

## SUBSTANTIALLY UNEQUIVALENT: REFORMING FDA REGULATION OF MEDICAL DEVICES

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*Amidst today's era of ever-growing advances in technology lies an ever-increasing wealth of knowledge and information regarding the human body and the innumerable health issues and risks people encounter on a daily basis. Naturally, such advances in technology have led to groundbreaking medical techniques and treatments. Indeed, today's market is host to a myriad of evolving drugs and medical devices that allow patients the ability to put up stronger fights as they battle for improved health conditions and enhanced qualities of life.*

*With one's quality of life at stake, it follows that innovations in the treatment of medical issues do not simply gain blind public acceptance and implementation without first encountering strict scientific and technical scrutiny. Or, at least, so one would think. Certainly, as required by the FDA, drug manufacturers in the United States must subject their products to the most stringent of regulations and methodical testing and re-testing before receiving market approval. Nevertheless, while such cautious and meticulous safeguards exist among the regulation of drugs, regulation of medical devices has yet to receive the same careful consideration and inspection.*

*In fact, the FDA approval process for medical devices has been a topic of growing controversy. Over the past several years, reports have surfaced of patients being seriously injured—and even killed—by common medical devices, such as the seemingly harmless artificial hip implant. Currently, the 510(k) premarket approval process remains the means by which most new medical devices (approximately ninety-five percent), including high-risk devices, are cleared for the market. At the core of the 510(k) process exists the concept of “substantial equivalence,” whereby a device shown to be substantially similar to one already on the market will be approved without any clinical trials proving safety or efficacy.*

*Although the United States has begun taking a few steps in the right direction to protect its people from the risks associated with*

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*medical devices, the time has come for lawmakers to instigate a real change in the medical device regulatory system. This Note begins with an overview and comparison of the statutory history and regulatory systems for drug and medical devices in the United States. Next, this Note analyzes two different approaches to the 510(k) process that currently controls market acceptance for the majority of new medical devices. Finally, this Note demonstrates that a middle-ground approach that alters portions of the premarket and postmarket regulatory framework would be a beneficial way to begin the reformation process. Specifically, this Note emphasizes the importance of striking a balance between innovation, safety, and effectiveness when regulating medical devices.*

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## I. INTRODUCTION

“He could have been brought back to life had the device worked.”<sup>1</sup> Doctors spoke these unnerving words to the father of Joshua Oukrop, a twenty-one-year-old man with an inherited heart condition who died of a heart attack three years after having a cardiac defibrillator implanted into his chest.<sup>2</sup> The implantable cardioverter defibrillator (“ICD”) “uses electrical pulses or shocks to help” manage and treat irregular heartbeats.<sup>3</sup> For three years, routine tests and check-ups showed no signs of problems.<sup>4</sup> Three years after he had the device implanted, Joshua suddenly collapsed and died.<sup>5</sup> Instead of shocking the heart back into a normal rhythm, the coroner reported that the ICD had shorted out because it was faulty.<sup>6</sup> To make matters worse, Joshua’s cardiologist discovered that the manufacturer of the ICD, Guidant, had been aware that the device was faulty since 2002.<sup>7</sup>

Unfortunately, Joshua Oukrop is not the only victim of a faulty medical device. In the United States, tens of millions of people live with medical devices implanted into their bodies, including artificial joints, heart defibrillators, and surgical mesh.<sup>8</sup> Without a doubt, most people assume that someone tested the implantable devices for safety and effec-

1. Jim Axelrod, *When Medical Implants Fail*, CBSNEWS.COM (Apr. 1, 2012, 9:27 PM), [http://www.cbsnews.com/8301-3445\\_162-57407601/when-medical-implants-fail/](http://www.cbsnews.com/8301-3445_162-57407601/when-medical-implants-fail/).

2. *Id.*

3. *What Is an Implantable Cardioverter Defibrillator?*, NAT’L HEART, LUNG, & BLOOD INST. (Nov. 9, 2011), <http://www.nhlbi.nih.gov/health/health-topics/topics/icd/> (explaining the heart’s electrical system and discussing how any problem with the heart’s electrical system can cause an arrhythmia).

4. Axelrod, *supra* note 1.

5. *Id.*

6. *Id.*

7. *Id.*

8. *CR Investigates: Dangerous Medical Devices*, CONSUMERREPORTS.ORG. (May 2012), <http://www.consumerreports.org/cro/magazine/2012/04/cr-investigates-dangerous-medical-devices/index.htm> [hereinafter *CR Investigates*].

tiveness.<sup>9</sup> This, however, is “rarely the case.”<sup>10</sup> In fact, the manufacturers of many high-risk devices merely “file some paperwork and pay the Food and Drug Administration [(“FDA”)] a user fee of roughly [four thousand dollars] to start selling a product that can rack up many millions of dollars in revenue.”<sup>11</sup> In other words, the devices are not tested for safety and efficacy before they are marketed; “the only safety ‘testing’ that occurs is in the bodies of unsuspecting patients . . . .”<sup>12</sup>

The emerging information about serious health complications with several medical devices has become a cause for concern. Due to the increased concern about medical device safety, the approval process conducted by the FDA has been the subject of serious inquiry and examination.<sup>13</sup> The debate concerns FDA rule 510(k), which “allows manufacturers to fast-track new medical devices to market without human testing” if they are “substantially equivalent” to devices that are already present on the market.<sup>14</sup> The purpose of the law was to minimize the approval process time for low- and moderate-risk devices that generally do not require rigorous safety testing.<sup>15</sup> After lobbying by medical manufacturers, Congress changed the regulations to make it even easier for medical devices to gain clearance by the FDA.<sup>16</sup> In 1983, a House Report “concluded that nearly 1,000 of approximately 1,100 [of the most risky] devices that had been introduced to the market since 1976 were admitted as ‘substantial equivalents’” and without any review or clinical testing.<sup>17</sup> Today, FDA officials report that approximately “[ninety] percent of the devices on the market are cleared for use through the 510(k) process.”<sup>18</sup>

In recent years, some of the nation’s leading orthopedic surgeons became concerned with a type of artificial hip replacement, called a “metal[-]on[-]metal” implant.<sup>19</sup> These implants have been “used in about one-third of the approximately 250,000 hip replacements performed annually” in the United States.<sup>20</sup> Although this type of artificial hip was originally believed to be more durable than previous types of implants, recent studies have shown a cause for concern. Because of the nature of

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9. *Id.*

10. *Id.*

11. *Id.*

12. *Id.*

13. Katie Moisse & Lana Zak, *Medical Device Recalls Reveal Cracks in Regulatory Procedures, Researchers Say*, ABC NEWS (Feb. 14, 2011), <http://abcnews.go.com/Health/Wellness/recalls-reveal-problems-fdas-medical-device-approval-process/story?id=12911682>.

14. Tony Saavedra & Courtney Perkes, *FDA Rule Clears Medical Devices Without Human Testing*, ORANGE COUNTY REG. (May 18, 2012), <http://www.ocregister.com/articles/devices-354854-fda-device.html>.

15. *Id.*

16. *Id.*

17. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477–479 (1996).

18. Saavedra & Perkes, *supra* note 14.

19. Barry Meier, *Concerns Over ‘Metal on Metal’ Hip Implants*, NY TIMES, Mar. 3, 2010, <http://www.nytimes.com/2010/03/04/health/04metalhip.html>.

20. *Id.*

the ball and socket hip joint, all hip devices create debris.<sup>21</sup> Studies have shown that the metal-on-metal hips, in particular, generate high volumes of metallic debris that are absorbed into the body.<sup>22</sup> The absorption of metallic debris, such as chromium and cobalt, into the bloodstream or tissue can cause severe tissue and bone damage.<sup>23</sup> As a consequence, more than ten thousand lawsuits are now pending against Johnson & Johnson, the seller of a metal-on-metal hip called the DePuy “Articular Surface Replacement.”<sup>24</sup> Approximately thirty-one thousand people in the United States were implanted with the DePuy ASR, and for years DePuy insisted that the device’s design was not defective.<sup>25</sup> In fact, “internal DePuy documents disclosed during a trial [in 2013]” that DePuy was warned about a “design flaw” in the device in 2008.<sup>26</sup> In the first of these ten thousand metal-on-metal hip implant lawsuits, a jury ordered Johnson & Johnson to pay more than eight million in damages to a Montana man for his injuries caused by a DePuy hip replacement.<sup>27</sup> Many lawyers and industry analysts expect the suits will ultimately cost Johnson & Johnson billions of dollars to resolve.<sup>28</sup> As of November 2013, Johnson & Johnson reached a tentative multibillion-dollar settlement for the DePuy lawsuits.<sup>29</sup> Under the proposed deal, Johnson & Johnson agreed to pay approximately two and a half billion dollars to about eight thousand patients who were affected by the faulty hip replacement.<sup>30</sup> The company also “agreed to pay all medical costs related to such procedures, expenses that could raise the deal’s cost to . . . [three] billion [dollars].”<sup>31</sup>

Surgical mesh and the Lap-Band adjustable gastric band are two more examples of dangerous medical devices.<sup>32</sup> After a surgical mesh was implanted in Janet Holt, she was in so much pain that she could not sit, stand, or walk.<sup>33</sup> “Holt is one of hundreds of thousands of women implanted with [the] transvaginal mesh for prolapse repair and bladder support,” and she has gone through eight surgeries to adjust and remove the mesh, leaving her with painful nerve damage in one of her legs.<sup>34</sup>

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21. *Id.*

22. *Id.*

23. *Id.*

24. Barry Meier, *J.&J. Loses First Case Over Faulty Hip Implant*, N.Y. TIMES, Mar. 8, 2013, [http://www.nytimes.com/2013/03/09/business/johnson-johnson-must-pay-in-first-hip-implant-case.html?\\_r=0](http://www.nytimes.com/2013/03/09/business/johnson-johnson-must-pay-in-first-hip-implant-case.html?_r=0) [hereinafter *J.&J. Loses First Case*].

25. Barry Meier, *Johnson & Johnson Said to Agree to \$4 Billion Settlement Over Hip Implants*, N.Y. TIMES, Nov. 12, 2013, <http://www.nytimes.com/2013/11/13/business/johnson-and-johnson-said-to-agree-to-4-billion-settlement-over-hip-implants.html>.

26. *Id.*

27. *J & J Loses First Case*, *supra* note 24.

28. *Id.*

29. Barry Meier, *Johnson & Johnson in Deal to Settle Hip Implant Lawsuits*, N.Y. TIMES, Nov. 19, 2013, <http://www.nytimes.com/2013/11/20/business/johnson-johnson-to-offer-2-5-billion-hip-device-settlement.html>.

30. *Id.*

31. *Id.*

32. *CR Investigates*, *supra* note 8.

33. *Id.*

34. *Id.*

Although there have been thousands of reports of adverse events and multiple lawsuits, the surgical mesh products are still being sold and classified as “moderate risk” devices.<sup>35</sup>

Approval of the Lap-Band was based on *one* study of approximately three hundred participants.<sup>36</sup> “[Fifty-one] percent reported nausea, vomiting, or both, and [twenty-five] percent had their bands removed before the end of the three-year study [due to] complications or failure to lose enough weight.”<sup>37</sup> Although these complications are not life threatening, the recall rate for this product, and the fact that approval was based on one lone study, is concerning. “Consumers and regulators would be up in arms” if a car had a recall rate that high.<sup>38</sup>

Yet issues with medical devices often stay hidden, perhaps due to insufficient postmarketing surveillance and recall regimes.<sup>39</sup> Further, once problems with dangerous medical devices are detected, there is no easy solution. Unlike a prescription drug, the patient cannot just stop taking it.<sup>40</sup> A recalled medical device is likely to involve multiple surgeries to remedy the problem, or even worse, grave consequences.<sup>41</sup>

This Note addresses many of the issues with FDA regulation of medical devices. It begins by giving an overview of the statutory history of drug and medical device regulation in Part II. Part II also explains the drug approval process and the medical device regulation system implemented by the FDA. Part III analyzes two approaches to the 510(k) premarket notification process. Finally, Part IV recommends a revision of the Class III device definition, elimination of piggybacking in the 510(k) process, and the establishment of a national medical device registry and unique device identification system.

## II. BACKGROUND

In the United States, the FDA promotes public health and is responsible for the control and safety of the nation’s food supply, human and veterinary drugs, medical devices, vaccines, biologics, cosmetics, and radiation-emitting products.<sup>42</sup> As defined by statute, the term “drug” encompasses articles (other than food) intended “for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals . . . to affect the structure or any function of the body of man or other animals . . . .”<sup>43</sup> A “medical device” is:

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35. *Id.*

31. *Id.*

37. *Id.*

38. *Id.*

39. *Id.*

40. *Id.*

41. *See id.*

42. *Statement of FDA Mission*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM298331.pdf>.

43. 21 U.S.C. § 321(g)(1) (2012).

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or . . . intended to affect the structure or function of the body . . . and which does not achieve its primary intended purposes through chemical action within or on the body . . . .<sup>44</sup>

The FDA is accountable for reviewing and assessing the safety and efficacy of each product, because “[i]t is generally recognized that all drugs and medical devices carry some level of risk.”<sup>45</sup>

The FDA applies varying levels of regulation depending on the type of product it seeks to regulate. The regulatory regimes for both drugs and devices are “much more rigorous” than the regimes for food or cosmetics.<sup>46</sup> Although drugs and devices are subject to higher standards of approval, there remains a large discrepancy in the regulation of drugs and medical devices. Due to the concerns of the public, legislators, the Government Accountability Office, the Department of Health and Human Services Office of the Inspector General, and the Supreme Court, the FDA appointed the Institute of Medicine (“IOM”) to review the 510(k) process.<sup>47</sup> The IOM is “an independent, nonprofit organization that works outside of government to provide unbiased and authoritative advice to decision makers and the public.”<sup>48</sup> After reviewing the 510(k) process, which is “used to clear at least [ninety-five] percent of moderate- and high-risk medical devices,” the IOM concluded that the process “is so lacking in its ability to ensure safety . . . that it [should] be scuttled.”<sup>49</sup>

### A. Drugs

The United States has stringent standards that create perhaps the most demanding drug approval process in the world.<sup>50</sup> In order to keep pace with advances in technology and the pharmaceutical industry, along with growing consumer safety concerns, the standards and statutes have started to evolve, albeit somewhat slowly.<sup>51</sup> An overview of the history

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44. *Id.* § 321(h).

45. 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, 42 (2011) (stating that “each year approximately 1-2 drugs and 6-8 medical devices are removed from the U.S. market because of safety concerns”).

46. PETER BARTON HUTT ET AL., *FOOD AND DRUG LAW* 39 (3d. ed. 2007).

47. INST. MED., *MEDICAL DEVICES AND THE PUBLIC’S HEALTH: THE FDA 510(k) CLEARANCE PROCESS AT 35 YEARS* xi (2011), available at <http://www.iom.edu/Reports/2011/Medical-Devices-and-the-Publics-Health-The-FDA-510k-Clearance-Process-at-35-Years.aspx> [hereinafter *MEDICAL DEVICES AND THE PUBLIC’S HEALTH*]; see *supra* Part I.

48. *About the IOM*, INST. MED., <http://www.iom.edu/About-IOM.aspx> (last visited Apr. 17, 2014).

49. NEGAH MOUZOON & MICHAEL CAROME, *SUBSTANTIALLY UNSAFE: MEDICAL DEVICES POSE GREAT THREAT TO PATIENTS; SAFEGUARDS MUST BE STRENGTHENED, NOT WEAKENED* 4 (2012).

50. BLANCHARD RANDALL IV, *THE U.S. DRUG APPROVAL PROCESS: A PRIMER* 1 (2001).

51. *Id.*

of the federal legislation of drugs and the drug approval process will provide a more in-depth look into the FDA's complex regulatory system.

1. *History: The Evolution of Federal Legislation of Drugs*

Most of the advances in drug regulation have been prompted by misfortune, disaster, and tragedy.<sup>52</sup> Up until the early 1900s, there existed no federal laws requiring drug manufacturers to verify the quality of products they sold in America.<sup>53</sup> In comparison to other countries, such as Great Britain, the United States “was very slow to recognize the need for a national food and drug law.”<sup>54</sup> Many remedies and medicinal products for various ailments were not actually tested for their safety or effectiveness and were generally sold without guarantee of their safety, quality, or proven benefit.<sup>55</sup> Although “federal concern for [the safety and effectiveness of] drugs” began in the 1800s, it was not until the early 1900s that health advocates began to push for reforms that would provide consumers with some protection against the increasing quantity of unproven health claims present in various advertising and labeling.<sup>56</sup>

a. The Federal Food and Drugs Act of 1906

In response to the public concerns about worthless or dangerous drugs and public disclosures about the unsanitary conditions in meat-packing plants, Congress passed the Federal Food and Drugs Act of 1906 (“1906 Act”).<sup>57</sup> The 1906 Act was a key piece of legislation, as it was the first to provide for national regulation of all drugs made for human consumption.<sup>58</sup> The Act was a supplement to state regulations and common-law liability, which were the predominant sources of consumer protection regarding the food and drug industry at that time.<sup>59</sup>

One primary purpose of the 1906 Act was to prohibit adulterated or misbranded food and drug products in interstate commerce.<sup>60</sup> It authorized the seizure of “offending products” and also provided for criminal penalties for a violation of the Act.<sup>61</sup> Although the 1906 Act made significant contributions to the improvement of public health and safety through regulation of the food and drug industry, it also contained seri-

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52. Martin S. Lipsky & Lisa K. Sharp, *From Idea to Market: The Drug Approval Process*, 14 J. AM. BOARD FAM. PRAC. 362, 363 (2001).

53. RANDALL, *supra* note 50, at 1.

54. Wallace F. Janssen, *The Story of the Laws Behind the Labels*, U.S. FOOD & DRUG ADMIN. (June 1981), <http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm056044.htm> (noting that Great Britain passed its first national food law in 1860).

55. RANDALL, *supra* note 50, at 1.

56. *Id.*; Janssen, *supra* note 54.

57. Lipsky & Sharp, *supra* note 52, at 363.

58. HUTT ET AL., *supra* note 46, at 467; *see generally* Food and Drugs Act, Pub. L. No. 384, 34 Stat. 768 (1906).

59. *Wyeth v. Levine*, 555 U.S. 555, 566 (2009).

60. Lauffer T. Hayes & Frank J. Ruff, *The Administration of the Federal Food and Drugs Act*, 1 LAW & CONTEMP. PROBS. 16, 16 (1933).

61. *Id.*



ous limitations.<sup>62</sup> For example, under the Act, pharmaceutical companies were not required to prove the safety and effectiveness of their drugs,<sup>63</sup> and legal standards for “fraudulent medical devices used for therapeutic purposes” were not included.<sup>64</sup>

b. The Federal Food, Drug, and Cosmetic Act of 1938

Although the 1906 Act raised the standards of the food and drug industry, “[b]y the 1930s it was widely recognized” that the law was outdated and in need of a replacement.<sup>65</sup> During September and October 1937, a drug called “Elixir Sulfanilamide,” used to treat streptococcal infections, caused the deaths of more than one hundred people.<sup>66</sup> At this time, there were no regulations in place requiring drug manufacturers to prove the safety of their drugs. Sulfanilamide had been widely used and shown to be effective in tablet and powder form.<sup>67</sup> Because of a demand for a liquid form of the medicine, a new formulation was created using a chemical that turned out to be a deadly poison.<sup>68</sup> Unfortunately, the new formulation had not been tested for toxicity because the food and drug laws did not require that safety studies be done on new drugs.<sup>69</sup>

Following the Elixir Sulfanilamide tragedy, Congress passed the Federal Food, Drug, and Cosmetic Act of 1938 (“FDCA”).<sup>70</sup> The FDCA added new quality standards for both food and drugs.<sup>71</sup> More importantly, for the first time, the Act “required drug manufacturers to provide evidence that their products were safe before they could be approved” by the FDA for marketing.<sup>72</sup> “[T]he law authorized the FDA to demand evidence of safety for new drugs, issue standards for food, and conduct factory inspections.”<sup>73</sup> The FDCA also contains definitions elaborating the concepts of “adulteration” and “misbranding.”<sup>74</sup> Many provisions describe “circumstances under which a food, drug, device, or cosmetic will be considered to be adulterated or misbranded under the law and thus subject to FDA enforcement action.”<sup>75</sup>

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62. HUTT ET AL., *supra* note 46, at 12.

63. RANDALL, *supra* note 50, at 1.

64. HUTT ET AL., *supra* note 46, at 12.

65. Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, U.S. FOOD & DRUG ADMIN. (June 1981), <http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SulfanilamideDisaster/default.htm>.

66. *Id.*

67. *Id.*

68. *Id.*

69. *Id.*

70. RANDALL, *supra* note 50, at 1; *see generally* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 717, 52 Stat. 1040 (1938).

71. RANDALL, *supra* note 50, at 1.

72. *Id.*; *see also* Sweet et al., *supra* note 45, at 40 (“The FDCA required that new drugs be proven safe prior to marketing, but there was no requirement to prove efficacy.”).

73. *Regulatory Information: Legislation*, U.S. FOOD & DRUG ADMIN. (July 9, 2012), <http://www.fda.gov/regulatoryinformation/legislation/default.htm> [hereinafter *Regulatory Information: Legislation*].

74. HUTT ET AL., *supra* note 46, at 13.

75. *Id.*

c. The Drug Amendments of 1962

The first significant amendment to the FDCA was the Drug Amendments of 1962 (“1962 Amendments”).<sup>76</sup> These amendments made the drug safety regulations more stringent; for example, manufacturers were required to prove the effectiveness of their drugs.<sup>77</sup> The 1962 Amendments primarily “restructured the way in which FDA regulated new medicines . . . .”<sup>78</sup> The Amendments “transform[ed] a system of premarket notification into one that requires individual premarket approval of the safety and effectiveness of every new drug.”<sup>79</sup>

d. Prescription Drug User Fee Act of 1992

Throughout the 1990s, the pharmaceutical industry and consumer groups became troubled by the amount of time it was taking for new drugs to be approved by the FDA.<sup>80</sup> In order to accelerate the drug review process while still maintaining approval standards, Congress passed the Prescription Drug User Fee Act (“PDUFA”).<sup>81</sup> Under this law, “drug companies are assessed several different types of fees, including application fees, annual establishment fees, and product fees.”<sup>82</sup> The FDA uses the extra revenue generated by these fees to hire additional staff members to review new drug products and to upgrade FDA’s information technology in order to reduce the length of time it takes to review and approve new drug applications.<sup>83</sup> The PDUFA was renewed in 1997 and, currently, user fees fund about half of the new drug review costs.<sup>84</sup>

After Congress enacted the law, the approval times for new drug applications gradually decreased.<sup>85</sup> Furthermore, more than one thousand drugs for various illnesses and infections such as cancer, AIDS, diabetes, and cardiovascular disease have entered the market.<sup>86</sup> The PDUFA has also allowed the FDA to “increase surveillance of the safety of medicines during their first two years on the market, or three years for potentially dangerous medications.”<sup>87</sup> During this time, the FDA is best able to identify adverse side effects that were not present in clinical tri-

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76. *Regulatory Information: Legislation*, *supra* note 73 (stating that the 1962 Amendments “were inspired by the thalidomide tragedy in Europe”).

77. *Id.*

78. HUTT ET AL., *supra* note 46, at 14.

79. *Id.*

80. RANDALL, *supra* note 50, at 2.

81. *Id.*

82. *Id.*

83. *Id.*

84. HUTT ET AL., *supra* note 46, at 680; *Prescription Drug User Fee Act*, U.S. FOOD & DRUG ADMIN. (Dec. 16, 2013), <http://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/default.htm>.

85. RANDALL, *supra* note 50, at 2.

86. *FDA’s Drug Review Process: Continued*, U.S. FOOD & DRUG ADMIN. (Mar. 13, 2012), <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm289601.htm>.

87. *Id.*

als.<sup>88</sup> Overall, the PDUFA lowers the development costs, shortens review time, and ensures that the “time and effort patients put in to clinical trials provide useful data.”<sup>89</sup>

## 2. *Current Regime: Overview of the Drug Approval Process*

United States law requires all new drugs to be proven safe and effective before the FDA approves them for marketing.<sup>90</sup> Although this is the standard now, it took “a century of law and rulemaking” before this requirement became “the nation’s gold standard.”<sup>91</sup> The drug development process takes approximately eight to ten years.<sup>92</sup> The journey of a new drug through the FDA review process can also cost hundreds of millions of dollars, due to the costs associated with clinical testing that must be done in order to prove safety and effectiveness.<sup>93</sup>

The drug approval process begins with the discovery of a new drug and a series of preliminary experiments by the drug manufacturer to find out how the substance works and whether it may be safe for use in patients.<sup>94</sup> In this preclinical research and testing phase, the experiments generally start in a laboratory with *in vitro* tests and tests on animal models, because “all experimental drugs must be tested in animals before they can be given to patients in clinical trials.”<sup>95</sup> Testing is also performed in tissue cell cultures and computer-driven analysis systems.<sup>96</sup> The main goal in preclinical testing is “to determine if the chemical compound is reasonably safe for initial use in humans, and whether it has enough pharmacological activity to justify further commercial development.”<sup>97</sup> The tests can also provide insight into the possible carcinogenic, teratogenic, and mutagenic effects that the drug may have.<sup>98</sup>

For the compounds that merit further development, the results of the preclinical research and testing phase will be compiled and used to design clinical trials in human subjects.<sup>99</sup> Before clinical trials can begin, the manufacturer must file an Investigational New Drug (“IND”) application with the FDA.<sup>100</sup> The shipment of drugs in interstate commerce without FDA approval is prohibited by statute, but the IND allows experimental drugs to be shipped in interstate commerce before the FDA approves the drugs.<sup>101</sup> Drug manufacturers must include a wealth of in-

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88. *Id.*

89. HUTT ET AL., *supra* note 46, at 680.

90. RANDALL, *supra* note 50, at 6.

91. *Id.* at summary.

92. Sweet et al., *supra* note 45, at 43.

93. RANDALL, *supra* note 50, at summary.

94. *Id.* at 7.

95. *Id.*

96. *Id.*

97. *Id.*

98. *Id.*

99. *Id.*

100. *Id.*

101. *Id.* at 7–8.

formation in the IND, including “all information and data from preclinical studies, an explanation of the investigational drug’s intended medical use, and a full description of the clinical trial protocols designed to document the drug’s safety and effectiveness.”<sup>102</sup> The IND must describe in detail how many patients will be involved in clinical trials, how the drug will be administered, the dosage level that will be used, the names and qualifications of the clinical investigators, and where the studies will be conducted.<sup>103</sup> Furthermore, information about the chemical composition of the drug and details about the manufacturing process must also be included.<sup>104</sup> The FDA has thirty days to review an IND, and if there are no objections to the protocol’s design, the manufacturer may begin clinical testing.<sup>105</sup> Also, “[b]y FDA regulation, every investigation involving human test subjects must be overseen by an Institutional Review Board” (“IRB”).<sup>106</sup> The IRB must have at least five members with varying backgrounds, who are capable of evaluating the ethical aspects of the proposed study in order to protect the rights and welfare of the potential human subjects.<sup>107</sup>

After the FDA concludes that the investigational drug is safe enough to be tested in humans, clinical studies can begin.<sup>108</sup> There are four phases of clinical trials, three of which must be completed before the FDA can approve the drug.<sup>109</sup> Phase I studies are the first studies conducted with healthy human volunteers and “are designed to establish the safety, pharmacology, pharmacokinetics, and safe dose range of the drug.”<sup>110</sup> The number of human subjects varies, but it usually remains within the range of twenty to eighty.<sup>111</sup> Phase II clinical studies include patients with the target disease and thus help “determine the common short-term side effects and risks associated with the drug.”<sup>112</sup> This phase usually involves several hundred people, and the main goal is to determine the appropriate dosage level that will “maximize efficacy while minimizing toxicity.”<sup>113</sup> The trials are “randomized, well-controlled, double-blind clinical investigations.”<sup>114</sup> Phase III studies are “intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug.”<sup>115</sup>

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102. *Id.* at 8.

103. *Id.*

104. *Id.*

105. *Id.*

106. *Id.*

107. *Id.*; see also HUTT ET AL., *supra* note 46, at 634 (explaining that the IRB is expected to give a hard look at protocols, assure that the written informed consent form is sufficiently simple and clear to be understood by the test subjects, monitor the progress of the testing, and maintain substantial records of these activities).

108. RANDALL, *supra* note 50, at 9.

109. Sweet et al., *supra* note 45, at 43.

110. HUTT ET AL., *supra* note 46, at 630; Sweet et al., *supra* note 45, at 43.

111. HUTT ET AL., *supra* note 46, at 630.

112. *Id.* at 631.

113. *Id.* at 631; Sweet et al., *supra* note 45, at 43.

114. RANDALL, *supra* note 50, at 9.

115. HUTT ET AL., *supra* note 46, at 631.

These studies typically involve a large number of subjects, ranging from hundreds to thousands of patients.<sup>116</sup> After the drug or treatment has been marketed, Phase IV studies are performed “to gather information on the drug’s effect in various populations and any side effects associated with long-term use.”<sup>117</sup>

After a new drug is deemed relatively safe and effective through clinical trials, the manufacturer must file a New Drug Application (“NDA”).<sup>118</sup> The NDA is “the actual request to manufacture and sell the drug in the United States,” and there are several requirements for the content and format of the NDA set forth by FDA regulations.<sup>119</sup> The NDA will potentially contain tens of thousands or even hundreds of thousands of pages encompassing a summary, proposed labeling, and technical sections relating to “(1) chemistry, manufacturing and controls, (2) non-clinical pharmacology and toxicology, (3) human pharmacokinetics and bioavailability, (4) microbiology, (5) clinical data, and (6) statistics.”<sup>120</sup> Additionally, the NDA must provide information about the facilities in which the drug will be produced, and it must also offer guarantees that the finished product will be made in compliance with good manufacturing practices.<sup>121</sup> The review process of the NDA involves several steps and can last anywhere from months to several years depending upon the application’s complexity and size.<sup>122</sup> Agency statisticians and epidemiologists review safety and efficacy data for the drug, while other agency officials review the labeling to ensure that it is accurate.<sup>123</sup> In order to be approved, the evidence presented by the drug manufacturer must show that the drug is safe “by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions of use prescribed, recommended, or suggested” in the proposed labeling.<sup>124</sup> Stated differently, the FDA does not require drug companies to prove that their drug is one hundred percent safe and effective for all patients before it can be approved.<sup>125</sup>

Finally, the FDA is also “responsible for monitoring the safety of pharmaceutical products once they are approved for marketing in the United States.”<sup>126</sup> These systems are designed to look for any safety

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116. Sweet et al., *supra* note 45, at 43.

117. *FAQ: Clinical Trial Phases*, U.S. NAT’L LIBR. MED. (Apr. 18, 2008), <http://www.nlm.nih.gov/services/ctphases.html>.

118. RANDALL, *supra* note 50, at 10.

119. HUTT ET AL., *supra* note 46, at 676 (citing Peter Barton Hutt, *The Regulation of Drug Products by the United States Food and Drug Administration*, in *THE TEXTBOOK OF PHARMACEUTICAL MEDICINE* (John P. Griffin & John O’Grady eds., 5th ed. 2006)); *see also* RANDALL, *supra* note 50, at 10.

120. HUTT ET AL., *supra* note 46, at 676-77 (citing PETER BARTON HUTT, *The Regulation of Drug Products by the United States Food and Drug Administration*, in *THE TEXTBOOK OF PHARMACEUTICAL MEDICINE* (John P. Griffin & John O’Grady eds., 5th ed. 2006)).

121. RANDALL, *supra* note 50, at 10.

122. *Id.*

123. *Id.*

124. HUTT ET AL., *supra* note 46, at 685.

125. RANDALL, *supra* note 50, at 10.

126. *Id.* at 12.

problems that may arise.<sup>127</sup> By law, pharmaceutical companies must report all serious and unexpected adverse reactions “associated with” the use of the drug to the FDA within fifteen days of becoming aware of the problem.<sup>128</sup> All other adverse effects must be reported to the FDA at quarterly intervals for the first three years under the NDA and at annual intervals thereafter.<sup>129</sup> On the other hand, health care professionals and consumers are merely encouraged to report adverse reactions.<sup>130</sup> Post-market reporting systems assist the FDA in determining whether adverse effects in large user populations are severe enough to warrant some form of regulatory action.<sup>131</sup>

### B. Medical Devices

Medical devices play a crucial role in the health of people around the world.<sup>132</sup> In the United States, medical device manufacturers “continue to benefit from the aging . . . population, [and] the influx of newly insured people due to the healthcare reform bill will drive up demand for devices.”<sup>133</sup> The United States dominates the global medical device industry, which is worth approximately three-hundred and fifty billion dollars.<sup>134</sup> The industry includes medical products ranging from the basic bandages and tongue depressors, to life-sustaining and life-saving devices, such as pacemakers and brain stents.<sup>135</sup> Despite the similar purpose shared by medical devices and drugs in treating health issues, the regulation of medical devices in the U.S. is drastically different than the regulation of drugs. An overview of the historical background of medical device legislation and the current regulatory regime is provided below.

#### 1. History: The Evolution of Federal Legislation of Medical Devices

Whereas the regulation of drugs began in 1906, the regulation of medical devices did not start until after the enactment of the FDCA in

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127. *Id.*

128. HUTT ET AL., *supra* note 46, at 736; RANDALL, *supra* note 46, at 12–13.

129. HUTT ET AL., *supra* note 46, at 736.

130. RANDALL, *supra* note 50, at 13.

131. *Id.*

132. INST. MED., MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 173 (2011), <http://www.iom.edu/~media/Files/Report%20Files/2011/Medical-Devices-and-the-Publics-Health-The-FDA-510k-Clearance-Process-at-35-Years/510k%20Clearance%20Process%202011%20Report%20Brief.pdf> [hereinafter REPORT BRIEF FOR MEDICAL DEVICES AND THE PUBLIC'S HEALTH].

133. Yair Holtzman, *The U.S. Medical Device Industry in 2012: Challenges at Home and Abroad*, MED. DEVICE & DIAGNOSTIC INDUSTRY NEWS PRODUCTS & SUPPLIERS (July 17, 2012), <http://www.mddionline.com/print/9436>.

134. MOUZOON & CAROME, *supra* note 49, at 4; Holtzman, *supra* note 133 (explaining that “more than half of the leading . . . medical device companies [are] based in the United States”); *Medical Device Industry Faces ‘Unprecedented Challenges,’* ADVANCING SAFETY IN MED. TECH., (July 18, 2012), [http://www.aami.org/news/2012/071812\\_US\\_devices.html](http://www.aami.org/news/2012/071812_US_devices.html) (“Thirty-two of the 46 medical technology companies with more than \$1 billion in annual revenue are based in the United States.”).

135. MOUZOON & CAROME, *supra* note 49, at 4; REPORT BRIEF FOR MEDICAL DEVICES AND THE PUBLIC'S HEALTH, *supra* note 132, at 17.

1938.<sup>136</sup> As technology further developed, and as medicine increasingly began relying on a vast assortment of complex medical equipment, both the public and policymakers became worried about the potential of severe injuries due to the failure of such devices.<sup>137</sup> Nonetheless, it was not until the 1976 passage of the Medical Device Amendment (“MDA”) that medical device manufacturers were required to register with the FDA and to adhere to quality control standards before marketing.<sup>138</sup>

a. The Federal Food, Drug, and Cosmetic Act of 1938

The FDCA “gave FDA jurisdiction over medical devices, but did not give the agency authority to review them for safety or effectiveness prior to marketing, nor to establish or enforce performance standards.”<sup>139</sup> Medical devices were made subject to the FDCA “largely because of Congressional concern about the growing number of fraudulent—and in many instances implausible—instruments being marketed during the 1930s.”<sup>140</sup> While the FDCA included “premarket review of safety data” for drugs, the law did not give the government control over the medical devices in the same way because “premarket review was not extended to devices.”<sup>141</sup> Nevertheless, the FDCA did “grant the government post-market oversight of devices” by allowing for enforcement actions in cases involving misbranding and adulteration.<sup>142</sup>

b. The Drug Amendments of 1962

The medical devices used in the 1930s and 1940s were rather elementary and uncomplicated.<sup>143</sup> The post-war years, however, brought forth several “quack” devices and a revolution in biomedical technology.<sup>144</sup> The “increased sophistication of medical products, coupled with a stronger authority to regulate drugs, caused the FDA to classify some of the new products as drugs.”<sup>145</sup>

Although predominantly related to the regulation of drugs, the 1962 Amendments allowed the FDA to use its authority to regulate certain devices as though they were drugs.<sup>146</sup> For instance, the 1962 Amendments permitted the FDA to regulate contact lenses and sutures under a

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136. Sweet et al., *supra* note 45, at 41.

137. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996).

138. Sweet et al., *supra* note 45, at 41.

139. HUTT ET AL., *supra* note 46, at 968.

140. *Id.* at 967.

141. 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).

142. *Id.*

143. H.R. Committee on Interstate and Foreign Commerce, *Medical Device Legislation – 1975*, H.R. Committee Print No. 94-11, at 4 (1975).

144. HUTT ET AL., *supra* note 46, at 969.

145. *Id.*

146. Flaherty, *supra* note 141, at 904; *see also* Sweet et al., *supra* note 45, at 41 (“It was not until the passage of the Medical Device Amendment in 1976 that manufacturers of medical devices were required to register with the FDA and to follow quality control standards prior to marketing.”).

broad definition of “drug.”<sup>147</sup> The vast majority of medical devices, though, “remained unregulated by [the] FDA with respect to premarket regulation.”<sup>148</sup>

c. Medical Device Amendments of 1976

During the late 1950s and 1960s, medical devices quickly became more numerous and more complex.<sup>149</sup> These devices included implanted devices, such as pacemakers, cardiac and renal catheters, artificial vessels and heart valves, and surgical implants.<sup>150</sup> In the 1970s, “several high-profile public-health problems that involved medical devices were observed;” one of the most infamous cases is the Dalkon Shield, an “intrauterine contraceptive device” that was pulled off the market after six years due to numerous deaths, miscarriages, and cases of pelvic infection.<sup>151</sup>

Because of the new developments and focus on the hazards of certain medical devices, Congress enacted the MDA of 1976, “the second amendment of significance to the FDCA.”<sup>152</sup> The MDA was the “culmination of fifteen years of careful study and debate, not only within Congress and the agency, but also among representatives of clinical medicine, biomedical engineering, device manufacturers, and consumer groups.”<sup>153</sup> With the MDA, Congress implemented a new regulation system for medical devices.<sup>154</sup> The new system focused “on the development, market introduction, and post-launch marketing of [medical] devices.”<sup>155</sup> Though the MDA allowed the FDA to perform premarket review, the Act’s basic adulteration and misbranding provisions remain important regulatory tools.<sup>156</sup>

Although the MDA added more than a dozen provisions to the 1938 Act, there are six key features of the MDA.<sup>157</sup> First, the MDA revised the definition of a “device” to “convert some medical products then being regulated as drugs to devices,” and to include products intended “to diagnose physiological conditions that are not ordinarily regarded as diseases, such as pregnancy.”<sup>158</sup> Second, the MDA provided a classification system for all medical devices, “in accordance with the relative degree of assurance of their safety and effectiveness.”<sup>159</sup> Third, the MDA provided three ways a medical device can be marketed through a

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147. Flaherty, *supra* note 141, at 904.

148. *Id.*

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

150. HUTT ET AL., *supra* note 46, at 978.

151. MEDICAL DEVICES AND THE PUBLIC’S HEALTH, *supra* note 47, at 213.

152. Flaherty, *supra* note 141, at 904.

153. HUTT ET AL., *supra* note 46, at 14–15.

154. Flaherty, *supra* note 141, at 904.

155. *Id.* at 904–05.

156. HUTT ET AL., *supra* note 46, at 969.

157. *Id.* at 980.

158. *Id.*

159. *Id.*



comprehensive control system.<sup>160</sup> Fourth, the MDA subjected two classes of pre-1976 medical devices to special requirements.<sup>161</sup> Fifth, all medical devices are subjected to the general regulatory controls, namely the adulteration and misbranding provisions under the FDCA.<sup>162</sup> Finally, Congress enacted special rules for specific types of devices, such as custom devices and high-risk devices.<sup>163</sup>

i. Classification of Medical Devices Under the MDA

The MDA categorizes medical devices into three classifications “based on the risk that they pose to the public.”<sup>164</sup> The classification system is important because it determines the level of regulation for the device.<sup>165</sup> The FDA is required to classify all medical devices intended for humans into one of the three classes, contained in section 513 of the FDCA.<sup>166</sup> Class I devices pose the least level of risk to patients; Class III devices present the greatest risk.<sup>167</sup> The classification procedures contained in section 513(b)-(d) of the FDCA apply to “old” devices, which are devices that were in commercial distribution before the 1976 Amendments were passed, or are substantially equivalent to devices in distribution before 1976.<sup>168</sup> Section 513(f) also contains special provisions for “new” devices, which are devices that were not in distribution before 1976, and are not substantially equivalent to any device that was in circulation before 1976.<sup>169</sup>

Devices “present[ing] no unreasonable risk of illness or injury” are labeled as Class I and “are subject only to minimal regulation by ‘general controls.’”<sup>170</sup> The “general control provisions of the Medical Device Amendments, and the adulteration and misbranding sections of the FDCA[,]” are sufficient to ensure the safety of Class I devices.<sup>171</sup> Class I devices are “not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in

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160. *Id.* at 981.

161. *Id.*

162. *Id.*

163. *Id.*

164. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996); *see also* Flaherty, *supra* note 141, at 906 (“When initially classifying devices, the FDCA requires that the least restrictive classification must first be considered, and only when the device in question cannot meet the definition of a less restrictive class can more restrictive classifications be considered.”).

165. Flaherty, *supra* note 141, at 906 (explaining that “the FDA seeks to winnow out lower risk devices through the classification process” so that mid-risk devices are subject to the 510(k) process and only the highest risk devices are subject to the PMA process).

166. HUTT ET AL., *supra* note 46, at 985 (citing 42 Fed. Reg. 46028).

167. Flaherty, *supra* note 141, at 906.

168. HUTT ET AL., *supra* note 46, at 985 (citing 42 Fed. Reg. 46028).

169. *Id.*

170. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476–77; *see also* 21 U.S.C. § 360c(a)(1)(A) (2012).

171. Flaherty, *supra* note 141, at 906 (citing Jonathan S. Kahan, *Premarket Approval versus Premarket Notification: Different Routes to the Same Market*, 39 FOOD DRUG COSM. L.J. 510, 511 (1984)). For an explanation of the adulteration and misbranding provisions of the FDCA, *see* HUTT ET AL., *supra* note 46, at 1034.

preventing impairment of human health . . . .”<sup>172</sup> Examples of common Class I devices include elastic bandages, examination gloves, and tongue depressors.<sup>173</sup>

Moderate-risk devices are designated Class II.<sup>174</sup> Manufacturers of these devices must comply with “special controls,” but the devices can “be marketed without advance approval.”<sup>175</sup> Although general controls alone “are insufficient to provide reasonable assurance of the safety and effectiveness” for these devices, enough information exists “to establish special controls to provide such assurance . . . .”<sup>176</sup> The special controls include “performance standards, postmarket surveillance, patient registries, [and] development and dissemination of guidelines.”<sup>177</sup> Examples of Class II devices include dental floss, forceps, and surgical lasers.<sup>178</sup>

The most dangerous devices are designated as Class III. For devices in this category, there is insufficient information to determine that general controls and special controls will assure their safety and effectiveness.<sup>179</sup> Class III devices 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, or [which] presents a potential unreasonable risk of illness or injury.”<sup>180</sup> Class III devices also potentially present an “unreasonable risk of illness or injury” and include novel devices that do not have a substantially equivalent predicate device.<sup>181</sup> Because of the risk involved, Class III devices require FDA approval through the premarket approval process before they can be marketed.<sup>182</sup> Examples of Class III devices include pacemakers, artificial joints, breast implants, and surgical mesh.<sup>183</sup>

#### d. 1990 Safe Medical Devices Act

Under the Safe Medical Devices Act of 1990 (“SMDA”), device user facilities are required to report device-related deaths and serious injuries to both the FDA and the manufacturer.<sup>184</sup> Additionally, SMDA also mandates that device user facilities provide the FDA with semiannual summaries of all reports submitted during that time period.<sup>185</sup> Con-

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172. 21 U.S.C. § 360c(a)(1)(A)(ii)(I) (2012); *see also* HUTT ET AL., *supra* note 46, at 1034.

173. Sweet et al., *supra* note 45, at 43.

174. *Medtronic*, 518 U.S. at 477.

175. *Id.*

176. 21 U.S.C. § 360c(a)(1)(B) (2012).

177. *Id.*

178. Sweet et al., *supra* note 45, at 43; *What Does it Mean for FDA to “Classify” a Medical Device?*, U.S. FOOD & DRUG ADMIN. (May 12, 2014), <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194438.htm>.

179. HUTT ET AL., *supra* note 46, at 985 (citing 42 Fed. Reg. 46028).

180. 21 U.S.C. § 360c(a)(1)(C)(ii)(I)–(II) (2012).

181. *Id.* § 360c(a)(1)(C)(ii)(II); § 360c(f)(1)(A)(ii).

182. *Id.* § 360c(a)(1)(C).

183. *See* Sweet et al., *supra* note 45, at 43.

184. *Medical Device Reporting*, U.S. FOOD & DRUG IN. (Apr. 19, 2013), <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

185. *Id.*

gress also “validated FDA’s premarket review system” through this Act.<sup>186</sup>

e. FDA Modernization Act of 1997

In the FDA Modernization Act of 1997 (“FDAMA”), Congress revolutionized the 510(k) process.<sup>187</sup> Two additional pathways for introducing a new medical device onto the market were established.<sup>188</sup> First, a procedure was created requiring the FDA to classify a device with no substantially equivalent predicate into Class I or Class II instead of Class III.<sup>189</sup> Second, Congress automatically exempted most Class I devices from the premarket notification process and authorized the FDA to exempt Class II devices where appropriate.<sup>190</sup>

Today, most Class I devices and some Class II devices are exempt from the premarket notification requirement.<sup>191</sup> Although Congress originally intended to have the FDA approve all devices before entering the market, it is now common that manufacturers of less risky devices routinely determine substantial equivalence for themselves.<sup>192</sup>

2. *Current Regime: Regulation of Market Entry*

While both medical devices and drugs must adhere to various federal regulations relating to production, labeling, advertising, and post-marketing surveillance, differences exist among the FDA review processes.<sup>193</sup> One notable difference is that the majority of medical devices are *cleared* by the FDA for human use, rather than *approved* by the FDA like drugs.<sup>194</sup> To be cleared, a device must be “substantially equivalent” to a predicate device; to be approved, the applicant must provide a “reasonable assurance” of the device’s safety and effectiveness.<sup>195</sup> Also, as a result of the wide assortment of devices that exist, the MDA acknowledged that not all devices require the same level of regulation and thus created the classification system.<sup>196</sup> All medical devices are required to abide by the adulteration and misbranding provisions of the FDCA.<sup>197</sup> “Generally, Class I devices are not subject to any premarket review process, while Class II devices are subject to the 510(k) premarket notification process, and Class III products are subject to the [premarket ap-

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186. Benjamin A. Goldberger, *The Evolution of Substantial Equivalence in FDA’s Premarket Review of Medical Devices*, 56 FOOD & DRUG L.J. 317, 326 (2001).

187. HUTT ET AL., *supra* note 46, at 996.

188. *Id.* at 991.

189. *Id.* at 992.

190. *Id.*

191. *Id.* at 996.

192. *Id.*

193. Sweet et al., *supra* note 45, at 40.

194. MEDICAL DEVICES AND THE PUBLIC’S HEALTH, *supra* note 47, at xi.

195. *What Does it Mean When FDA “Clears” or “Approves” a Medical Device?*, U.S. FOOD & DRUG ADMIN. (May 12, 2014), <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194460.htm>.

196. Sweet et al., *supra* note 45, at 43.

197. 21 U.S.C. §§ 351–52 (2012); Sweet et al., *supra* note 45, at 43.

proval (“PMA”)] process.”<sup>198</sup> However, simply because a Class III device has received FDA clearance does not necessarily mean that it has been proven safe and effective or even that clinical trials have been conducted.<sup>199</sup> An overview of the market introduction procedures for medical devices provides a more detailed explanation.

a. Distinction Between “Old” and “New” Devices

After the enactment of the MDA in 1976, FDA officials were faced with the dilemma of how to treat “old” Class III devices, or devices on the market before 1976, and “new” devices; the distinction was important, because had the FDA decided to treat the “old” and “new” devices the same, all the “old” devices would have to be pulled off the market until they completed the review process.<sup>200</sup> Congress was not prepared to require that every preamendment Class III device be pulled from the market immediately upon classification, because an enormous backlog would be created and would keep many well-established and important devices off the market for several years.<sup>201</sup>

To avoid this result, Congress created two exceptions to the general premarket review format for medical devices.<sup>202</sup> First, it created a “grandfathering” provision, where any Class III device on the market before 1976 need not secure any FDA approval of safety and effectiveness until the FDA promulgates a regulation triggering an approval requirement for the specific type of device.<sup>203</sup> Second, any post-1976 amendment device, including Class III, that is “substantially equivalent” to a pre-1976 device or a post-1976 device that has received FDA clearance can go on the market immediately, with only the submission of a 510(k) premarket notification.<sup>204</sup> Although the MDA did not include a definition of “substantially equivalent,” the legislative history indicates that Congress intended for “substantial equivalence” to be “assessed not merely in terms of physical characteristics and intended use, but also in terms of safety and effectiveness.”<sup>205</sup> This provision was included in order to “prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle, and to ensure that improvements to existing devices can be rapidly introduced into the market . . . .”<sup>206</sup>

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198. Flaherty, *supra* note 141, at 906.

199. Sweet et al., *supra* note 45, at 40.

200. HUTT ET AL., *supra* note 46, at 987.

201. *Id.* at 987–88.

202. Flaherty, *supra* note 141, at 906–07.

203. HUTT ET AL., *supra* note 46, at 988; 21 U.S.C. § 360c(f)(1)(A)(i) (2012).

204. HUTT ET AL., *supra* note 46, at 988; Sweet et al., *supra* note 45, at 43.

205. Flaherty, *supra* note 141, at 907; *see also* HUTT ET AL., *supra* note 46, at 994–95 (quoting H.R. REP. NO. 94-853, at 36–37 (1976)) (“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 marketed device do not relate to safety and effectiveness.”).

206. Medtronic, Inc. v. Lohr, 518 U.S. 470, 478 (1996).

b. Premarket Notification: The 510(k) Process

Although every medical device that is marketed in this country must comply with the controls outlined in the FDCA, such as adherence to good manufacturing practices, proper labeling, and adequate packaging, most devices enter the U.S. market “through an approval process that is less demanding than that required for drugs and which does not require a true clinical trial testing for safety and efficacy.”<sup>207</sup> This process is known as the 510(k) premarket notification, and it was intended to require every person who wanted to market a medical device to submit a 510(k) to the FDA, unless it was a Class III device that requires premarket approval.<sup>208</sup> In 1997, the FDAMA essentially eliminated the need for a 510(k) for most Class I and some Class II devices.<sup>209</sup> A 510(k) is required in three circumstances. First, a manufacturer who wishes to introduce a device into commercial distribution for the first time must submit a 510(k).<sup>210</sup> Second, if the proposed intended use is different than the intended use of the “substantially equivalent” predicate device that is already in commercial distribution, a 510(k) is needed.<sup>211</sup> Third, a 510(k) is necessary when there is “a change or modification of a legally marketed device that could significantly affect its safety or effectiveness.”<sup>212</sup>

The 510(k) process is the method by which the majority of new medical devices, including Class III devices, receive market approval.<sup>213</sup> Between 1976 and 1990, more than ninety-eight percent of new medical devices entered the market by demonstrating substantial equivalence to a preamendment device.<sup>214</sup>

i. “Substantial Equivalence”

The idea of “substantial equivalence” lies at the center of the 510(k) premarket notification process.<sup>215</sup> A 510(k) submission requires a demonstration that the device to be marketed is “at least as safe and effective, that is, substantially equivalent, to a legally marketed device . . . that is not subject to PMA.”<sup>216</sup> The MDA did not contain a definition of substantial equivalence.<sup>217</sup> In 1990, the SMDA codified a definition of substantial equivalence, explaining that “with respect to a device being compared to a predicate device, . . . the device has the same intended use

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207. Sweet et al., *supra* note 45, at 43.

208. *Premarket Notification (510k)*, U.S. FOOD & DRUG ADMIN. (Jan. 3, 2014), <http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketnotification510k/default.htm>.

209. HUTT ET AL., *supra* note 46, at 996.

210. *Premarket Notification (510k)*, *supra* note 208.

211. *Id.*

212. *Id.*

213. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 479 (1996).

214. HUTT ET AL., *supra* note 46, at 991.

215. Flaherty, *supra* note 141, at 907.

216. *Premarket Notification (510k)*, *supra* note 208.

217. HUTT ET AL., *supra* note 46, at 994.

as the predicate device and that the Secretary by order has found that the device”.<sup>218</sup>

- (i) has the same technological characteristics as the predicate device, or
- (ii) (I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 360m of this title, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.<sup>219</sup>

After a 510(k) is submitted, it must be established that both the new device and the predicate device “share the same intended use.”<sup>220</sup> The predicate device, however, is not required to be the “best” predicate device and may not even be in use anymore because of poor clinical performance.<sup>221</sup> Thus, “a product that was truly inferior to the current state of the art could still enter the market if the manufacturer could identify any predicate that had not been removed from the market and to which it was substantially equivalent.”<sup>222</sup> Once substantial equivalence is established, “the focus of the substantial equivalence determination turns to the technological characteristics of the new and predicate devices.”<sup>223</sup> In reality, the majority of studies that support a 510(k) are not true clinical trials establishing safety and efficacy.<sup>224</sup> “By statute, the FDA has 90 days in which to respond to a 510(k) notification.”<sup>225</sup> In 1996, the U.S. Supreme Court observed that the FDA spent on average about twenty hours evaluating each 510(k) submission.<sup>226</sup>

### c. Premarket Approval

“The PMA is the most rigorous device application” and can be equated to the NDA process for drugs.<sup>227</sup> The PMA process is required for the majority of Class III devices,<sup>228</sup> yet, it remains noteworthy that only two percent of devices receive approval through the PMA process.<sup>229</sup> The PMA application must contain full reports of all safety and effec-

218. 21 U.S.C. § 360c(i)(1)(A) (2012).

219. *Id.*

220. Flaherty, *supra* note 141, at 908.

221. MEDICAL DEVICES AND THE PUBLIC’S HEALTH, *supra* note 47, at 89; Brent M. Ardaugh et al., *The 510(k) Ancestry of a Metal-on-Metal Hip Implant*, 368 NEW. ENG. J. MED. 97–98 (2013) (explaining that voluntarily recalled devices can be predicate devices, as long as the FDA did not recall them or deem them adulterated or misbranded).

222. MEDICAL DEVICES AND THE PUBLIC’S HEALTH, *supra* note 47, at 89.

223. Flaherty, *supra* note 141, at 908.

224. Sweet et al., *supra* note 45, at 44.

225. HUTT ET AL., *supra* note 46, at 993.

226. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 479 (1996).

227. Sweet et al., *supra* note 45, at 44.

228. *Id.*

229. *Id.*

tiveness information known to the applicant, a complete statement of the components and properties of the device and of the principles of its operation, and a description of the methods, facilities, and controls used for its manufacture, processing, and packaging.<sup>230</sup> Approximately 1200 hours are necessary to complete a PMA review—significantly longer than the twenty hours required for a 510(k) submission.<sup>231</sup>

Medical device manufacturers seeking premarket approval are subject to “a more flexible standard of proof of safety and effectiveness than new drugs sponsors.”<sup>232</sup> In contrast to the drug provisions, Section 513(a)(1)(C) of the FDCA states that premarket approval of devices is intended to provide “reasonable assurance” of safety and effectiveness.<sup>233</sup> “Section 513(a)(1)(C) states that effectiveness may be established ‘on the basis of well-controlled investigations, including clinical investigations *where appropriate* . . . .’”<sup>234</sup> There is also an alternative method for proving a device’s effectiveness.<sup>235</sup> Section 513(a)(1)(B) states that if the Secretary can fairly and responsibly determine that there is valid scientific evidence (other than evidence derived from well-controlled investigations), the Secretary may authorize effectiveness of the device based on that evidence.<sup>236</sup> These provisions do not specifically require well-controlled, clinical investigations for new devices.

By statute, the FDA has 180 days to issue an order approving or denying approval once it receives a PMA.<sup>237</sup> Yet, in actuality, the review time is much longer.<sup>238</sup> After a PMA application is approved, the applicant still has to obtain further approvals “before making changes in the labeling of the device, its indications for use, its packaging or sterilization procedures, its performance or design specifications, or its components, principles of operation, or physical layout.”<sup>239</sup>

#### d. Postmarket Surveillance

Because it is impossible to ensure the complete safety of all devices before they appear on the market, a strong surveillance system capable of monitoring the safety of medical devices is crucial.<sup>240</sup> FDA regulations define postmarket surveillance as “the active, systematic, scientifically valid collection, analysis, and interpretation of data or other information

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230. MEDICAL DEVICES AND THE PUBLIC’S HEALTH, *supra* note 47, at 69.

231. *Medtronic*, 518 U.S. at 479.

232. HUTT ET AL., *supra* note 46, at 1011.

233. *Id.* at 1010.

234. *Id.* at 1011.

235. *Id.*

236. *Id.*

237. *Id.* at 1014.

238. *Premarket Approval (PMA)*, U.S. FOOD & DRUG ADMIN. (Jan. 24, 2012), <http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarket submissions/premarketapprovalpma/default.htm>.

239. MEDICAL DEVICES AND THE PUBLIC’S HEALTH, *supra* note 47, at 70.

240. *Id.* at 123.

about a marketed device.”<sup>241</sup> The FDA may order any manufacturer of a Class II or Class III device to conduct postmarket surveillance if the failure of the device would be reasonably likely to cause adverse health consequences.<sup>242</sup> For medical devices, there are several programs, including adverse event reporting by manufacturers, third-party safety monitoring, and FDA-academic collaborations.<sup>243</sup> After a manufacturer receives a postmarket surveillance order, they must submit a surveillance plan for FDA approval within thirty days.<sup>244</sup>

#### e. Device Tracking

The tracking provisions that are found in section 519(e) of the FDCA were added in 1990 by the SMDA and later amended in 1997 by the FDAMA.<sup>245</sup> These provisions require that manufacturers track certain Class II or Class III devices *when the FDA orders them to do so*.<sup>246</sup> Tracking is intended to facilitate notification and recall if the failure of the device would be “‘reasonably likely to have serious adverse health consequences,’ if it is intended to be implanted in the body for more than one year, or if it is intended to be used outside a user facility to support or sustain life.”<sup>247</sup> Originally, tracking was mandatory for the manufacturers of all devices fitting the statutory criteria.<sup>248</sup> When section 519(e) was amended by the FDAMA, the FDA was given discretion as to whether or not to require tracking for such devices, and accordingly, the FDA rescinded the tracking orders for fourteen types of devices.<sup>249</sup>

Recently, the FDA issued a final rule establishing a new tracking system, aiming to “increase patient safety and streamline product recall.”<sup>250</sup> The new system will assign tracking numbers, known as Unique Device Identifiers (“UDIs”), to high-risk medical devices.<sup>251</sup> The UDI operates “‘as a key to certain basic identifying information about a device, such as the name of the manufacturer, type of device, expiration date and batch or lot number.’”<sup>252</sup> The UDIs will allow the FDA to access information maintained by agencies, insurers, and hospitals regarding devices that possess high degrees of failure.<sup>253</sup> Product information

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241. HUTT ET AL., *supra* note 46, at 1058 (citing 21 C.F.R. 822.3(h)).

242. *Id.* at 1057 (citing FD&C Act 522(a); 21 C.F.R. 822.1).

243. MEDICAL DEVICES AND THE PUBLIC’S HEALTH, *supra* note 47, at 123.

244. HUTT ET AL., *supra* note 46, at 1057–58.

245. CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION, OMB CONTROL NO. 0910-0442, MEDICAL DEVICE TRACKING: GUIDANCE FOR INDUSTRY AND FDA STAFF 4 (2010), available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071775.pdf> [hereinafter MEDICAL DEVICE TRACKING].

246. HUTT ET AL., *supra* note 46, at 1058; MEDICAL DEVICE TRACKING, *supra* note 245, at 2.

247. 21 U.S.C. § 360i(e) (2012); HUTT ET AL., *supra* note 46, at 1058.

248. HUTT ET AL., *supra* note 46, at 1058.

249. *Id.* at 1058–59.

250. Unique Device Identification System, 78 Fed. Reg. 58786 (Sept. 24, 2013); Simi Botic & Stacey Borowicz, *FDA Unveils a New System to Track Medical Devices*, 6 MED. DEVICES L. & INDUSTRY REP. (2012).

251. Botic & Borowicz, *supra* note 250.

252. *Id.* (citation omitted).

253. *Id.*



will also be available “to patients, doctors, industry regulators[,] and consumer advocates.”<sup>254</sup>

### III. ANALYSIS

When the 510(k) route to market entry was established, Congress did not anticipate the vast number of postamendment Class III devices that would successfully be cleared through this process.<sup>255</sup> Many lawmakers, regulators, independent reviewers, doctors, and consumer advocates are in agreement that the 510(k) process contains critical flaws<sup>256</sup> and “opens the door for defective devices to make their way onto the market and jeopardize patient safety.”<sup>257</sup> Both patients and policymakers have voiced “concern about the ability of the 510(k) process to ensure that medical devices on the market are safe and effective.”<sup>258</sup> As discussed in Part I, the FDA appointed the IOM to review the 510(k) process.<sup>259</sup> The IOM ultimately concluded that the “510(k) process is flawed based on its legislative foundation” and stated that the FDA’s limited resources would be more wisely invested in establishing a brand new premarket and postmarket regulatory framework.<sup>260</sup> Nonetheless, there are scholars at the other end of the spectrum who believe that the 510(k) process is appropriate and plays an essential role in the regulatory framework for medical devices. Two approaches to the 510(k) premarket notification process are explained in detail below.

#### A. *Elimination of the 510(k) Process for Medical Devices*

The use of the substantial equivalence standard for premarket notification “is intended to accelerate the timetable for a product to receive FDA clearance.”<sup>261</sup> As stated above, a 510(k) review only requires about twenty hours to complete.<sup>262</sup> Opponents of the 510(k) process argue that this standard does not implement adequate safeguards to assure the safety and effectiveness of the most dangerous medical devices. Recalls of medical devices are also on the rise, which is evidence of the inadequacy of the process to assure safety and effectiveness. Furthermore, most of

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254. *Id.*

255. HUTT ET AL., *supra* note 46, at 988.

256. Saavedra & Perkes, *supra* note 14; *see also* Letter from Edward J. Markey, Member of Congress, and Jeff Merkley, U.S. Senator, to Jeffrey Shuren, Dir. of Ctr. for Devices and Radiological Health, on Weaknesses in Premarket Review (2012), *available at* <http://safepatientproject.org/wordpress/wp-content/uploads/2012/08/Letter-to-FDA-on-501k-databases.pdf> [hereinafter Letter from Edward J. Markey and Jeff Merkley].

257. Letter from Edward J. Markey and Jeff Merkley, *supra* note 256.

258. REPORT BRIEF FOR MEDICAL DEVICES AND THE PUBLIC’S HEALTH, *supra* note 132, at 1.

259. *See supra* Part I; MEDICAL DEVICES AND THE PUBLIC’S HEALTH, *supra* note 47, at xi.

260. REPORT BRIEF FOR MEDICAL DEVICES AND THE PUBLIC’S HEALTH, *supra* note 132, at 3.

261. MOUZOON & CAROME, *supra* note 49, at 5.

262. *See supra* Part II.B.2.b.

the products already on the market were never tested to ensure that they are safe because of a concept called “piggybacking.”<sup>263</sup>

### 1. *Failure to Incorporate Basic Safeguards*

The SMDA of 1990 provided the first definition for “substantial equivalence” in the context of the 510(k) process.<sup>264</sup> As discussed above in Part II.B.2.b.i, a standard of substantial equivalence only requires the new device to perform in a similar manner and to be at least as safe and effective as the predicate device, which may not actually be safe or effective because clinical data demonstrating safety and effectiveness generally are not required.<sup>265</sup> Consequently, if the earlier device is dangerous or ineffective, the new device might also pose a risk or be ineffective.<sup>266</sup> Furthermore, as discussed in Part II.B.2, medical devices subjected to the 510(k) review process are not *approved* by the FDA; they are merely *FDA-cleared*.<sup>267</sup> FDA clearance only requires proof that the device is similar to a predicate device, rather than requiring an assurance of safety and effectiveness necessary for approval.<sup>268</sup>

The Supreme Court has noted the “logical flaw” in relying on this standard.<sup>269</sup> As the name suggests, “substantial equivalence” is focused on *equivalence*, not safety, and therefore provides little protection to the public.<sup>270</sup> Solely proving substantial equivalence to an existing product does not guarantee safety or effectiveness.<sup>271</sup> The IOM report concluded that “[t]he 510(k) process cannot be transformed into a premarket evaluation of safety and effectiveness as long as the standard for clearance is substantial equivalence to any previously cleared device.”<sup>272</sup> Without clinical trials or substantial data to ensure safety and effectiveness, patients’ bodies will continue to be the sole testing mechanisms for potentially dangerous devices. Examples of the failure of the 510(k) process, such as metal-on-metal hip implants and surgical mesh, are explained in Part I above.<sup>273</sup> The lack of safety measures before a device is marketed can have serious consequences on both the consumer and the manufacturers, as discussed in Part I.<sup>274</sup>

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263. See *supra* Part II.B.2.b; HUTT ET AL., *supra* note 46, at 998–999 (explaining that “piggybacking,” when carried through several generations, may lead to the marketing of new devices that bear little resemblance to any preamendment products).

264. MOUZON & CAROME, *supra* note 49, at 35.

265. 21 U.S.C. § 360c(i) (2012); JUDITH A. JOHNSON, FDA REGULATION OF MEDICAL DEVICES 4 (2012); Sweet et al., *supra* note 45, at 43–44; see *supra* Part II.B.2.b.i.

266. Medtronic, Inc. v. Lohr, 518 U.S. 470, 493 (1996).

267. See *supra* Part II.B.2; Sweet et al., *supra* note 45, at 44.

268. See *What Does it Mean When FDA “Clears” or “Approves” a Medical Device?*, *supra* note 195.

269. MOUZON & CAROME, *supra* note 49, at 35.

270. *Medtronic*, 518 U.S. at 493.

271. MOUZON & CAROME, *supra* note 49, at 35.

272. MEDICAL DEVICES AND THE PUBLIC’S HEALTH, *supra* note 47, at 193.

273. See *supra* Part I.

274. See *supra* Part I.

## 2. *Recalls are Rising*

Recalls are also on the rise, which implies that the 510(k) process is not working as intended. Manufacturers send out thousands of recall letters, some of which go unnoticed.<sup>275</sup> Often times, devices are recalled and known to be faulty by the manufacturer, yet are still marketed and implanted in unsuspecting patients.<sup>276</sup> Devices involved in the recalls include tracheal tubes, catheters, pacemakers, prosthetic hips, screws, pain pumps, and pieces of artificial spine.<sup>277</sup> A substantial amount of the devices recalled were “ranked as ‘Class 1’ recalls by the FDA, which involve a defect serious enough to create a ‘reasonable probability of adverse health consequences or death.’”<sup>278</sup> According to performance reports from the FDA in 2010, the quantity of new product applications has not accompanied the growing quantity of recalls, indicating that the rise in recalls has been the result of the decrease in safety.<sup>279</sup> Two studies evaluating recall rates during the years 2006-2009 found that the majority of recalls were for devices cleared through the 510(k) process.<sup>280</sup> Of the devices that were recalled, the studies also found that the majority had a larger number of predicates, were life-sustaining, or were Class III devices.<sup>281</sup> These findings reveal “systematic problems in the implementation of existing medical device regulations that have exposed patients to serious harm.”<sup>282</sup>

## 3. *“Piggybacking”*

When the substantial equivalence process is carried through multiple generations, it may lead to the marketing of devices that bear little resemblance to any predicate devices, leading to the phenomenon known as “piggybacking.”<sup>283</sup> Piggybacking allows “a chain of devices to link a new postamendment device to earlier postamendment devices that ultimately could be traced back to a preamendment device.”<sup>284</sup> For example, “Device A might be found substantially equivalent to Device B, which had been found equivalent to Device C, which had been found equivalent to Device D,” which had been found substantially equivalent to De-

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275. *US Has No Good System to Track Medical Implants*, CBSNEWS.COM (Oct. 5, 2009, 3:12 PM), [http://www.cbsnews.com/2100-501367\\_162-5364655.html](http://www.cbsnews.com/2100-501367_162-5364655.html).

276. Axelrod, *supra* note 1.

277. *US Has No Good System to Track Medical Implants*, *supra* note 275 (explaining that in the first seven months of 2009, more than 1,000 devices were recalled, including the ones listed).

278. *Id.*

279. MOUZOON & CAROME, *supra* note 49, at 16.

280. MEDICAL DEVICES AND THE PUBLIC'S HEALTH, *supra* note 47, at 136.

281. *Id.* at 136-37.

282. Diana M. Zuckerman et al., *Medical Device Recalls and the FDA Approval Process*, 171 ARCH INTERN MED. 1006, 1009 (2011).

283. HUTT ET AL., *supra* note 46, at 998.

284. MEDICAL DEVICES AND THE PUBLIC'S HEALTH, *supra* note 47, at 33.

vice E, a device on the market before 1976.<sup>285</sup> Over time, each product likely differs slightly from an earlier product, yet is still approved.<sup>286</sup>

Thus, an important question is raised: can products that are created out of a novel material or through the use of the latest technology “realistically be considered safe” and effective without undergoing a comprehensive review or clinical trials?<sup>287</sup> Under the 510(k) process, a device will be approved whether or not it is superior or inferior to the predicate device, because the 510(k) submitter is not required to rely on the safest and most up-to-date predicate devices.<sup>288</sup> Furthermore, substantial equivalence can be proven through a long line of predicate devices, leading to a new product that bears “only a distant resemblance to the pre-enactment devices to which it was supposedly substantially equivalent.”<sup>289</sup> The products may be dissimilar “in purported intended use or in technological features.”<sup>290</sup> The majority of 510(k) “submissions for devices that have new technologic characteristics receive a determination of substantial equivalence.”<sup>291</sup> The technological characteristics belonging to the new device do not necessarily have to be similar to those possessed by the predicate device, provided that the characteristics do not trigger new questions of safety or effectiveness.<sup>292</sup> Piggybacking issues are apparent in many cases, such as the DePuy hip replacement, discussed in Part I above.<sup>293</sup> The consequences are well illustrated in that case.<sup>294</sup>

#### B. *The Essential Role of the 510(k) Premarket Notification Process*

Proponents of the 510(k) premarket notification process contend that by using the standard of substantial equivalence, “the 510(k) process compares and equates a new device to a *successful* device already on the market and in clinical use,” which “establish[es] a reasonable assurance of safety and effectiveness for the new device.”<sup>295</sup> The 510(k) submission has become the option of choice for bringing a new device to market for several reasons.<sup>296</sup> The 510(k) submission is fair, requires fewer resources and less information, has a speedy and efficient application process, and has a higher likelihood of FDA acceptance than the other pathways.<sup>297</sup>

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285. *Id.*

286. MOUZON & CAROME, *supra* note 49, at 38–39.

287. Ingrid Mezo, *Scrutinizing 510(k)s: Critical Voices Get Heard in Congress*, THE GRAY SHEET (July 16, 2007), <http://www.fdcalerts.typepad.com/medicaldevicestoday.com/2007/07/scrutinizing-51.html>.

288. MEDICAL DEVICES AND THE PUBLIC’S HEALTH, *supra* note 47, at 88–89.

289. Robert B. Leflar, *Public Accountability and Medical Device Regulation*, 2 HARV. J.L. & TECH. 1, 51 (1989) (citation omitted).

290. MOUZON & CAROME, *supra* note 49, at 38–39.

291. MEDICAL DEVICES AND THE PUBLIC’S HEALTH, *supra* note 47, at 191.

292. MOUZON & CAROME, *supra* note 49, at 38.

293. *See supra* Part I.

294. *J.&J. Loses First Case*, *supra* note 24 (noting that the cup and ball in the DePuy hip replacement resulted in “shedding of metallic debris,” which not only “inflamed and damaged tissue,” but also caused pain or even permanent injuries).

295. Flaherty, *supra* note 141, at 923.

296. HUTT ET AL., *supra* note 46, at 993.

297. *Id.*

### 1. *Fairness*

“In drafting the Amendments, Congress determined that it would be unfair to” implement rigorous regulations on devices that are determined to be “substantially equivalent to a pre[ ] amendment device.”<sup>298</sup> The rationale behind this determination is that if a manufacturer can prove the substantial equivalence of its device to a device that has already been approved and is on the market, there is no need to subject the new device to the same rigorous requirements that the approved device fulfilled.<sup>299</sup>

“First, the manufacturer of the new device would have to incur far more start-up costs than the manufacturer of the old device, who never had to submit a PMA.”<sup>300</sup> Ultimately, this burden could harm competition.<sup>301</sup> “Second, requiring PMAs for all post[ ] amendment devices would enormously increase the administrative burden on FDA” and create a massive backlog.<sup>302</sup> Requiring every device to go through the PMA process would also impede innovation, which is unfair to innovators, manufacturers, and consumers. Third, “the regulatory value of close scrutiny of substantially equivalent post[ ] amendment devices is questionable, for it would still leave the pre[ ] amendment device on the market—a device whose safety and effectiveness had not yet been subjected to close FDA review.”<sup>303</sup>

Further, the medical device classification system already takes risk into account, so it would be unfair to require certain lower risk devices to go through a rigorous and unnecessary approval process. In order to promote public health, lower risk devices should have a less tedious and burdensome path to market in order to “encourage manufacturers to develop lower risk devices and speed these types of devices to market.”<sup>304</sup> This situation is fairer to the consumers who will ultimately benefit from the product and for the innovators who are working to promote the public health with new medical devices.

### 2. *Fewer Resources and Less Information Required*

Compared to the PMA, the data requirements for 510(k) submissions are relatively minimal.<sup>305</sup> The vast majority of 510(k) applications only require submitters to “compare their device to one or more similar legally marketed devices and make and support their substantial equivalency claims.”<sup>306</sup> This process allows the Center for Devices and Radio-

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298. Jonathan S. Kahan, *Premarket Approval Versus Premarket Notification: Different Routes to the Same Market*, 39 FOOD DRUG COSM. L.J. 510, 514 (1984).

299. *Id.*

300. *Id.* at 515.

301. *Id.* at 514–15.

302. *Id.* at 515.

303. *Id.*

304. Flaherty, *supra* note at 923.

305. Kahan, *supra* note 298, at 515.

306. *Premarket Notification (510k)*, *supra* note 208.

logical Health at the FDA to “review thousands of devices each year.”<sup>307</sup> In 2005, the average cost for the FDA to review a PMA submission was \$870,000, while the 510(k) submission only cost about \$18,200 to review.<sup>308</sup> The 510(k) process saves both time and money.

The FDA created “heightened” requirements for certain devices. An April 9, 2009 order published by the FDA “requir[ed] the manufacturers of twenty-five Class III preamendment devices to submit to [the] FDA a summary of . . . any known, or otherwise available, safety or efficacy information . . . .”<sup>309</sup> If the manufacturer is not cognizant of information that would support the reclassification of the device into Class I or Class II, it must submit additional information, including: indications for use, device description, other device labeling, risks, alternative practices and procedures, summary of preclinical and clinical data, and a bibliography.<sup>310</sup> If the manufacturer is aware of information that would support the reclassification of the device, the following supplementary information must be submitted: identification, risks to health, recommendation, summary of reasons for recommendation, and a summary of valid scientific evidence on which the recommendation is based.<sup>311</sup> Even with these “heightened” requirements for certain devices, the 510(k) process still has less requirements than the PMA process.

Further, because the 510(k) process requires fewer resources than does a PMA application, it “allows the FDA to handle its large workload by requiring less of the manufacturers.”<sup>312</sup> To require every device to gain approval through the PMA process would substantially “increase the need for personnel to review PMA applications or to reclassify post-amendment devices down from Class III.”<sup>313</sup> Both of these are “labor-intensive activities” and would have far-reaching effects beyond difficulties at the FDA.<sup>314</sup> A PMA requirement for every device would create an enormous backlog at the FDA, stifle innovation, and prevent beneficial devices from coming to the market to benefit consumers. The limited information and resources required for the 510(k) process allow innovators to create novel devices without having to go through the tedious PMA process, benefiting consumers by bringing new technology to the market sooner.

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307. Zuckerman, *supra* note 282, at 1009.

308. *Id.*

309. *Required Submission of Safety and Effectiveness Information for Certain Class III Devices*, U.S. FOOD & DRUG ADMIN. (Aug. 7, 2009), <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm133989.htm> (listing the device type, classification regulation, and corresponding product code for all devices that must comply with the order).

310. *Id.*

311. *Id.* (providing more detail for each required section of the reclassification petition).

312. William H. Maisel, *Medical Device Regulation: An Introduction for the Practicing Physician*, 140 ANNALS INTERNAL MED. 296, 298 (2004).

313. MEDICAL DEVICES AND THE PUBLIC'S HEALTH, *supra* note 47, at 33.

314. *Id.*

### 3. *Efficiency of Application Process & Higher Likelihood of FDA Acceptance*

The 510(k) process is much more efficient than the PMA process. By law, the “FDA has ninety days in which to respond to a 510(k) notification,” and they have historically met that deadline.<sup>315</sup> Even though the review time for 510(k) submissions has lengthened as the number of applications has increased, it is still substantially less than the PMA approval time.<sup>316</sup> In contrast to the 510(k) process, the PMA review process takes about eight months or more to complete, because the FDA often returns the application “to the sponsor for additional data.”<sup>317</sup> According to data on the average time to decision in the 510(k) process, the total average time it took to clear a 510(k) steadily rose from 90 days (3 months) to 153 days (5 months) between 2005 and 2010.<sup>318</sup> In 2011, the average number of days to a decision decreased from a high of 147 days in 2010 to 143 days.<sup>319</sup> Still, the length of the PMA review process is more than double the 510(k) process.<sup>320</sup> Between 2003 and 2009, the length of time increased from 320 days (10.5 months) to 464 days (15.2 months).<sup>321</sup> The shorter review period has both cost and time advantages.<sup>322</sup> The 510(k) process also allows manufacturers to develop and market lower risk devices in an efficient manner in order “to promote public health.”<sup>323</sup>

Also, the “FDA has consistently had a very high rate of finding post[.]amendment devices to be substantially equivalent to pre[.]amendment devices.”<sup>324</sup> In 2012, approximately eighty percent of 510(k) applications received by the FDA were granted substantially equivalent status.<sup>325</sup> This number is “up from [seventy-eight percent] of applications in 2011 and [seventy-three percent] in 2010.”<sup>326</sup> High rates of substantial equivalence determinations mean that the public will potentially benefit from novel devices sooner than from a device that is not determined to be substantially equivalent, because the review time is much less.

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315. Kahan, *supra* note 298, at 517.

316. See generally IMPROVEMENTS IN DEVICE REVIEW: RESULTS OF CDRH’S PLAN OF ACTION FOR PREMARKET REVIEW OF DEVICES, U.S. FOOD & DRUG ADMIN. (2012) [hereinafter IMPROVEMENTS IN DEVICE REVIEW].

317. Kahan, *supra* note 298, at 518.

318. *Id.* at 13.

319. *Id.* at 14.

320. *Id.* at 17–18.

321. *Id.*

322. *Id.* at 516.

323. Flaherty, *supra* note 141, at 923.

324. Kahan, *supra* note 298, at 516.

325. Stewart Eisenhart, *FDA Report Claims Improved 510(k), PMA Review Times*, MASSDEVICE (Dec. 17, 2012), <http://www.massdevice.com/blogs/massdevice/fda-report-claims-improved-510k-pma-review-times>; see also IMPROVEMENTS IN DEVICE REVIEW, *supra* note 316, at 16.

326. Eisenhart, *supra* note 325; see also IMPROVEMENTS IN DEVICE REVIEW, *supra* note 316, at 16.

### C. Summary

Before proceeding to the Recommendation section, it is helpful to recap the important points made in the Analysis above. Opponents of 510(k) notification argue that the “substantial equivalence” standard is focused on *equivalence*, not safety, as evidenced by the failure to incorporate basic safeguards into the process. The recall rate of medical devices is also increasing, potentially demonstrating a flaw in the system due to the serious consequences of many 510(k) cleared devices. Further, the concept of piggybacking has led to the marketing of devices that bear little resemblance to any predicate devices, therefore introducing novel devices to the market that have never been proven safe or effective in any way.

There are, however, several advantages to 510(k) notification. Proponents of the system argue that the system is fair, allowing manufacturers to develop lower-risk devices and introduce them to the market to promote public health sooner than the PMA process. Also, 510(k) notification requires less resources and information, saving the FDA both time and money. Lastly, the process is efficient and has a high likelihood of FDA acceptance.

## IV. RECOMMENDATION

In the interest of balancing innovation with safety and effectiveness, this Recommendation takes a middle-ground approach and proposes three changes to the premarket regulation and postmarket surveillance of medical devices based on the current FDA regulation system. In order to advance human health, “patients must have easy access to innovative medical devices” that are approved through an efficient process.<sup>327</sup> Nevertheless, no one will benefit from “putting defective medical devices onto the market where they cause harm to patients, waste health care dollars, and may kill jobs when they are withdrawn.”<sup>328</sup> The purpose of this Recommendation is to strike a proper balance between the advancement of human health by innovative devices and regulation ensuring safety and effectiveness.

Part A suggests a general change to the categorization of new medical devices that are not substantially equivalent to a predicate device. Part B seeks to eliminate piggybacking in the 510(k) process. Part C suggests an addition to the postmarket surveillance of medical devices: the establishment of a National Medical Device Registry to ensure the safety and effectiveness of medical devices that are approved and on the market, in conjunction with a unique device identification system.

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327. Gregory D. Curfman & Rita F. Redberg, *Medical Devices – Balancing Regulation and Innovation*, 365 N. ENG. J. MED. 975, 977 (2011).

328. *Id.*



A. *Definition of “Class III” Device*

Although Class III devices are generally implantable and life-saving or life-sustaining devices, such is not always the case.<sup>329</sup> For example, when a brand new device comes onto the market and is not substantially equivalent to a predicate device, it is automatically categorized as Class III.<sup>330</sup> As some critics correctly point out, this automatic categorization will potentially impede innovation and lead to lag and device loss.<sup>331</sup>

The Sensor Pad is an example of device delayed due to its automatic classification as a Class III device.<sup>332</sup> The Sensor Pad is a particularly simple device: “it is two sheets of sealed plastic that sandwich a silicon lubricant.”<sup>333</sup> The intended use of the device is for early detection of breast cancer.<sup>334</sup> The Sensor Pad is used outside the body and allows a woman to “more easily detect unusual breast lumps in a self-examination.”<sup>335</sup> When the application for FDA approval was submitted, the FDA could not find any other substantially equivalent products on the market, and consequently, the device was automatically classified as a high-risk, Class III device.<sup>336</sup> The manufacturer of the product submitted hundreds of pages documenting the safety and effectiveness of the Sensor Pad, yet the FDA still wanted more documents in the following years, even though other countries rapidly approved the device for immediate use.<sup>337</sup> This result seems absurd: why should “a device substantially less complicated and less dangerous than a toaster oven” be subjected to the PMA process?<sup>338</sup>

A change in the early stages of the application process will help curb this result. Instead of requiring a device without a substantially equivalent predicate to be automatically classified as a Class III device, the FDA should classify such devices as Class II *unless* the novel device is implantable in the human body. As a result, *implantable* devices without a substantially equivalent predicate would still be classified as Class III and subject to the PMA process. On the other hand, *non-implantable* devices without a substantially equivalent predicate would be classified as Class II and subject to the 510(k) process on the grounds that it will be introduced into commercial distribution for the first time.<sup>339</sup> Making a distinction between implantable and non-implantable devices is important, especially because the novel devices are not required to have the same technological characteristics (design, materials, and energy sources)

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329. See *supra* Part II.B.1.c.i.

330. See *supra* Part II.B.1.c.i.

331. *Some Remarks About Medical Devices*, FDAREVIEW.ORG, [http:// http://fdareview.org/devices.shtml](http://fdareview.org/devices.shtml).

332. *Id.*

333. *Id.*

334. *Id.*

335. *Id.*

336. *Id.*

337. *Id.*

338. *Id.*

339. 21 C.F.R. § 807.81 (2007).

as the predicate device.<sup>340</sup> Implantable devices carry inherent risks and have the potential to cause more damage than a device that is used outside the body and thus should be subjected to more rigorous approval standards. Narrowing the definition of a Class III device and drawing a clear line between implantable devices and devices that are used outside the body will also aid in avoiding cases like the Sensor Pad, allowing potentially useful technologies to reach the market faster. Further, this change will increase the speed and efficiency of the PMA reviews for other devices.

Therefore, the definition of a Class III device should be limited to devices intended for life-sustaining or life-supporting purposes and those presenting a potential “unreasonable risk of illness or injury.”<sup>341</sup> Furthermore, the Class III definition should only include *implantable* medical devices that are not substantially equivalent to devices on the market, rather than *all* medical devices that are not substantially equivalent to a predicate device.

### B. Elimination of Piggybacking in the 510(k) Process

Piggybacking, or the use of “multiple predicates,” in the 510(k) process should be eliminated.<sup>342</sup> As discussed in Part III.A.1, the safety and effectiveness of many predicate devices has never been demonstrated by valid scientific studies.<sup>343</sup> Further, predicate devices do not necessarily have to be marketed.<sup>344</sup> Therefore, along with a lack of clinical trials, there may be no “real-world experience” proving the safety and effectiveness of the device.<sup>345</sup> As a consequence, new devices that are substantially equivalent are likely to have the same safety and effectiveness concerns as the predicate device.<sup>346</sup> More importantly, piggybacking allows “a novel device without any single product to which it is similar [to] be cleared by having various characteristics that are equivalent to individual traits of two, three, or more different previously cleared devices.”<sup>347</sup>

The concept of piggybacking defeats the purpose of “substantial equivalence” by allowing a device to be equivalent to various components of multiple predicate devices.<sup>348</sup> If substantial equivalence of a new device to *one* predicate device cannot be proven, how can it be considered *substantially equivalent* to anything? Just because the characteris-

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340. Janice Hogan & Gwyn Simmons, *Standards for Clearance of 510(k) Premarket Notifications in the US*, RAJDEVICES.COM (Sept. 2008), <http://www.hoganlovells.com/files/Publication/c6c923f0-742a-4b63-be7a-eb10fc689261/Presentation/PublicationAttachment/db563313-55cf-4519-9c8a-1417ccd17afb/RAJ.pdf>.

341. 21 U.S.C. § 360c(a)(1)(C)(ii) (2012).

342. Curfman & Redberg, *supra* note 327, at 977.

343. *See supra* Part III.A.1.

344. David R. Challoner & William W. Vodra, *Medical Devices and Health – Creating a New Regulatory Framework for Moderate-Risk Devices*, 365 N. ENG. J. MED. 977, 978 (2011).

345. *Id.*

346. Leflar, *supra* note 289, at 33; *see supra* Part III.A.1.

347. Challoner & Vodra, *supra* note 344, at 978.

348. *See id.*

tics of a device are equivalent to multiple predicate devices does not mean that the device as a whole is equivalent and therefore safe and effective.

Take, for example, the notable case of the DePuy Articular Surface Replacement (“ASR”) XL acetabular component, a metal-on-metal hip implant.<sup>349</sup> This implant received FDA clearance in July 2008 without a clinical study.<sup>350</sup> According to the 510(k) submission for this device, DePuy listed seven substantially equivalent devices, and “[n]one of the predicates in the ancestry had the same combination of characteristics as the ASR XL acetabular component.”<sup>351</sup> The 510(k) clearance for the ASR focused on characteristics that were a unique combination in the ASR; none of the predicate devices contained all of the same characteristics.<sup>352</sup> Substantial equivalence was based on a comparison of select characteristics “to three prostheses that were used before 1976: the McKee-Farrar, Ring, and Sivash metal-on-metal total hip prostheses,” which were all discontinued long before the clearance of the ASR because “their risk of revision was so much higher than that of other hip prostheses.”<sup>353</sup> Although the device was proven “substantially equivalent” to predicate devices, the device was voluntarily recalled in 2010 due to a lack of safety and effectiveness.<sup>354</sup> The patients themselves effectively served as the clinical trials. As a result, many of them have suffered from pain and permanent damage due to shedding of metallic debris, and they will have to undergo a second operation to remove the defective device.<sup>355</sup>

As the DePuy ASR XL metal-on-metal hip implant demonstrates, the use of multiple predicates to “prove substantial equivalence” does not prove equivalence, or safety and effectiveness, at all. If anything, it merely proves that certain parts of a device are equivalent to characteristics of a predicate device, not the substantial equivalence to the device as a whole. Furthermore, this mischaracterization as “substantially equivalent” can lead to meaningful consequences for the patients, manufacturers, and sellers of such products. As discussed in Part I, Johnson & Johnson is expected to pay billions of dollars in lawsuits related to this one type of hip implant.<sup>356</sup> Injured patients will also have to bear significant costs mentally, physically, and economically.

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349. Ardaugh, *supra* note 221, at 98; *see supra* Part I.

350. Ardaugh, *supra* note 221, at 98.

351. *Id.*

352. *Id.*

353. *Id.*

354. *Id.*

355. *J.&J. Loses First Case*, *supra* note 24.

356. *See supra* Part I.

C. *Creation of a National Medical Device Registry*

The 510(k) process is dependent upon the effectiveness of other components of the medical device regulatory framework.<sup>357</sup> Strengthening the postmarket surveillance system will complement changes made to the premarket regulations.<sup>358</sup> Currently, there is no reliable or centralized system in place for manufacturers all over the world to track medical devices throughout their life span.<sup>359</sup> In turn, it is difficult “to locate actual patients who have received their devices.”<sup>360</sup> “The FDA’s active postmarketing surveillance programs, such as MedSun and MD EpiNet, have potential but will require stable, adequate resources and resolution of various technical issues to achieve their full promise . . . .”<sup>361</sup> In Europe, there are national registries that list *every* device implanted in order to easily track problems.<sup>362</sup> For example, the Medicines and Healthcare Products Regulatory Agency in England has a Medical Devices Register, which lists manufacturers in alphabetical order, as well as the devices that they produce.<sup>363</sup> Independent companies in the United States have also created their own registries, including the Kaiser Permanente health system in California.<sup>364</sup> Kaiser Permanente’s registry keeps track of seventy-five thousand artificial joints and provides doctors valuable data regarding how often they break down.<sup>365</sup> Dr. Thomas Barber, an orthopedic surgeon in California who receives information from Kaiser Permanente’s registry, stated “[w]ithin [twenty-four] hours, we get a printout, by patient and by doctor, of who has those [devices].”<sup>366</sup> He further stated that without that system, hospitals often have to keep track of devices “using a system involving stickers, provided by the manufacturers, pasted into the pages of operating room log books.”<sup>367</sup> The American Academy of Orthopaedic Surgeons also established a

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357. MEDICAL DEVICES AND THE PUBLIC’S HEALTH, *supra* note 47, at 198.

358. Nathaniel Weixel, *FDA Releases Report on Strengthening National Device Postmarket Surveillance Plan*, 6 MED. DEVICES L. & INDUSTRY REP. (2012).

359. *US Has No Good System to Track Medical Implants*, *supra* note 277.

360. MOUZOON & CAROME, *supra* note 49, at 42.

361. MEDICAL DEVICES AND THE PUBLIC’S HEALTH, *supra* note 47, at 198. For a description of MedSun, see *MedSun: Medical Product Safety Network*, available at <http://www.fda.gov/medical-devices/safety/medsunmedicalproductsafetynetwork/default.htm>. For an explanation of MD EpiNet, see *Medical Device Epidemiology Network Initiative (MDEpiNet)*, available at <http://www.fda.gov/MedicalDevices/ScienceandResearch/EpidemiologyMedicalDevices/MedicalDeviceEpidemiologyNetworkMDEpiNet/default.htm>.

362. *CR Investigates*, *supra* note 8 (explaining that “[a]lthough the hip was invented and manufactured by an American company,” the American engineers assured that there were no problems, while “regulators in Australia, England, and Wales were noticing serious problems” and “were able to do so because they have national joint registries”).

363. *Regulation of Medical Devices*, MEDICINE AND HEALTHCARE PRODUCTS REGULATORY AGENCY (Oct. 28, 2013), <http://www.mhra.gov.uk/Howweregulate/Devices/Registrationofmedical-devices/index.htm#1>; *Public Access Database for Medical Device Registration*, MEDICINE AND HEALTHCARE PRODUCTS REGULATORY AGENCY, available at <http://aic.mhra.gov.uk/era/pdr.nsf/name?openpage&start=1&count=200>.

364. *US Has No Good System to Track Medical Implants*, *supra* note 275.

365. *Id.*

366. *Id.* (internal quotation marks omitted).

367. *Id.*

nonprofit organization “with the goal of building a national joint implant registry . . . .”<sup>368</sup> Furthermore, the device registry allows any person to sign up for free and automatically receive e-mails concerning potential safety issues with his or her implant.<sup>369</sup>

Recently, the United States has taken a few steps in the right direction. Initially, the Affordable Care Act proposed a National Medical Device Registry (“NMDR”), established by the Department of Health and Human Services,<sup>370</sup> to “facilitate analysis of postmarket safety and outcomes data on each covered device.”<sup>371</sup> “Covered device” included each Class III device and any Class II device “that is life-supporting or life-sustaining” that the Secretary deemed appropriate.<sup>372</sup> Although the NMDR was not included in the final version of the bill,<sup>373</sup> “its proposed creation is an indicator of the potential future government role of tracking medical devices.”<sup>374</sup> The registry was intended to assist in the evaluation of safety and effectiveness of all implantable medical devices, by linking data provided by manufacturers to the FDA with “outcomes data drawn from many sources, including Medicare claims data and electronic medical records.”<sup>375</sup>

Similar to the Medical Device Registry in England, the NMDR would contain a list of devices, specifying the type, model and serial number, or some other unique identifier.<sup>376</sup> Ideally, the registry would also contain a mechanism to inform the sellers, physicians, and patients immediately of any recalls or problems with the devices. That way, anyone affected by a potentially faulty and hazardous device would be directly informed and could proceed as necessary as soon as possible. As discussed in Part II.B.2.e, the FDA has recently established a rule that most medical devices in the United States carry a UDI.<sup>377</sup> A UDI is a number or alphanumeric code that includes “a Device Identifier, which is specific to a device model, and a Production Identifier, which includes the current production information for that specific device, such as the lot or batch number, the serial number and/or expiration date.”<sup>378</sup>

There are several benefits of unique device identification. First, it will allow for more accurate adverse event reporting and reviewing so that problem devices can be identified and corrected more quickly.<sup>379</sup> A

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368. *Id.*

369. *Id.*

370. Manish K. Sethi et al., *The Affordable Care Act and Medical Devices: What You Need to Know as an Orthopaedic Surgeon*, AAOS NOW (Feb. 2011), <http://www.aaos.org/news/aaosnow/feb11/advocacy2.asp>.

371. H.R. 3962, 111th Cong. (1st Sess. 2009); *see also* Sethi, *supra* note 370.

372. H.R. 3962, 111th Cong. (1st Sess. 2009).

373. *See* Pub. L. No. 111-152, 124 Stat. 1029; *see also* H.R. 3590, 111th Cong. (2d Sess. 2010).

374. Sethi, *supra* note 370.

375. *Id.*

376. *Id.*

377. Unique Device Identification System, *supra* note 250.

378. *Unique Device Identification (UDI) Proposed Rule*, U.S. FOOD & DRUG ADMIN. (July 3, 2012), <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm310872.htm>.

379. Unique Device Identification System, *supra* note 250.

physician from Northwestern University, Dr. Alan Kadish, believes that a well-run national registry is beneficial “because it [can] look at far more patients” than individual studies or small registries.<sup>380</sup> Second, it will enable health care professionals to identify a device and obtain information concerning the characteristics of the device, which can reduce medical errors.<sup>381</sup> Third, the UDI system may enhance the FDA’s analysis of devices on the market “by providing a standard and clear way to document device use in electronic health records, clinical information systems, claim data sources[,] and registries.”<sup>382</sup> Fourth, “a standardized identifier . . . will allow manufacturers, distributors and healthcare facilities to more effectively manage medical device recalls.”<sup>383</sup> An identification system will allow manufacturers to track products throughout their life span.<sup>384</sup> Without a standardized identifier, devices will continue to be recalled without assurance that physicians and patients will be notified.<sup>385</sup> Fifth, UDI may “[l]ead to the development of a medical device identification system that is recognized around the world.”<sup>386</sup> A globalized medical device registry, including unique identification and recall information, would be one of the most effective ways to reduce medical errors and patient injuries around the world, because “this is not just an issue in the United States [it] is an issue across the globe” that needs to be addressed.<sup>387</sup>

## V. CONCLUSION

“He was young. It shouldn’t have happened.”<sup>388</sup> The case of Joshua Oukrup’s faulty ICD is only one of millions that demonstrate a need for change in both the premarket and postmarket regulatory framework for medical devices in the United States. Although the United States has taken a few steps in the right direction, the time has come to implement a real change in the system in order to properly safeguard medical device consumers. This Note attempts to demonstrate that a middle-ground approach altering portions of the premarket and postmarket regulatory framework will be a beneficial way to begin the reformation process, by striking a balance between innovation, safety, and effectiveness.

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380. Barry Meier, *Heart Device Dispute Renews Push for User Registry*, N.Y. TIMES, Feb. 29, 2009, [http://www.nytimes.com/2009/02/27/business/27device.html?\\_r=0](http://www.nytimes.com/2009/02/27/business/27device.html?_r=0).

381. Unique Device Identification System, *supra* note 250.

382. *Unique Device Identification (UDI)*, U.S. FOOD & DRUG ADMIN. (May 15, 2014), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/>.

383. *Id.*

384. See *US Has No Good System to Track Medical Implants*, *supra* note 282.

385. See *id.* (providing several examples of urgent recalls that have failed to reach physicians and patients, such as the Hem-o-lok kidney fastener recall, which had grave effects and continued to be implanted in patients).

386. *Unique Device Identification (UDI)*, *supra* note 382.

387. *US Has No Good System to Track Medical Implants*, *supra* note 275.

388. Axelrod, *supra* note 1.