of Justice (DOJ) represents HHS in Court; and U.S. Court of Federal Claims makes the final decision regarding whether a petition is compensated and the type and amount of compensation.¹⁵⁶

In the medical device context, a Medical Device Injury Compensation Fund (MDICF) could act like the VICP and obtain funding by an excise tax on medical devices.¹⁵⁷ The MDICF could impose penalties or premiums on device manufacturers that put defective products on the market. By taxing manufacturers proportionate to injury, this route would compensate victims as well as hold large and small manufacturers accountable in an equitable manner.

Delegating authority to administrative agencies, and away from the courts, has many potential benefits. For example, it relieves the tort system from mass tort cases that strain the judicial system—this addresses the criticism that removing preemption would clog the Courts with frivolous lawsuits.¹⁵⁸ As in the vaccine circumstance, HHS can easily bring its medical device expertise to bear and more effectively adjudicate device failure claims. One benefit from the VICP is that “aggregation [of specific claims] can attract the support of skilled counsel and medical experts in early stages of the litigation, helping resolve both large and small claims.”¹⁵⁹ In fact, agency adjudication for “group litigation may help resolve cases more efficiently in the long run.”¹⁶⁰ Designating a special court

154. *Id.*

155. 42 U.S.C. § 300aa-10 (2018).

156. *Id.* § 300aa-11; *National Vaccine Injury Compensation Program*, *supra* note 153.

157. *National Vaccine Injury Compensation Program*, *supra* note 153 (providing that vaccines have a 75 cents excise tax per dose).

158. See generally Robert L. Rabin, *Some Thoughts on the Efficacy of a Mass Toxics Administrative Compensation Scheme*, 52 MD. L. REV. 951 (1993).

159. Michael Sant’Ambrogio & Adam S. Zimmerman, *Inside the Agency Class Action*, 126 YALE L.J. 1634, 1698–99 (2017).

160. *Id.* at 1698.

within HHS and the FDA has the potential to more efficiently and effectively deal with medical device claims.

Centralizing these claims into a “Medical Device Court” also has the potential to “save cash-strapped government enforcers money by encouraging private parties to police misconduct when they bring claims on their own,”¹⁶¹ as seen in the vaccine context. As noted in Section III, the FDA can sometimes take a while to even realize there is a problem. This route would encourage private parties to bring problems to the agency’s attention at a faster rate. Encouraging the public to seek remedy for their injuries could enable the FDA to quickly detect patterns in device failure and thus remove the device from the market before more people are hurt.

This route is more beneficial for medical devices than it is for prescription drugs because medical devices are used at a much lower rate. Two studies illustrate this point in reviewing American consumption of medical innovation. First, in the case of prescription drugs, “36.5% of adults aged 18–44, 69.6% of adults aged 45–64, and 90.8% of those aged 65 and over took a prescription drug” during one month.¹⁶² In contrast, the study analyzing implantable medical devices found that “8% to 10% of the population in America and 5% to 6% of people in industrialized countries have experienced an implantable medical device for rebuilding body functions, achieving a better quality of life, or expanding longevity.”¹⁶³ These statistics demonstrate that high-risk medical devices are used in much lower percentages than prescription drugs. Second, a HHS 2016 survey shows that the vaccine rate of young children for select diseases averages around 80%.¹⁶⁴ Higher percentages of prescription drug use and vaccines occur in the United States, yet it is the smaller percentage of medical device usage that is barred from injury compensation. Creating a Medical Device Court can serve to remedy this disparity in an economical and fair manner.

There are several problems with instituting a compensation program, however. First, Congress would have to enact an amendment to the FDCA delegating authority to HHS to adjudicate medical device failures. This seems unlikely. Without political pressure

161. *Id.* at 1699.

162. NAT’L CENTER FOR HEALTH STATISTICS, 2017–1232, HEALTH, UNITED STATES, 2016: WITH CHARTBOOK ON LONG-TERM HEALTH TRENDS 25 (2017), [https://www.cdc.gov/nchs/data/16.pdf#079](https://www.cdc.gov/nchs/data/hus/16.pdf#079).

163. Yeun-Ho Joung, *Development of Implantable Medical Devices: From an Engineering Perspective*, 17 INT’L NEUROUROLOGY J. 98 (2013). Note that while implantable devices do not consist of all Class III medical devices, for purposes of this Note it is used to generally capture the amount of people that use higher risk devices.

164. *Vaccination Coverage Among Children Aged 19–35 Months — United States, 2015*, CTRS. FOR DISEASE CONTROL & PREVENTION <https://www.cdc.gov/mmwr/volumes/65/wr/mm6539a4.htm> (last updated Aug. 17, 2017).

from the public or medical community, it seems doubtful that Congress would prioritize this issue. Second, in the vaccine context, injury is rare.¹⁶⁵ But in the medical device context, faulty products can affect hundreds of thousands of patients.¹⁶⁶ The medical device fund would have to be significantly larger than the VICP. There would be intense pushback from medical manufacturers if they were forced to contribute to this type of fund. It is also possible that the fund would be insufficient to cover all injured patients, and some would still be left without recourse. These drawbacks indicate that a specialized court could be overwhelmed and not cost effective. But despite the weaknesses of this solution, Congress should consider providing an alternative compensation mechanism for patients injured by faulty medical products.

CONCLUSION

Deregulation and streamlining the efficiency of the FDA medical device regulatory system is a great and necessary idea, but not at the cost of patient safety and reducing a patient's ability to be made whole. The Cures Act introduces innovative new pathways that encourage innovation and speed to the process of regulatory approval. The Cures Act tips the balance between innovation and patient safety, though. The Cures Act introduces more risk of patient injury because of the deregulatory effects on high-risk medical device approval. Thus, the Court's *Riegel* decision should be reconsidered. This Note considered the likelihood of the Court overruling *Riegel* and rejected this as unlikely. Likewise, because Congress passed the Cures Act without removing the preemption and has in the past rejected other bills targeted at removing preemption, Congressional override of *Riegel* is also unlikely. This Note favors a solution where Congress creates a victim compensation fund for injured patients modeled after the VICP. If medical devices have a greater likelihood of injuring patients, then those patients should have the option of holding medical device manufacturers accountable. It is not only unjust to accept irreparable harm inflicted on patients, it is unnecessary.

165. Susan G. Clark, *The National Childhood Vaccine Injury Act the National Vaccine Injury Compensation Program*, 94 ED. LAW REP. 671, 674 (1994); see also *National Vaccine Injury Compensation Program*, *supra* note 153 (noting that most people who get vaccines have no serious problems). Vaccines, like any medicines, can cause side effects, but most are very rare and very mild. Some health problems that follow vaccinations are not caused by vaccines. *Id.*

166. Block, *supra* note 119; Thomas, *supra* note 96.