



**Nova Southeastern University**

---

**From the Selected Works of Marilyn Uzdavines**

---

2018

# Dying For A Solution: The Regulation Of Medical Devices Falls Short In The 21st Century Cures Act

Marilyn Uzdavines

---

NOVA SOUTHEASTERN  
UNIVERSITY

**NSU**  
Florida

Available at: <https://works.bepress.com/>

[marilyn\\_uzdavines/4/](#)

# DYING FOR A SOLUTION: THE REGULATION OF MEDICAL DEVICES FALLS SHORT IN THE 21<sup>ST</sup> CENTURY CURES ACT

Marilyn Uzdavines\*

## TABLE OF CONTENTS

INTRODUCTION .....	630
I. THE HISTORY OF THE FDA REVEALS FAILURE TO KEEP UP WITH TECHNOLOGY .....	633
A. <i>Public Outcry over Harrowing Conditions in Meatpacking         Facilities Prompts the Enactment of the Pure Food and Drug         Act of 1906</i> .....	633
B. <i>The Elixir of Sulfanilamide Tragedy of 1937 Prompts         Congress to Enact the Food and Drug Cosmetic Act of 1938</i> .....	636
C. <i>Thalidomide Tragedy Prompts the Enactment of The         Kefauver-Harris Amendments of 1962</i> .....	637
D. <i>The Dalkon Shield Tragedy Prompts the Enactment of the         Medical Device Amendments of 1976</i> .....	639
E. <i>Further Injuries Prompt the Enactment of the Safe Medical         Devices Act of 1990</i> .....	642
F. <i>Food and Drug Administration Modernization Act of 1997—A         Move for Faster Access to Drugs and Devices</i> .....	643
II. THE 21ST CENTURY CURES ACT DELIVERS FASTER ACCESS WITH LESS OVERSIGHT ON MEDICAL DEVICES .....	644
A. <i>Breakthrough Medical Device</i> .....	645
B. <i>Expanded Class II Exemptions from Premarket Notification</i> .....	645
C. <i>Humanitarian Device Exemption</i> .....	646

---

\* Associate Professor of Law, Nova Southeastern University, Shepard Broad Law Center. I am grateful to Professor Robert L. Schwartz for his help with brainstorming these ideas in the beginning stages of this article. I also truly appreciate the comments I received on this article from Professor Kathy Cerminara and Professor Tamara F. Lawson and all of the attendees of the South Florida Developing Ideas Workshop in June 2016, of which I was privileged to be a part. I would also like to thank Adam Wagner for his valuable research and editing assistance. Finally, I would like to thank my husband for his unfailing support.

III. REGULATION, PREEMPTION AND TORT LAW — A BALANCED APPROACH TO SAFETY AND INNOVATION .....	648
A. <i>Federal Preemption as a “Carrot” to Encourage Manufacturers to Seek Voluntary FDA Approval for Safety</i> .....	649
B. <i>Tort Law as a “Stick” to Encourage Manufacturers to Produce Safe Products</i> .....	653
CONCLUSION .....	654

## INTRODUCTION

On October 19, 2015, Chelsea Patricia Ake-Salvacion, an employee at a Las Vegas health spa, entered one of its cryotherapy chambers after hours for a treatment. She was found dead the next morning as a frozen block of ice.<sup>1</sup> The cryotherapy chamber, touted for the benefits it provides in rejuvenating and healing the body, was not, and is still not, regulated by the United States Food & Drug Administration (“FDA”).<sup>2</sup> This tragedy is not unique. Other dangerous medical devices are slipping past regulations straight to the consumer market because the FDA lacks sufficient resources to monitor new innovations and keep pace with technology.<sup>3</sup>

From its earliest days, the FDA has been charged with a two-fold task—protect the public by regulating the food and drugs it consumes and the devices it uses, while at the same time fostering innovation and ensuring valuable medical products reach those who would benefit from them.<sup>4</sup> Protecting the public is necessary because the public is vulnerable to the manufacturers of medical products. Fostering innovation allows manufacturers to take advantage of the ever-expanding technology and create safe, well-regulated medical products for everyone.

<sup>1</sup> *Woman’s Death Raises Cryotherapy Safety Concerns*, CBS NEWS (Oct. 29, 2015, 1:50 PM), <http://www.cbsnews.com/news/womans-death-raises-cryotherapy-safety-concerns/> [https://perma.cc/62LN-CN4X].

<sup>2</sup> *Whole Body Cryotherapy (WBC): A “Cool” Trend that’s Lacks Evidence, Poses Risks*, U.S. FOOD & DRUG ADMIN. (July 5, 2016), <https://www.fda.gov/forconsumers/consumerupdates/ucm508739.htm> [https://perma.cc/39QE-G8SG]. Only a consumer update was given, not a full review of the product to determine whether it was sufficiently safe or effective to be used by the public.

<sup>3</sup> See Jean Macchiaroli Eggen, *Navigating Between Scylla and Charybdis: Preemption of Medical Device “Parallel Claims,”* 9 J. HEALTH & BIOMEDICAL L. 159, 204 (2013); Neil M. Issar, *Preemption of State Law Claims Involving Medical Devices: Why Increasing Liability for Manufacturers Is a Perilous but Pivotal Proposition*, 17 VAND. J. ENT. & TECH. L. 1085, 1113 (2015).

<sup>4</sup> See JAMES T. O’REILLY & KATHARINE A. VAN TASSEL, FOOD & DRUG ADMINISTRATION § 12:28 (4th ed. 2017); Lars Noah, *The Little Agency That Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 CORNELL L. REV. 901, 901–02 (2008); cf. Charles J. Walsh & Alissa Pyrich, *Rationalizing the Regulation of Prescription Drugs and Medical Devices: Perspectives on Private Certification and Tort Reform*, 48 RUTGERS L. REV. 883, 903 (1996).

The public faces two main vulnerabilities from medical product manufacturers. The first vulnerability arises from the desperation of the sick to be healthy.<sup>5</sup> When a product is touted as “breakthrough” medicine, those who have been told that conventional medicine cannot heal them are given hope, sometimes falsely so. In this same vein, much of the public is desperate to be physically fit or desirable.<sup>6</sup> While this may seem like a modern trend, the allure dates back to the earliest days of the FDA, with products focused on weight loss emerging as early as the late 1800s.<sup>7</sup>

The second form of vulnerability is known as “information asymmetry,” where the seller of a product has more information about its product than the public.<sup>8</sup> As medical devices have become more complex, the level of information asymmetry continues to grow.<sup>9</sup> A manufacturer knows virtually everything about the mechanics of its device, while the public knows less—sometimes significantly less.

Unfortunately, as the manufacturers innovate and create new products, the FDA is only able to react when a new product comes on the market. A review of the FDA legislative history clearly shows the cycle of high profile catastrophes followed by legislation—a continuous cycle of the FDA playing “catch up” with innovation.<sup>10</sup> The legislative history is marked more with reaction to tragedy than of comprehensive foresight.<sup>11</sup> Technology has consistently outpaced legislation, even dating back to the early 20<sup>th</sup> century, leaving some drugs and devices outside of the purview of the FDA.<sup>12</sup> Further frustrating the FDA’s purpose, manufacturers have continued to evade regulation by finding

<sup>5</sup> O’REILLY & TASSEL, *supra* note 4, at § 12:9.

<sup>6</sup> Katharine A. Van Tassel, *Slaying the Hydra: The History of Quack Medicine, the Obesity Epidemic and the FDA’s Battle to Regulate Dietary Supplements Marketed as Weight Loss Aids*, 6 IND. HEALTH L. REV. 203, 205–06 (2009).

<sup>7</sup> Frank Whittemore, *The History of Diet Pills*, LIVESTRONG.COM (July 18, 2017), <http://www.livestrong.com/article/74336-history-diet-pills/> [https://perma.cc/D88E-DA4Q]; see also Denise Grady, *History Counsels Caution on Diet Pills*, N.Y. TIMES (May 25, 1999), <http://www.nytimes.com/1999/05/25/health/history-counsels-caution-on-diet-pills.html> [https://perma.cc/CDU9-FY2X].

<sup>8</sup> ROBERT COOTER & THOMAS ULEN, LAW & ECONOMICS 46 (5th ed. 2008) (When sellers know more about a product than do buyers, or vice versa, information is said to be distributed asymmetrically in the market. Under some circumstances, these asymmetries can be corrected by the mechanism of voluntary exchange, for example, by the seller’s willingness to provide a warranty to guarantee the quality of a product. But severe asymmetries can disrupt markets so much that a social optimum cannot be achieved by voluntary exchange. When that happens, government intervention in the market can ideally correct for the informational asymmetries and induce more nearly optimal exchange).

<sup>9</sup> The tongue depressor has very little, if any, information asymmetry—a patient can ascertain all of the relevant information about the product. 21 C.F.R. § 880.6230 (2017). On the other hand, the public has a nearly impossible task in assessing the safety and efficacy of a pace maker, for example.

<sup>10</sup> See *infra* Part II, Sections B–E.

<sup>11</sup> O’REILLY & VAN TASSEL, *supra* note 4, at § 12:28.

<sup>12</sup> *Id.*

loopholes in ambiguously drafted legislation regarding what constitutes a “medical device.”<sup>13</sup>

Furthermore, past FDA legislation has placed too high a burden on the FDA in regulating medical products and has failed to account for the limitation of resources at the agency’s disposal. In its earliest incarnation, the FDA had the almost impossible burden of proving the danger of a product.<sup>14</sup> And in more recent years, the reporting requirements for manufacturers of medical devices were so burdensome that the FDA had neither the ability nor the resources to adequately process them.<sup>15</sup> The result has been inconsistent regulation of potentially harmful products.

Each piece of legislation enacted to improve food and drug safety over the last one hundred years has consistently taken a myopic view of the agency’s duty to the public. Each amendment has chosen to focus on either protecting the public by expanding the scope of FDA regulation,<sup>16</sup> thereby increasing the burden on manufacturers to bring products to market, or on fostering innovation and the public’s access to drugs and devices,<sup>17</sup> thereby reducing the burden on manufacturers without accounting for impact on safety to the public. Additionally, at each stage, the resource limitations of the FDA have been ignored.<sup>18</sup> At no point has a comprehensive approach been taken, where *both* the vulnerable public and the burden on manufacturers has been the focus, while at the same time attempting to reduce the burden on the FDA by utilizing other tools at the legislature’s disposal.

This article highlights problems with the current medical device regulatory scheme and offers solutions that both reduce the impact on the FDA’s resources and allow for tort law to balance the scales between manufacturer and public. Part II of this article will explore the last century of the FDA and its evolution through the tragedies it has witnessed. It will show how the FDA has oscillated between excessive regulations and failing to adequately regulate drugs and devices. It will also discuss the various Acts that have shaped the agency through today, from the Pure Food and Drug Act of 1906 (“PFDA”), which formed the initial incarnation of the FDA, through the Food and Drug Administration

---

<sup>13</sup> See Susan Bartlett Foote, *The Impact of Public Policy on Medical Device Innovation: A Case of Polyintervention*, in 2 MEDICAL INNOVATION AT THE CROSSROADS, THE CHANGING ECONOMICS OF MEDICAL TECHNOLOGY 69, 76 (Annetine C. Gelijns & Ethan A. Halm eds., 1991).

<sup>14</sup> O’REILLY & VAN TASSEL, *supra* note 4.

<sup>15</sup> U.S. GOV’T GEN. ACCOUNTING OFF., GAO/HEHS-97-21, MEDICAL DEVICE REPORTING: IMPROVEMENTS NEEDED IN FDA’S SYSTEM FOR MONITORING PROBLEMS WITH APPROVED DEVICES 2–3, 5, 9, 11 (1997).

<sup>16</sup> See Drug Amendments of 1962, Pub. L. No. 87-781, §§ 101, 107, 76 Stat. 780, 780–81, 788–89 (1962); Deborah G. Parver, *Expediting the Drug Approval Process: An Analysis of the FDA Modernization Act of 1997*, 51 ADMIN. L. REV. 1249, 1252–53 (1999).

<sup>17</sup> See 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016); see also U.S. FOOD & DRUG ADMIN., FDA STRATEGIC PRIORITIES 2014–2018 (2014).

<sup>18</sup> Noah, *supra* note 4, at 902.

Winter 2018]

DYING FOR A SOLUTION

633

Modernization Act of 1997 (“FDAMA”), which attempted—but failed—to give the public quicker access to medical devices.<sup>19</sup>

Part III of this article begins by explaining relevant portions of the newly enacted 21st Century Cures Act (“21CCA”) that pertain to regulation of medical devices. This Part will discuss how the new legislation failed to heed the mistakes of past Acts governing the FDA. While in spirit the Act purports to grant patients faster access to new medical products, it ignores the limitations of the FDA and disregards the role the public could play in achieving its ultimate goal.

Finally, in Part IV, this Article will explain how utilizing economic forces is critical in crafting legislation to effectively regulate medical devices. This Part will examine potential revisions to the 21CCA that could accomplish the goal of getting products to market that genuinely help the public, while putting checks in place to restrict harmful products from reaching the public. I propose using a combination of deregulation, tort law, and federal preemption power as tools to achieve this goal.

#### I. THE HISTORY OF THE FDA REVEALS FAILURE TO KEEP UP WITH TECHNOLOGY

##### A. *Public Outcry over Harrowing Conditions in Meatpacking Facilities Prompts the Enactment of the Pure Food and Drug Act of 1906*

*There would be meat that had tumbled out on the floor, in the dirt and sawdust, where the workers had tramped and spit uncounted billions of consumption germs. There would be meat stored in great piles in rooms; and the water from leaky roofs would drip over it, and thousands of rats would race about on it. . . . This is no fairy story and no joke; the meat would be shovelled into carts, and the man who did the shovelling would not trouble to lift out a rat even when he saw one—there were things that went into the sausage in comparison with which a poisoned rat was a tidbit.*<sup>20</sup>

In 1906, President Roosevelt signed into law the first piece of legislation that aimed at protecting the public from certain foods and drugs.<sup>21</sup> Although nearly one hundred bills had been introduced to Congress up to that point, it was not until public outcry over the nauseating conditions in the meatpacking industry were exposed that a law was enacted to protect the public.<sup>22</sup> It was in

<sup>19</sup> Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997); Pure Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768, *repealed by* Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 301 (1938).

<sup>20</sup> UPTON SINCLAIR, *THE JUNGLE* 161–62 (1906).

<sup>21</sup> *FDA's Origins & Functions Part I: The 1906 Food and Drug Act and Its Enforcement*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/aboutfda/whatwedo/history/origin/ucm054819.htm> [https://perma.cc/7GE2-RBM2] (last updated Feb. 1, 2018).

<sup>22</sup> *Id.*

1906 that Upton Sinclair published *The Jungle*, which highlighted the plight of immigrant workers in industrialized cities.<sup>23</sup> The book had an unintended effect in that it also portrayed the unsanitary conditions of meatpacking facilities. The public was outraged by this exposé of the meatpacking industry,<sup>24</sup> resulting in a public movement to reform the food industry and, ultimately, in the passage of the PFDA of 1906.<sup>25</sup> The PFDA created an agency within the Department of Agriculture called the Bureau of Chemistry, which was tasked with preventing and prosecuting the manufacture of food or drugs that were “adulterated or misbranded.”<sup>26</sup> This legislation did not require manufacturers to prove that food and drugs were safe or effective, only that the food and drugs were not adulterated or misbranded.<sup>27</sup> As discussed below, the Bureau of Chemistry was the agency that would eventually be renamed the Food and Drug Administration (“FDA”). For continuity in this article, the agency will be referred to as “the FDA,” even when describing its previous incarnations.

The FDA was largely ineffective in its early attempts to protect the public from unsafe products. The PFDA placed the burden of proof about a product’s claims not on the manufacturer, but on the FDA.<sup>28</sup> The lack of data for adverse events and insufficient scientific evidence of a product’s effects on people led to a string of losses for the FDA in prosecuting manufacturers for harmful products.<sup>29</sup> The result was that unsafe or misleading products continued to be freely sold in the market while dishonest manufacturers profited off of the uninformed public.<sup>30</sup> The poorly-drafted PFDA evidenced a failure by Congress to understand the nature of technology, especially the speed at which it advances. The PFDA was focused only on preventing food or drugs from being adulterated or misbranded.<sup>31</sup> Drugs deemed adulterated are those sold under a recog-

<sup>23</sup> See generally SINCLAIR, *supra* note 20.

<sup>24</sup> Shauna Manion, *A Science-Based Endeavor: Interpreting Contamination Prevention in The Food Safety Modernization Act*, 117 PENN ST. L. REV. 537, 540–41 (2012).

<sup>25</sup> Baylen J. Linnekin & Emily M. Broad Leib, *Food Law & Policy: The Fertile Field’s Origins and First Decade*, 2014 WIS. L. REV. 557, 562 (2014); see also *The Pure Food and Drug Act*, U.S. HOUSE OF REPRESENTATIVES: HISTORY, ART & ARCHIVES, <http://history.house.gov/HistoricalHighlight/Detail/15032393280> [https://perma.cc/GBM3-RTJ7] (last visited Feb. 27, 2017).

<sup>26</sup> Pure Food and Drugs Act of 1906, ch. 3915, § 4, 34 Stat. 768 (1906), *repealed by* Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 301 (1938), *amended by* Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 126(B), 111 Stat. 2296 (1997); Jeffrey E. Shuren, *The Modern Regulatory Administrative State: A Response to Changing Circumstances*, 38 HARV. J. ON LEGIS. 291, 300 (2001).

<sup>27</sup> Shuren, *supra* note 26.

<sup>28</sup> O’REILLY & VAN TASSEL, *supra* note 4, at § 12:4. At this time in its history, the FDA regulated only false labeling, and not safety and efficacy of drugs; see Sue McGrath, Note, *Only a Matter of Time: Lessons Unlearned at the Food and Drug Administration Keep Americans at Risk*, 60 FOOD & DRUG L.J. 603, 604 (2005).

<sup>29</sup> O’REILLY & VAN TASSEL, *supra* note 4, at § 12:4; see also *Seven Cases v. United States*, 239 U.S. 510, 511 (1916); *United States v. Johnson*, 221 U.S. 488, 495 (1911).

<sup>30</sup> O’REILLY & VAN TASSEL, *supra* note 4, at § 12:6.

<sup>31</sup> Shuren, *supra* note 26.

nized name but differ from the standards of strength, quality or purity as set forth in the United States Pharmacopoeia or National Formulary or those which fall below the professed standard or quality under which it is sold.<sup>32</sup> As for food, there are many ways in which they may become adulterated.<sup>33</sup> These include but are not limited to foods in which a substance is mixed or packed with it which reduces or lowers its quality or strength; the food is altered to conceal damage or inferiority; or if the foods contain any added poisonous or other deleterious ingredients which may render the food harmful to one's health.<sup>34</sup> A food or drug becomes misbranded when the package or label bears any statement, design, or device which is either false or misleading in any way.<sup>35</sup> Unfortunately, the legislation did not account for the fact that new technology would have a dramatic impact on the way food and drugs were processed.

One such technological advancement that outpaced the PFDA was food processing.<sup>36</sup> The fast freezing machine was invented in 1924, and by the 1930s packaged food had begun a revolution.<sup>37</sup> The problem for consumers was that they had no means of knowing exactly what was in packaged foods.<sup>38</sup> Additionally, a proviso in the PFDA carved out an exception for products marketed under a "distinctive name," meaning they could not be prosecuted as adulterated or misbranded.<sup>39</sup> One example was "BRED-SPRED," a purported strawberry jelly that contained no strawberries, but did contain "highly carcinogenic coal tar, several chemical preservatives, artificial chemical pectin, artificial chemical flavorings, and grass seeds to add a touch of realism."<sup>40</sup> Though under the Act it would have been deemed both adulterated and misbranded, due to the carve-out, BRED-SPRED was unregulated, as were a plethora of other products, such as milk being watered down and preserved with formaldehyde.<sup>41</sup> The result was a public unable to make informed decisions due to the lack of information and agency oversight.<sup>42</sup>

This same harm befell the public when it came to drugs. There was no requirement in place to require that medical products on the market be either safe

---

<sup>32</sup> Pure Food and Drugs Act of 1906, ch. 3915, § 7, 34 Stat. 768, *repealed by* Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 301 (1938).

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* § 8.

<sup>36</sup> O'REILLY & VAN TASSEL, *supra* note 4, at § 12:7.

<sup>37</sup> *Id.*

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

<sup>39</sup> *United States v. Forty Barrels & Twenty Kegs of Coca-Cola*, 191 F. 431, 434 (E.D. Tenn. 1911), *rev'd*, 241 U.S. 265 (1916).

<sup>40</sup> O'REILLY & VAN TASSEL, *supra* note 4, at § 12:7.

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*



or effective.<sup>43</sup> Drugs and devices touted false therapeutic claims, and the law as written did not protect the public from these scams.<sup>44</sup> It would take another high profile catastrophe resulting in public outcry to urge Congress to pass additional legislation to protect the public.<sup>45</sup> In 1938, Congress took steps to repeal the PFDA and enacted new legislation with a goal to protect the vulnerable public from untested and potentially dangerous drugs that purported to increase an individual's health.<sup>46</sup>

*B. The Elixir of Sulfanilamide Tragedy of 1937 Prompts Congress to Enact the Food and Drug Cosmetic Act of 1938*

Although a bill to strengthen the regulations of food and drugs had been languishing in Congress for nearly five years, tragedy was the catalyst that finally prompted the repeal of the PFDA.<sup>47</sup> A manufacturer that previously produced an antibiotic pill called sulfanilamide offered the product “‘Elixir of Sulfanilamide,’” which was a liquid version of the antibiotic meant to treat bacterial infections in children.<sup>48</sup> To create the solution, the manufacturer combined the antibiotic with diethylene glycol—known today as a major component in antifreeze.<sup>49</sup> The result was the deaths of over 100 people, the majority of them children.<sup>50</sup> Additionally, the chemist who created the solution committed suicide after the incident.<sup>51</sup> Even worse, this tragedy was avoidable; proper vetting of the drug would have stopped its production before ever reaching the market.<sup>52</sup>

The result of the “Elixir of Sulfanilamide” tragedy was the passage of the Federal Food, Drug, and Cosmetic Act of 1938 (“FDCA”).<sup>53</sup> Initially introduced in 1933, but not passed until after the “Elixir” incident, the FDCA re-

<sup>43</sup> Sheryl Lawrence, *What Would You Do with a Fluorescent Green Pig?: How Novel Transgenic Products Reveal Flaws in the Foundational Assumptions for the Regulation of Biotechnology*, 34 *ECOLOGICAL L.Q.* 201, 215 (2007).

<sup>44</sup> O'REILLY & VAN TASSEL, *supra* note 4, at § 12:4; *see generally* United States v. Johnson, 221 U.S. 488 (1911) (where a drug label improperly implied the contents were effective in curing cancer).

<sup>45</sup> Noah, *supra* note 4, at 901 (discussing the Elixir Sulfanilamide tragedy); Van Tassel, *supra* note 6, at 223–24.

<sup>46</sup> Lawrence, *supra* note 43, at 215.

<sup>47</sup> McGrath, *supra* note 28 at 604.

<sup>48</sup> Karen Baswell, Note, *Time for a Change: Why the FDA Should Require Greater Disclosure of Differences of Opinion on the Safety and Efficacy of Approved Drugs*, 35 *HOFSTRA L. REV.* 1799, 1809 (2007).

<sup>49</sup> McGrath, *supra* note 28 at 604.

<sup>50</sup> Nancy E. Pirt, *Regulation of the Export of Pharmaceuticals to Developing Countries*, 25 *DUQ. L. REV.* 255, 259 (1987).

<sup>51</sup> *Id.*

<sup>52</sup> “What the chemist who invented the elixir did not know, although others did, was that diethylene glycol, when ingested, would convert into deadly oxalic acid, a poison that destroys the kidneys.” *Id.*

<sup>53</sup> Baswell, *supra* note 48, at 1809.

quired a drug to be safe based on its intended use per the labeling.<sup>54</sup> Additionally, a seminal feature of the FDCA was that it expanded the FDA's scope to include medical devices.<sup>55</sup>

Until 1938, the FDA had no jurisdiction over medical devices. But by that time, Congress had become concerned with the rise in fraudulent medical devices being marketed.<sup>56</sup> The FDCA granted the FDA the authority to regulate post-market devices for misbranding and adulteration, but stopped short of giving the FDA pre-market review.<sup>57</sup> However, it did grant pre-market safety review of drugs, maintaining the disparity in FDA oversight between devices and drugs.<sup>58</sup> The FDCA also established a tenet of the FDA's purpose: that regulation should match "the level of vulnerability of the product's targeted population."<sup>59</sup> The FDCA of 1938 is still in effect today, but it has been amended many times since its inception.

*C. Thalidomide Tragedy Prompts the Enactment of The Kefauver-Harris Amendments of 1962*

The first major amendment to the FDCA came in 1962 after yet another tragedy involving a manufactured drug.<sup>60</sup> A sleeping pill called thalidomide was being marketed over the counter as "completely safe" for everyone from mothers to children. The drug was widely used by consumers, and was reportedly as prevalent as aspirin in the late 1950s.<sup>61</sup> The drug was also recommended by doctors as an off-label way to treat pregnant women with morning sickness.<sup>62</sup> However, doctors began to notice that the women that had used thalidomide while pregnant were giving birth to babies with severe birth defects.<sup>63</sup> The mothers who had taken the drug during pregnancy had a high likelihood of

---

<sup>54</sup> J. Richard Crout et al., *FDA's Role in the Pathway to Safe and Effective Drugs*, in *FDA: A CENTURY OF CONSUMER PROTECTION* 163 (Wayne L. Pines ed., 2006); see also O'REILLY & VAN TASSEL, *supra* note 4, at § 12:11.

<sup>55</sup> Ann Mileur Boeckman, *An Exercise in Administrative Creativity: The FDA's Assertion of Jurisdiction over Tobacco*, 45 CATH. U.L. REV. 991, 996–97 (1996).

<sup>56</sup> Kyle Lennox, *Substantially Unequivalent: Reforming FDA Regulation of Medical Devices*, 2014 U. ILL. L. REV. 1363, 1376–77 (2014).

<sup>57</sup> *Id.* at 1377.

<sup>58</sup> *Id.*

<sup>59</sup> O'REILLY & VAN TASSEL, *supra* note 4, at § 12:8. Discussed below, this vulnerability is greater today than ever.

<sup>60</sup> Bara Fintel et al., *The Thalidomide Tragedy: Lessons for Drug Safety and Regulation*, *HELIX MAG.* (July 28, 2009), <https://helix.northwestern.edu/article/thalidomide-tragedy-lessons-drug-safety-and-regulation> [<https://perma.cc/S935-QTVH>].

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

<sup>62</sup> *Id.*

<sup>63</sup> Michael Winierip, *The Death and Afterlife of Thalidomide*, *N.Y. TIMES* (Sept. 23, 2013), <http://www.nytimes.com/2013/09/23/booming/the-death-and-afterlife-of-thalidomide.html> [<https://perma.cc/8L5U-FS3S>].

having a child born with phocomelia, resulting in missing or deformed limbs.<sup>64</sup> Over ten thousand babies were reportedly born with this condition, and nearly 50 percent of those babies did not survive.<sup>65</sup>

The citizens of the United States did not endure this tragedy first-hand because the FDA had wisely blocked the use of thalidomide in the United States.<sup>66</sup> At that point in history, a pre-market approval was required to show the safety of a drug.<sup>67</sup> Data on thalidomide's safety, especially regarding pregnant women, was insufficient, so FDA inspector Frances Kelsey prevented the drug's approval in the United States despite pressure from the pharmaceutical company and FDA supervisors. Regulators had done their job to protect the public, but this unimaginable worldwide tragedy raised questions as to whether more regulations were needed to protect the public.<sup>68</sup> Public concern grew over the number of other products entering the market for which manufacturers were not required to show efficacy.<sup>69</sup> The result was the 1962 Kefauver-Harris Amendments, which changed the law to require manufacturers to show "safety and efficacy" before marketing new drugs.<sup>70</sup> The amendment also blurred the line between drug and device, with the definitions "overlapping" each other.<sup>71</sup> As a result of these overlapping definitions, the FDA began to regulate new devices in the same way as drugs, requiring them to undergo the same pre-market approval process.<sup>72</sup> However, despite a few judicial victories where a court was convinced that a device should be regulated the same as drugs, continuous litigation proved too difficult for the FDA to continue enforcing pre-market approval on devices.<sup>73</sup> The ambiguity in the statute, combined with the significant increase of medical devices in the 1960s and 1970s, made it clear that the statu-

---

<sup>64</sup> Henry N. Butler, *REMS-Restricted Drug Distribution Programs and the Antitrust Economics of Refusals to Deal with Potential Generic Competitors*, 67 FLA. L. REV. 977, 1005–06 (2015).

<sup>65</sup> *Id.*

<sup>66</sup> Michael I. Krauss, *Loosening the FDA's Drug Certification Monopoly: Implications for Tort Law and Consumer Welfare*, 4 GEO. MASON L. REV. 457, 467 n.47 (1996).

<sup>67</sup> *Id.* at 461–62.

<sup>68</sup> Van Tassel, *supra* note 6, at 228.

<sup>69</sup> Jordan Bauman, *The "Déjà Vu Effect:" Evaluation of United States Medical Device Legislation, Regulation, and the Food and Drug Administration's Contentious 510(k) Program*, 67 FOOD & DRUG L.J. 337, 340 (2012). "Later, it was discovered that Thalidomide had already been provided to 20,000 patients in the United States as part of an 'investigational study' while Thalidomide's application for approval was on hold." O'REILLY & VAN TASSEL, *supra* note 4, at § 12:16.

<sup>70</sup> O'REILLY & VAN TASSEL, *supra* note 4, at § 12:16.

<sup>71</sup> Bauman, *supra* note 69, at 340.

<sup>72</sup> *Id.*

<sup>73</sup> *Id.* Although the FDA was successful in convincing courts to declare some devices as drugs under the statute—and therefore subject to premarket review—it clearly could not maintain litigating those types of cases in perpetuity. *See* AMP, Inc. v. Gardner, 389 F.2d 825, 829–30 (2d Cir. 1968), *cert. denied*, AMP, Inc. v. Cohen, 393 U.S. 825, 825 (1968).

Winter 2018]

DYING FOR A SOLUTION

639

tory language was insufficient to adequately protect the public from harmful devices.<sup>74</sup>

Thus, once again, the FDA found itself chained to legislation that failed to account for the pace of technological innovation and failed to account for the limited resources available to the agency. In September 1970, Dr. Theodore Cooper submitted a report on a ten-year study of medical devices to the secretary of the Department of Health, Education, and Welfare.<sup>75</sup> The study “revealed over 731 deaths and 9,000 injuries from medical devices.”<sup>76</sup> Dr. Cooper’s opinion was that, due to the increasing amount and complexity of medical devices entering the market and the variance in issues presented by devices compared to drugs, the FDA should revamp its method in regulating devices.<sup>77</sup> Not unlike the FDCA of 1938, which was presented years before it was enacted and only passed in response to tragedy, Dr. Cooper’s report produced no formal legislation until 1976, when another product was linked to mass injury and death.<sup>78</sup>

#### D. *The Dalkon Shield Tragedy Prompts the Enactment of the Medical Device Amendments of 1976*

The Dalkon Shield entered the market in 1970 as a device designed to prevent pregnancy.<sup>79</sup> When placed in the uterus, part of the Dalkon Shield was exposed through the cervix to allow for easier removal.<sup>80</sup> The composition of the “tail” that was exposed compromised the sterile environment of the uterus, leading to complications and infections.<sup>81</sup> In 1974, after receiving reports of ineffectiveness, infections, and even deaths, the manufacturer was forced to pull the device from the market.<sup>82</sup> In the end, the manufacturer faced over three hundred thousand complaints over the Dalkon Shield.<sup>83</sup>

In addition, a report was issued that pointed to ten thousand device-related injuries and 751 deaths from 1960 to 1970.<sup>84</sup> This report recommended legisla-

<sup>74</sup> Bauman, *supra* note 69, at 340. See *United States v. Bacto-Unidisk*, 394 U.S. 784, 798–99 (1969); *Gardner*, 389 F.2d at 830, *cert. denied*, *Cohen*, 393 U.S. at 825 (1968).

<sup>75</sup> INST. OF MED., MEDICAL DEVICES AND THE PUBLIC’S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 213 (2011), <https://www.nap.edu/read/13150/chapter/1> [https://perma.cc/H8ZP-7F68].

<sup>76</sup> Mindy H. Chapman, *Rx: Just What the Doctor Ordered: International Standards for Medical Devices*, 14 NW. J. INT’L L. & BUS. 566, 573 (1994).

<sup>77</sup> *Id.* at 573–74.

<sup>78</sup> *Id.* at 574.

<sup>79</sup> Tamsen Valoir & Shubha Ghosh, *FDA Preemption of Drug and Device Labeling: Who Should Decide What Goes on a Drug Label?*, 21 HEALTH MATRIX 555, 567 (2011).

<sup>80</sup> *Id.*

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

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

<sup>83</sup> *Id.* at 568.

<sup>84</sup> This report was completed in 1970 by the blue-ribbon Cooper Committee (a study group on medical devices convened in 1969 by the Secretary of Health, Education, and Welfare).

tive reform of medical device regulation.<sup>85</sup> Congress finally acted in 1976 by passing the Medical Device Amendments (“MDA”) in which many of Dr. Cooper’s recommendations were implemented.<sup>86</sup>

The MDA’s primary purpose was to ensure devices were safe and effective.<sup>87</sup> Devices were now grouped by level of risk and intended use into three classes: Class I being the lowest risk and Class III being the highest risk.<sup>88</sup> Currently, Class I devices account for 47 percent of medical devices, have a very simple design, and present minimal risk.<sup>89</sup> Some examples of Class I devices would be tongue depressors or cold packs.<sup>90</sup> Approximately 43 percent of medical devices are considered Class II.<sup>91</sup> These devices are more complicated and have more risk than Class I devices, but are not life-sustaining.<sup>92</sup> Examples of Class II devices include contact lenses or powered wheelchairs.<sup>93</sup> Finally, Class III devices account for approximately 10 percent of devices on the market; they sustain or support life and carry an unreasonably high risk of harm.<sup>94</sup> Examples of Class III devices include breast implants or cardiac pacemakers.<sup>95</sup> The level of regulation required for each product depends on its level of classification.<sup>96</sup>

In addition to the general controls to which all devices must adhere,<sup>97</sup> Class I and Class II devices are required to fulfill pre-market notification requirements.<sup>98</sup> The pre-market notification requires the manufacturer to register its

---

Robert B. Leflar, *Public Accountability and Medical Device Regulation*, 2 HARV. J.L. & TECH. 1, 6, 6 n.15 (1989).

<sup>85</sup> *Id.*

<sup>86</sup> Bauman, *supra* note 69, at 341.

<sup>87</sup> *Id.*

<sup>88</sup> 21 U.S.C. § 360c(a) (2012).

<sup>89</sup> *Learn If a Medical Device Has Been Cleared by FDA for Marketing*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/MedicalDevices/ResourcesforYou/Consumers/ucm142523.htm> [<https://perma.cc/5CNK-E863>] (last updated Dec. 29, 2017).

<sup>90</sup> Stephen D. Harris, *Preemption of State Tort Claims Under the Medical Device Amendments*, 24 COLO. LAW. 2217, 2217 (1995).

<sup>91</sup> David Chang, *Internalizing the External Costs of Medical Device Preemption*, 65 HASTINGS L.J. 283, 288 (2013).

<sup>92</sup> Robin Helmick Turner, *Preemption of State Product Liability Claims Involving Medical Devices: Premarket Approval as a Shield Against Liability*, 72 WASH. L. REV. 963, 966–67 (1997).

<sup>93</sup> Alex Krouse, *iPads, iPhones, Androids, and Smartphones: FDA Regulation of Mobile Phone Applications as Medical Devices*, 9 IND. HEALTH L. REV. 731, 747 (2012); Walsh & Pyrich, *supra* note 4, at 919.

<sup>94</sup> Chang, *supra* note 91, at 288–89.

<sup>95</sup> Issar, *supra* note 3, at 1089 n.24 (2015).

<sup>96</sup> Turner, *supra* note 92, at 966.

<sup>97</sup> *Class I/II Exemptions*, U.S. FOOD & DRUG ADMIN. <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051549.htm> [<https://perma.cc/G396-NQFU>] (last updated June 26, 2014).

<sup>98</sup> 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, 906 (2008).

intent to market a medical device with the FDA.<sup>99</sup> The FDA offers a limited review process for qualifying devices that are substantially equivalent to a pre-existing device.<sup>100</sup> This process is known as the 510(k) process, and the focus is on equivalence rather than safety.<sup>101</sup> Statute 510(k) requires that the manufacturer establish that the device was either legally on the market before May 28, 1976, or that the device is substantially equivalent to a device marketed before that date.<sup>102</sup> Today, as discussed below, most Class I devices are exempt from this requirement because they pose little risk to the public.<sup>103</sup> However, most Class II devices are *not exempt* from this requirement.<sup>104</sup> If a Class II device does not meet the substantial equivalence test, it will have to go through the Class III pre-market approval process.<sup>105</sup> Finally, Class III devices must undergo the more rigorous pre-market approval process, which requires manufacturers to produce significant amounts of data that prove the product is safe and effective through clinical trials.<sup>106</sup>

Although the MDA created additional protections for the public, it still contained massive flaws. First, the “grandfather clause” allowed dangerous devices to remain on the market so long as they had been on the market prior to May 28, 1976.<sup>107</sup> Even worse, manufacturers were not required to test designs and materials prior to manufacturing.<sup>108</sup> This left medical devices with fatal flaws on the market at a time when the public “[i]ronically . . . finally felt more confident that medical devices were safe for use when the FDA approved them.”<sup>109</sup> Additionally, this new regulatory scheme did not account for the increased burden on the FDA and did not provide additional resources to meet that burden.<sup>110</sup> This resulted in regulations being enacted with an agency that lacked the resources to enforce them.

---

<sup>99</sup> Turner, *supra* note 92, at 967.

<sup>100</sup> Lewis v. Johnson & Johnson, 991 F. Supp. 2d 748, 751 (S.D. W. Va. 2014).

<sup>101</sup> *Id.* at 752.

<sup>102</sup> Daniel W. Whitney, *Guide to Preemption of State-Law Claims Against Class III PMA Medical Devices*, 65 FOOD & DRUG L.J. 113, 115–16 (2010).

<sup>103</sup> Flaherty, Jr., *supra* note 98, at 906.

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

<sup>106</sup> See Elliot Sheppard Tarloff, *Medical Devices and Preemption: A Defense of Parallel Claims Based on Violations of Non-Device Specific FDA Regulations*, 86 N.Y.U. L. REV. 1196, 1198–99 (2011).

<sup>107</sup> Chapman, *supra* note 76, at 575.

<sup>108</sup> *Id.*

<sup>109</sup> *Id.*

<sup>110</sup> Amanda Swanson, *510(k) Clearance: Opportunities to Incentivize Medical Device Safety Through Comparative Effectiveness Research*, 10 IND. HEALTH L. REV. 117, 153–54 (2013).

*E. Further Injuries Prompt the Enactment of the Safe Medical Devices Act of 1990*

Following the MDA of 1976, more reports of faulty devices dotted the headlines. In one case, sixty to eighty thousand patients received a faulty jaw implant designed to treat TMJ.<sup>111</sup> The implant would disintegrate when the patient chewed, resulting in “nausea, infections, dizziness, hearing and sight loss.”<sup>112</sup> The device was not reviewed before going to market because it was considered substantially equivalent to other jaw implants.<sup>113</sup> The weaknesses in the MDA were first addressed by the Safe Medical Devices Act of 1990 (“SMDA”).<sup>114</sup> The SMDA was necessary because implementing the MDA regulations was proving too difficult for the FDA.<sup>115</sup> The statutory language of the MDA was overly complex, the language was interpreted with conflicting results, and the FDA lacked the necessary resources to properly implement the regulations.<sup>116</sup>

In response to these flaws, the SMDA sought to prevent additional injuries from substantially equivalent devices by expanding the reporting requirements for devices.<sup>117</sup> Originally, only manufacturers had a duty to report the adverse effects of a device.<sup>118</sup> But the SMDA required hospitals and health care facilities to report any problems with a device.<sup>119</sup> Additionally, this amendment attempted to clarify the definition of “substantial equivalence” for new devices, and expanded recall authority of the FDA.<sup>120</sup>

But the SMDA created a scenario which overwhelmed the FDA. The FDA could not adequately process and document the massive flood of information

<sup>111</sup> Chapman, *supra* note 76, at 575.

<sup>112</sup> *Id.* at 575–76.

<sup>113</sup> *Id.* at 575.

<sup>114</sup> Bauman, *supra* note 69, at 346.

<sup>115</sup> H.R. REP. NO. 101-808, at 13 (1990), *reprinted in* 1990 U.S.C.C.A.N. 6305, 6306. The full section reads:

Since the comprehensive medical device law was enacted in 1976, difficulties have persisted in the implementation of the law. These implementation problems appear to be the result of: (1) complexities in the law; (2) the manner in which FDA interpreted certain provisions of the 1976 law; and (3) limited resources. The purpose of this legislation is to modify the underlying law in ways that will result in greater protection of the public health.

*Id.*

<sup>116</sup> *Id.*

<sup>117</sup> Michael VanBuren, *Closing the Loopholes in the Regulation of Medical Devices: The Need for Congress to Reevaluate Medical Device Regulation*, 17 HEALTH MATRIX 441, 458 (2007).

<sup>118</sup> Medical Device Amendments of 1976, Pub. L. No. 94-295, § 519, 90 Stat. 539, 564–65 (1976).

<sup>119</sup> Safe Medical Devices Act of 1990, 21 U.S.C. § 360i(b)(1)(A) (2012); Chapman, *supra* note 76, at 576.

<sup>120</sup> Bauman, *supra* note 69, at 348–49; Chapman, *supra* note 76, at 576.

and data from adverse events.<sup>121</sup> The lack of FDA resources was one explanation for the shortcomings of the SMDA.<sup>122</sup> Manufacturers complained that the regulatory process was hindering products from getting to market due to the “burdensome, expensive, and time-consuming” process.<sup>123</sup> A House Committee report summarized the problem with a familiar mantra: “[T]he current regulatory system is not keeping pace with medical innovation.”<sup>124</sup> The introduction of the SMDA was a positive step for the FDA, but without the resources to implement and monitor the new regulations, the FDA continued to fall behind while technology continued moving forward.

*F. Food and Drug Administration Modernization Act of 1997—A Move for Faster Access to Drugs and Devices*

In 1997, the legislature responded to the call for better patient access to medical devices and drugs with the FDAMA.<sup>125</sup> In part, the FDAMA used a risk-based approach to the regulation of medical devices and introduced several new concepts in hopes of making the approval process more efficient.<sup>126</sup> One of these new concepts, in an acknowledgement of the FDA’s lack of resources to timely review applications, was authorization of third-party reviewers for Class I and some Class II products.<sup>127</sup> The use of the third-party reviewer would help

---

<sup>121</sup> U.S. GOV’T GEN. ACCOUNTING OFF., GAO/HEHS-97-21, MEDICAL DEVICE REPORTING: IMPROVEMENTS NEEDED IN FDA’S SYSTEM FOR MONITORING PROBLEMS WITH APPROVED DEVICES 11 (1997). In a report from the United States General Accounting Office that analyzed FDA reporting data (from the Center for Devices and Radiological Health, referred to in the report as CDRH) between 1987 and 1995, the GAO found:

Between March 1994 and April 1995, a backlog of about 48,900 malfunction reports from manufacturers accumulated at CDRH. Many of the malfunction reports were not entered into the adverse event reporting system and available for complete review and assessment until 1996. Although FDA assigns malfunction reports a lower priority than reports of death and serious injury, processing malfunction reports quickly is critical because of their potential to alert FDA to device problems that could cause or contribute to a death or serious injury if the malfunction were to recur. Entering all adverse event reports into the system promptly allows FDA analysts to perform more complete reviews and assessments on device problems. Further, entering event reports expeditiously is important because an event report, regardless of whether it requires immediate action, can become part of a group of reports that ultimately stimulates corrective action on a device problem.

*Id.*

<sup>122</sup> *Id.* at 21. “CDRH attributed its lack of documentation to the large volume of adverse event reports and limited staff resources.”

<sup>123</sup> H.R. REP. NO. 105-307, at 13 (1997).

<sup>124</sup> *Id.*

<sup>125</sup> Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (2012). “A House Committee report states that ‘in a number of cases, for both 510(k)-cleared and PMA products, increased requirements that are burdensome, expensive, and time-consuming have delayed patients’ access to new devices.’” Bauman, *supra* note 69, at 350.

<sup>126</sup> Flaherty, Jr., *supra* note 98, at 910.

<sup>127</sup> Bauman, *supra* note 69, at 350–51.



to alleviate the burden on the FDA by allowing other accredited persons to help with reviewing 510(k) applications.<sup>128</sup>

Another notable concept that was introduced with respect to pre-market clearance, was a series of changes to requirements for non-Class III devices. Most Class I devices and some Class II devices were exempted from the 510(k) notification requirements.<sup>129</sup> “As a result, FDAMA now allowed [most Class I and] some Class II devices to enter the market without any preclearance, some to enter the market after notification but without any special controls, and some to enter the market after notification and subject to special controls.”<sup>130</sup>

The FDAMA also restricted the FDA’s power to reject 510(k) applications based on substantial equivalence, so the FDA could only reject based on the intended use of the device.<sup>131</sup> Up until that point, “industry advocates believed FDA was denying many 510(k) submissions because of risks associated with off-label use. FDAMA specifically prohibited FDA from denying 510(k) submission for any uses other than the proposed intended use of the device.”<sup>132</sup> Additionally, reporting requirements were amended to require only post-market surveillance of higher risk devices, and allowed a representative sample of hospitals and health care facilities to report complications as opposed to all hospitals and facilities.<sup>133</sup> These changes helped alleviate some of the pressure on the FDA, because it met the public’s desire for faster access to drugs and devices, but the FDA was now allowing greater access to drugs and devices at the price of less direct oversight.<sup>134</sup> Despite decades of amendments, medical device regulation continued to fall short of achieving the FDA’s mandate of protecting a vulnerable while fostering innovation.

## II. THE 21ST CENTURY CURES ACT DELIVERS FASTER ACCESS WITH LESS OVERSIGHT ON MEDICAL DEVICES

The 21CCA, signed on Dec. 13, 2016, echoed the purpose of the FDAMA: to expedite the public’s access to new medical products and reduce the time and expense for manufacturers to obtain FDA approval.<sup>135</sup> The 21CCA introduced several new concepts, while restating some prior initiatives. The spirit of

<sup>128</sup> Nick Littlefield & Nicole R. Hadas, *A Survey of Developments in Food and Drug Law from July 1998 to November 1999*, 55 FOOD & DRUG L.J. 35, 41 (2000).

<sup>129</sup> Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360(l)(1), (m)(1) (2012).

<sup>130</sup> Bauman, *supra* note 69, at 350.

<sup>131</sup> *Id.* at 351.

<sup>132</sup> *Id.*

<sup>133</sup> Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360i(b)(5)(A) (2012).

<sup>134</sup> Cf. Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 2 YALE J. HEALTH POL’Y L. & ETHICS 587, 601–03 (2005); see also *FDA Backgrounder on FDAMA: The FDA Modernization Act of 1997*, FOOD & DRUG ADMIN. (Nov. 21, 1997), <https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCA/FDAMA/ucm089179.htm> [<https://perma.cc/GQ3J-YN68>].

<sup>135</sup> See 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016).

the Act was focused heavily on patient access to drugs and devices and constituted a new chapter in Congress's attempt to create a system that maximizes public safety and innovation. The Act was robust and varied in its changes, but three changes in particular were germane to medical device regulation.

*A. Breakthrough Medical Device*

One goal introduced in the act was getting “‘breakthrough’” medical devices to market as quickly as possible.<sup>136</sup> “FDA must offer a fast track toward approval for those . . . that can be considered to be a ‘breakthrough,’ which is a new legal status entitling their sponsors to ask . . . for a rapid evaluation and refinement of the device product’s application.”<sup>137</sup> While the particular language of this section is plagued with ambiguity and actually places a greater burden on the FDA, its importance lies in the desire to broaden public access to medical devices.<sup>138</sup> In particular, one attribute of a “breakthrough device,” as defined by the Act, is one that “offer[s] significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to . . . facilitate patients’ ability to manage their own care . . . .”<sup>139</sup> This vague language creates broad FDA discretion to decide which devices can bypass the expensive and time-consuming requirements to gain full premarket approval.

*B. Expanded Class II Exemptions from Premarket Notification*

Another section of the Act calls for the FDA to exempt certain non-Class III medical devices from 510(k) pre-market notification.<sup>140</sup> This concept is not new to the 21CCA—the FDAMA introduced it in 1997, and the FDA responded by exempting sixty-two Class II devices from pre-market notification requirements.<sup>141</sup> The 21CCA amended Section 510(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(m)) by instituting a requirement that the FDA publish a new list of exempted Class II devices within ninety days of the

<sup>136</sup> O'REILLY & VAN TASSEL, *supra* note 4 at § 18:63.

<sup>137</sup> *Id.*

<sup>138</sup> [I]t is debatable whether any particular serious illness or condition should be considered ‘life threatening’ or ‘irreversibly debilitating’ as a prospective, general matter across thousands of patients, since the common thread is how all users will need this device. The word ‘breakthrough’ is like beauty, in the eyes of the beholder, and is a comparative adjective concerning the effects this device can produce compared to others in breaking through a scientific or technical barrier to a cure.

*Id.*

<sup>139</sup> 21st Century Cures Act sec. 3051, § 515C(b)(2)(C), 130 Stat. at 1121–22.

<sup>140</sup> *FDA Proposes Devices to Be Exempted from 510 (k) Mandates Under Cures Act*, 25 GUIDE TO MED. DEVICE REG. NEWSL. 1 (Thompson Info. Servs., 2017).

<sup>141</sup> FOOD & DRUG ADMIN. & CTR. DEVICES & RADIOLOGICAL HEALTH, PROCEDURES FOR CLASS II DEVICE EXEMPTIONS FROM PREMARKET NOTIFICATION, GUIDANCE FOR INDUSTRY AND CDRH STAFF 1 (1998), <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080199.pdf> [<https://perma.cc/V6ZX-8RJR>].

21CCA, and every five years thereafter.<sup>142</sup> Once again, this was a movement away from strict regulation on non-Class III devices; this section of the 21CCA reinforces that notion.

### C. *Humanitarian Device Exemption*

The third feature of the 21CCA relevant to this discussion concerns the Humanitarian Device Exemption. The amended language of that section reads:

- (1) To the extent consistent with the protection of the public health and safety and with ethical standards, it is the purpose of this subsection to encourage the discovery and use of devices intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect not more than 8,000 individuals in the United States.
- (2) The Secretary may grant a request for an exemption from the effectiveness requirements of sections 360d and 360e of this title for a device for which the Secretary finds that--
  - (A) the device is designed to treat or diagnose a disease or condition that affects not more than 8,000 individuals in the United States,
  - (B) the device would not be available to a person with a disease or condition referred to in subparagraph (A) unless the Secretary grants such an exemption and there is no comparable device, other than under this exemption, available to treat or diagnose such disease or condition, and
  - (C) the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.<sup>143</sup>

The humanitarian device exemption is not new to the 21CCA; the new Act simply raises the maximum number of patients that would be helped by the new technology from four thousand to eight thousand.<sup>144</sup> Again, this is another move to grant faster access to medical devices by lessening the FDA oversight of devices that fall within this category. The humanitarian device exemption set a precedent that, for certain devices, proving safety instead of efficacy will be sufficient to gain FDA approval.<sup>145</sup>

Other significant changes to device regulation include: permitting centralized institutional review boards, or IRBs, for clinical trials of prospective de-

<sup>142</sup> 21st Century Cures Act § 3054(b)(1)(A), 130 Stat. at 1126.

<sup>143</sup> 21 U.S.C. § 360j(m) (2012).

<sup>144</sup> 21st Century Cures Act § 3052, 130 Stat. at 1124–25. In 1990, the SMDA added the humanitarian device exemption (HDE). The HDE is exempt from the effectiveness requirements of Sections 514 and 515 of the FDCA and is subject to certain profit and use restrictions. 21 U.S.C. § 360j(m); *Humanitarian Device Exemption*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/HumanitarianDeviceExemption/default.htm> [<https://perma.cc/4886-6KSK>] (last updated Feb. 1, 2018).

<sup>145</sup> 21 U.S.C. § 360j(m); *Humanitarian Device Exemption*, U.S. FOOD & DRUG ADMIN., *supra* note 144.

vices; requiring the FDA to consider the least burdensome means of demonstrating safety and effectiveness at the premarket approval stage; and creating five new categories of medical software that do not count as medical devices.<sup>146</sup>

With respect to medical devices, the 21CCA's purpose is clear: "The purpose of this section is to encourage the Secretary, and provide the Secretary with sufficient authority, to apply efficient and flexible approaches to expedite the development of, and prioritize the [FDA]'s review of, devices that represent breakthrough technologies."<sup>147</sup> The very moniker of a "breakthrough technology" carries with it both the optimism of the technology age but also the vapid promises of the snake-oil salesmen of a century ago.

Nevertheless, the legislature has made clear its intent that getting products to the public is of paramount importance: "Speed in product approval, and acceptance of wider and later sources of data about the new device, is the new 'ideal' which Congress wrote into the Act."<sup>148</sup> However, the key difference in the 21CCA is that, in the prior program, review of fast-tracked products was dependent upon the FDA's ability to provide staff and resources.<sup>149</sup> In the 21CCA, the FDA may no longer deny review for lack of resources, which theoretically removes a barrier for products to reach review.<sup>150</sup> However, the FDA has been plagued with a lack of resources for decades. When the SMDA was written, Congress explicitly stated that the FDA's lack of resources was a problem.<sup>151</sup> The SMDA acknowledged this failure and attributed "limited resources" as part of the reason for the lack of implementation of the 1976 Act.<sup>152</sup> One is left to wonder whether a future act will echo the SMDA, lamenting the FDA's failure to implement the 21CCA due to limited resources.

Additionally, the 21CCA appears, on its face, to be a pro-research piece of legislation, but the funding promised (\$4,796,000,000) is a non-guaranteed lump sum that will require additional legislation for it to be released.<sup>153</sup> Alt-

<sup>146</sup> See 21st Century Cures Act § 3060, 130 Stat. at 1130–31; *How the 21st Century Cures Act Impacts Medical Device Software*, METHOD SENSE (Dec. 21, 2016), <http://methodsense.com/21st-century-cures-act-impacts-medical-device-software/> [<https://perma.cc/NUR8-TNFU>]; *IDE Institutional Review Boards (IRB)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046745.htm> [<https://perma.cc/S3DT-RXHA>] (last updated Dec. 22, 2017). *But see* H.R. REP. NO. 105-307, at 6, 13 (1997).

<sup>147</sup> 21st Century Cures Act sec. 3051, § 515C(a), 130 Stat. at 1121.

<sup>148</sup> O'REILLY & VAN TASSEL, *supra* note 4.

<sup>149</sup> *Id.*

<sup>150</sup> *Id.*

<sup>151</sup> H.R. REP. NO. 101-808, at 13 (1990), *reprinted in* 1990 U.S.C.C.A.N. 6305, 6306.

<sup>152</sup> *Id.*

<sup>153</sup> 21st Century Cures Act, Pub. L. No. 114-255, § 1001, 130 Stat. 1033, 1039–40 (2016); *The 21st Century Cures Act of 2016*, PUBLIC CITIZEN, <https://www.citizen.org/our-work/health-and-safety/21st-century-cures-act-2016> [<https://perma.cc/BJ7F-Q4T9>] (last visited Feb. 27, 2018).

though the bill was passed with overwhelming bipartisan support,<sup>154</sup> many members of Congress, including Senators Bernie Sanders and Elizabeth Warren, have criticized this legislation because it gave too many concessions to the pharmaceutical companies.<sup>155</sup> Referred to by some as “an early Christmas present” to “Big Pharma,” the 21CCA promised faster and less expensive approval processes for certain medical devices.<sup>156</sup>

Although faster access to medical products is a sound goal, the Act suffers from being one-sided—benefiting the corporations manufacturing these devices rather than the public consuming them. Lessening regulations to encourage innovations is a noble goal, but without another mechanism in place to protect the public, the FDA is promoting innovation instead of patient safety. The solution to this problem will require a balanced approach that takes into account the need for faster access to innovative medical devices, the need to protect the public from unsafe devices, and the limited resources of the FDA to accomplish their charge.

### III. REGULATION, PREEMPTION AND TORT LAW—A BALANCED APPROACH TO SAFETY AND INNOVATION

As discussed above, the FDA historically has taken a defensive approach to regulation, acting only after tragedy strikes. It has also fought the battle of oversight by “chasing” manufacturers who do everything they can to avoid regulation.<sup>157</sup> Rather than create a system that spawns endless litigation between the FDA and manufacturers trying to avoid regulation, the system should motivate manufacturers to *seek out* FDA approval.

The FDA is currently failing to regulate devices that could cause extreme bodily harm and death while regulating other devices that pose little to no harm to a person.<sup>158</sup> One example of this is the cryotherapy chamber discussed at the beginning of this article. This popular device, used by celebrities, professional athletes, and the public, which subjects the human body to temperatures colder than any recorded temperature on earth, is not regulated by the FDA.<sup>159</sup> Hundreds of spas, salons, and quasi-medical facilities across our country are offer-

---

<sup>154</sup> The Senate vote was 94 to 5, and the House vote was 392 to 26. Mike DeBonis, *Congress Passes 21st Century Cures Act, Boosting Research and Easing Drug Approvals*, WASH. POST (Dec. 7, 2016), <https://www.washingtonpost.com/news/powerpost/wp/2016/12/07/congress-passes-21st-century-cures-act-boosting-research-and-easing-drug-approvals/> [https://perma.cc/CXV4-GUKA].

<sup>155</sup> *Id.*

<sup>156</sup> Michael Carome, *Pharma, Medical Device Industries Got an Early Christmas Present, But Not Everything on Their List*, PUBLIC CITIZEN (Dec. 7, 2016), <https://www.citizen.org/media/press-releases/pharma-medical-device-industries-got-early-christmas-present-not-everything> [https://perma.cc/62J8-N7PM].

<sup>157</sup> See *supra* Part II.

<sup>158</sup> Swanson, *supra* note 110, at 122; CBS NEWS, *supra* note 1; see also U.S. FOOD & DRUG ADMIN., *supra* note 89.

<sup>159</sup> U.S. FOOD & DRUG ADMIN., *supra* note 2.

ing this service and claiming benefits ranging from weight loss to reducing inflammation.<sup>160</sup> However, if the device is not used properly, it can result in frostbite, loss of limbs, or even death.<sup>161</sup> The manufacturers of this device skirted regulations, even though the device fell squarely within the FDA's definition of a "medical device."<sup>162</sup> On the other hand, the FDA is spending time and resources regulating devices as benign as exam gloves.<sup>163</sup> FDA resources could—and should—be allocated more efficiently.

A system that incentivizes manufacturers of dangerous products to seek out FDA approval, while allowing manufacturers of simple and harmless devices to avoid going through the approval process would be beneficial. This type of system would offer greater protection for the public, reduce administrative costs for the FDA, and presumably grant faster access to many medical devices. The FDAMA and the 21CCA did initiate a degree of risk-based regulation, but the legislation did not go far enough to achieve the goal of encouraging innovation while still protecting the public.

A. *Federal Preemption as a "Carrot" to Encourage Manufacturers to Seek Voluntary FDA Approval for Safety*

One way to encourage manufacturers of potentially dangerous Class II products to seek FDA approval is to offer a manufacturer federal preemption against state law tort claims for devices that have gone through—and have been granted—pre-market approval. This may seem counterintuitive as a means of protecting the public, but, as discussed below, when preemption is balanced with increased tort law damages for manufacturers that do not get approval, the public will have a strong tool against the manufacturer.

<sup>160</sup> *Whole Body Cryotherapy Provides Benefits in Three Primary Settings*, WHOLE BODY CRYOTHERAPY, <http://www.wholebodycryotherapy.org/benefits> [https://perma.cc/3SYG-KN5E] (last visited Feb. 27, 2018); U.S. FOOD & DRUG ADMIN., *supra* note 2.

<sup>161</sup> U.S. FOOD & DRUG ADMIN., *supra* note 2; CBS NEWS, *supra* note 1.

<sup>162</sup> Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(h) (2012).

The term 'device' . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

*Id.*

<sup>163</sup> *February 2017 510(k) Clearances*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm544999.htm> [https://perma.cc/RX5E-338Z] (last updated Dec. 7, 2017).

Currently, when a Class III device has been given pre-market approval, that product has federal preemption from state law tort claims.<sup>164</sup> In *Riegel v. Medtronic, Inc.*,<sup>165</sup> the United States Supreme Court held that the MDA's preemption clause barred common-law claims challenging the safety or effectiveness of a medical device marketed in a form that received pre-market approval from the FDA.<sup>166</sup>

The MDA prohibits states from imposing requirements "different from, or in addition to, any requirement applicable . . . to the device."<sup>167</sup> The Supreme Court has held that a state's common-law duties, including that of common-law liability in tort, constitute "requirements" as contemplated by the MDA.<sup>168</sup> Where a device has undergone the pre-market approval process by the FDA, the device is preempted from state law tort claims.<sup>169</sup> This means that private litigants may not sue for damages against a device manufacturer if the device has undergone FDA premarket approval.<sup>170</sup>

However, federal preemption of state law tort claims only applies to Class III devices that have received pre-market approval by the FDA.<sup>171</sup> As mentioned earlier, Class I and II devices account for nearly 90 percent of all medical devices.<sup>172</sup> Class I devices are almost all exempt from pre-market notification because they are simple and relatively safe.<sup>173</sup> Class II devices, unless exempt, must still go through a pre-market notification process.<sup>174</sup> This process would require the filing of a 510(k) to prove substantial equivalence to another product that is already legally on the market, or, if not substantially equivalent to another device, the Class II device would have to go through pre-market ap-

---

<sup>164</sup> *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323–24, 330 (2008); *see also* Whitney, *supra* note 102, at 118–19.

<sup>165</sup> *Riegel*, 552 U.S. at 312.

<sup>166</sup> *Id.* at 320–21, 330.

<sup>167</sup> Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a)(1) (2012); *Riegel*, 552 U.S. at 321 (quoting § 360k(a)(1)).

<sup>168</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 504–05 (1996) (Breyer, J., concurring in part and concurring in the judgment); *Id.* at 509 (O'Connor, J., concurring in part and dissenting in part).

Before a new Class III device may be introduced to the market, the manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. . . . Despite its relatively innocuous phrasing, the process of establishing this "reasonable assurance," which is known as the "premarket approval," or "PMA" process, is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission.

*Id.* at 477.

<sup>169</sup> *Riegel*, 552 U.S. at 317, 322.

<sup>170</sup> *Id.* at 333 (Ginsburg, J., dissenting).

<sup>171</sup> Whitney, *supra* note 102, at 118–19.

<sup>172</sup> *See supra* text accompanying notes 89, 91.

<sup>173</sup> *Medical Devices Exemptions 510(k) and GMP Requirements*, U.S. FOOD & DRUG ADMIN., <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/315.cfm> [https://perma.cc/J7AK-KBJR] (last updated Feb. 26, 2018).

<sup>174</sup> Flaherty, Jr., *supra* note 98, at 906.

proval.<sup>175</sup> Although the 21CCA calls for an updated list of Class II exempt devices, this list, and the updates required every five years,<sup>176</sup> will likely continue to result in wasted FDA resources due to processing pre-market notification applications of products that do not pose a significant risk to the public.

One part of this Article's proposed solution is to eliminate the mandatory pre-market notification requirements for all Class I and II devices. Essentially, I am proposing all Class I and II devices should be exempt from the pre-market notification process.<sup>177</sup> This will unlock countless hours of FDA resources currently being spent on processing thousands of applications for devices that are relatively safe.<sup>178</sup> Although the hours spent on an individual 510(k) application are minimal compared to the hours spent for pre-market approval, the sheer volume of 510(k) applications received each year require a significant amount of FDA resources to process.<sup>179</sup> The second part of this solution would be that manufacturers of Class II devices that voluntarily seek out and receive FDA approval would also be granted federal preemption from state tort law claims. This updated regulatory scheme would allow Class II devices that seek approv-

<sup>175</sup> *Id.* at 910–12. Alternatively, the manufacturer could seek classification as a Class I or Class II through the *de novo* pathway—where there is no substantial equivalence but the FDA determines it poses little to moderate safety risk. If the FDA approves the *de novo* application, the device would be categorized as a Class I or Class II and marketed immediately. The device may also serve as a future predicate device. The FDA would k U.S. FOOD & DRUG ADMIN., DE NOVO CLASSIFICATION PROCESS (EVALUATION OF AUTOMATIC CLASS III DESIGNATION): GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 5 (2017), <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM273903.pdf> [<https://perma.cc/C7ZD-CYQR>].

<sup>176</sup> 21st Century Cures Act, Pub. L. No. 114-255, § 3054(b)(1)(A), 130 Stat. 1033, 1126 (2016).

<sup>177</sup> The additional general controls required such as registration and listing, labeling, GMPs, are outside the scope of this article. Roger W. Bivans, *Substantially Equivalent? Federal Preemption of State Common-Law Claims Involving Medical Devices*, 74 TEX. L. REV. 1087, 1090–91 (1996); *Class I/II Exemptions*, *supra* note 97.

<sup>178</sup> Bivans, *supra* note 177, at 1121; Amy E. Todd, *No Need for More Regulation: Payors and Their Role in Balancing the Cost and Safety Considerations of Off-Label Prescriptions*, 37 AM. J.L. & MED. 422, 432 (2011). “[T]he FDA ‘lacks the resources needed to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future.’” Eggen, *supra* note 3, at 204; INST. OF MED. OF THE NAT’L ACADS., *THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC* 193 (Alina Baciú et al., eds., 2007).

<sup>179</sup> For example, in 2016 there were 2,931 devices cleared for approval through the 510(k) process, but only thirty-nine devices with original applications approved through the pre-market approval process. *Devices Cleared in 2016: 2016 Medical Device 510(k) Clearances*, U.S. FOOD & DRUG ADMIN., <http://wayback.archive-it.org/7993/20171114011521/https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm483517.htm> [<https://perma.cc/7YZC-23W3>] (last updated Jan. 4, 2017); *Devices Approved in 2016: 2016 Monthly PMA Listings*, U.S. FOOD & DRUG ADMIN., <http://wayback.archive-it.org/7993/20171114011458/https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm484383.htm> [<https://perma.cc/VNH8-WJEJ>] (last updated Jan. 19, 2017).



al to show only that the device is safe for public use. It would not require the manufacturer to show that the product was effective.<sup>180</sup> This is similar to the Humanitarian Device Exemptions implemented in 1990 and 2016, which required proof of safety only.<sup>181</sup> I propose this approach should be adopted for all Class II devices voluntarily seeking FDA approval. This would allow the FDA to continue its goal of protecting the public from harmful products, while allowing faster access to medical devices.

Preemption, therefore, would allow manufacturers to better quantify their potential costs while reducing or eliminating exposure to tort liability.<sup>182</sup> The value of preemption should not be underestimated.<sup>183</sup> Devices that do not qualify for federal preemption would remain exposed to state tort liability.

---

<sup>180</sup> To further ease the burden of the approval process for non-Class III devices, manufacturers should only be required to show the safety of their device, not efficacy. This principle has two goals in mind. First, it would focus the process on the main concern of protecting the public's safety, ensuring the proper controls are in place for the safe use of the device. The approval process would be the FDA's stamp of approval on the safety of a device, but it would be the public's role to investigate the efficacy of a product. Acts like the FDAMA and 21CCA have made clear the intent of Congress to provide earlier access to medical products and involving the public in their own medical care. Placing the duty of vetting efficacy in the hands of the public is far more equitable than it was a century ago. Today a consumer is able to use the internet to research the efficacy of a particular product, and the rise of areas like psychosomatic medicine further erode the idea that establishing efficacy is a necessity. See *Psychosomatic Medicine Fellowship: Consultation Liaison Psychiatry*, YALE SCH. OF MED. <http://medicine.yale.edu/psychiatry/psychosomatic/training/fellowship/> [https://perma.cc/W86M-48PK] (last visited Feb. 27, 2018). Moreover, beginning in 1962 when the FDA's oversight of medical products became "paternalistic," and gaining momentum during the AIDS crisis of the 1980s, patients' rights activists have clamored for a larger role of the public in deciding the efficacy of medical products. See Harold Edgar & David J. Rothman, *New Rules for New Drugs: The Challenge of AIDS to the Regulatory Process*, 68 MILBANK Q. SUPP. 1 111, 111-12, 121 (1990).

<sup>181</sup> 21st Century Cures Act, § 3052 at 1124-25; Safe Medical Devices Act of 1990, Pub. L. No. 101-629, § 14, 104 Stat. 4511, 4524.

<sup>182</sup> See David Brennan, *Federal Preemption of All State Law Tort Claims in Riegel v. Medtronic: A Need to Undo a Serious Wrong*, 36 W. ST. U. L. REV. 137, 138 (2009).

<sup>183</sup> See Walsh & Pyrich, *supra* note 4, at 953.

A significant disincentive to create new drugs and medical devices would still exist in the form of product liability lawsuits. Even where a drug or device has been approved by the FDA, product liability suits delve into the adequacy of a manufacturer's research, development and testing processes. If a manufacturer is held liable for producing a defective drug or medical device, it can be forced to pay damages awards far in excess of the cost of researching and developing the product, even including the high costs of the FDA approval process. The relative costs of undergoing FDA review for approval or complying with FDA regulations are small when compared to the potential costs of mass tort lawsuits and punitive damages. Any attempt to solve the problem of the costliness of compliance with FDA regulations will not be completely successful unless it addresses the costliness of product liability lawsuits as well.

*Id.* at 953-54.

Winter 2018]

DYING FOR A SOLUTION

653

*B. Tort Law as a “Stick” to Encourage Manufacturers to Produce Safe Products*

In order to balance the risk of potentially ineffective and dangerous Class II devices entering the market, the final part to this Article’s proposal is a significant increase in damages awards for plaintiffs injured by medical devices that do not have FDA approval. For example, a damages multiplier and punitive damages could be available remedies against a manufacturer who marketed a medical device without seeking FDA approval, and the device injured a plaintiff.<sup>184</sup>

Regulation and tort law have been described as a “dual track” of safety incentives.<sup>185</sup> Regulatory schemes work prophylactically while tort law acts in response to a manufacturer’s failure to discharge its duty of care.<sup>186</sup> But tort liability is a factor in a manufacturer’s decision-making process, particularly with respect to expending safety costs.<sup>187</sup>

Product liability has been called the most effective means of motivating manufacturers to design safe products.<sup>188</sup> “In industries with potentially high-hazard products, but not subject to significant product-related regulation (e.g., industrial machinery), product liability probably dominates design decisions, in terms of safety considerations.”<sup>189</sup> Even where products are highly regulated—like drugs—product liability remains at the forefront of design considerations.<sup>190</sup> Currently, high-hazard medical devices exist that the FDA has failed to regulate.<sup>191</sup> These high-hazard products are practically unregulated, and tort law remains the most effective way to protect the safety of a vulnerable populace.

One criticism in the use of tort law to shape manufacturer behaviors that tort law unreasonably dissuades manufacturers from innovation or production

<sup>184</sup> FDAMA authorizes the FDA to impose civil penalties for various acts or omissions that undermine its purpose; alternatively or concurrently, it could be expanded to include civil penalties for non-approved, non-Class III devices that cause serious harm. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 335b (2012). Whether a product that has not undergone the FDA approval process qualifies as a medical device, in this solution, would be an issue of fact and a matter for litigation. As suggested herein, expanding the public’s role in helping regulate devices is one that empowers the public and relieves the burden upon the FDA. Any product that applies for FDA approval but is denied by the FDA because it does not qualify as a medical device would not face increased tort liability. This would further incentivize manufacturers to unilaterally come to the FDA, rather than attempt to hide from it.

<sup>185</sup> Daniel R. Cahoy, *Medical Product Information Incentives and the Transparency Paradox*, 82 IND. L.J. 623, 637 (2007).

<sup>186</sup> *Id.* at 637.

<sup>187</sup> COOTER & ULEN, *supra* note 8, at 3–4.

<sup>188</sup> GEORGE EADS & PETER REUTER, *DESIGNING SAFER PRODUCTS: CORPORATE RESPONSES TO PRODUCT LIABILITY LAW AND REGULATION* viii (1983).

<sup>189</sup> *Id.*

<sup>190</sup> *Id.*

<sup>191</sup> *See* CBS NEWS, *supra* note 1.

of devices that would benefit the public.<sup>192</sup> Under this theory, the cost of litigation would negate the manufacturer's expected profits and the product would never be created.<sup>193</sup> The counter-argument is that, in the past, manufacturers have factored litigation into a cost/benefit analysis and determined it cheaper to pay injury claims than make a product safe or perform a recall.<sup>194</sup> Once again, both sides can cite specific examples of how tort law factors into device safety, either as too burdensome or too impotent.<sup>195</sup> The important point is that either way, it is clear that tort litigation matters to manufacturers because they factor potential litigation and injury costs into their decision-making processes.

Tort law is a necessary element in a regulatory system tasked with keeping pace with technology, an adversary it cannot possibly match.

[W]hile tort law does not provide a perfect regulatory system, it is a necessary supplement to the equally imperfect oversight by the FDA. As it currently stands, the FDA cannot adequately identify the risks associated with devices before they are on the market, nor can it effectively monitor and regulate those products once they are in widespread use.<sup>196</sup>

Tort law provides a compensatory scheme for those who are injured by defective devices, but, if used correctly in conjunction with the regulatory statutes, it could also serve a preventive purpose, incentivizing manufacturers to produce safe products and seek voluntary certification of safety from the FDA.<sup>197</sup>

#### CONCLUSION

The FDA's history shows a cycle of tragedy followed by legislative response. Unfortunately, because technology is increasing at a rate much faster than Congress can anticipate, the legislation is always playing "catch up" to adequately regulate new products and keep the public safe. Additionally, an under-funded and over-tasked FDA lacks the resources necessary to ensure the safety of medical devices on the market.

Described herein, the requirements imposed upon the FDA from its earliest days have always been more than it could bear. From the days when it was required to prove the lack of safety for a device—rather than the manufacturer

---

<sup>192</sup> Issar, *supra* note 3, at 1113.

<sup>193</sup> *Id.*

<sup>194</sup> See *Grimshaw v. Ford Motor Co.*, 174 Cal. Rptr. 348, 384 (Cal. Ct. App. 1981); Brian Leon, *Four-Wheeled Flubs: The 8 Biggest Automotive Scandals of All Time*, N.Y. DAILY NEWS (Sept. 24, 2015, 10:45 AM), <http://www.nydailynews.com/autos/7-biggest-automotive-scandals-time-article-1.2371949> [https://perma.cc/78A4-PJFS]; *Medical Device Maker Pleads Guilty to a Cover-Up, Agrees to Pay \$92.4 Million*, CEDAR VALLEY BUS. MONTHLY (June 13, 2003), [http://wcfcourier.com/business/local/medical-device-maker-pleads-guilty-to-a-cover-up-agrees/article\\_dafaac12-f4e2-5129-a785-37d788876f3e.html](http://wcfcourier.com/business/local/medical-device-maker-pleads-guilty-to-a-cover-up-agrees/article_dafaac12-f4e2-5129-a785-37d788876f3e.html) [https://perma.cc/J4G4-KM2B].

<sup>195</sup> See Issar, *supra* note 3, at 1113.

<sup>196</sup> *Id.* at 1113–14.

<sup>197</sup> *Id.* at 1114.

prove its safety and efficacy—to processing thousands of adverse reports, through the current landscape of minimizing the time it takes to get a product approved, the legislature has largely ignored the limitations of the FDA. Even the 21CCA, which seeks to address these limitations by reducing and eliminating requirements for certain non-Class III medical devices, has increased the expectations of the FDA’s performance by eliminating “lack of resources” as a reason to delay review and approval of devices.<sup>198</sup>

The more effective solution is to eliminate *mandatory* regulation of non-Class III devices altogether. Instead, as explained above, the FDA could remove *mandatory* premarket *notification* of Class I and II devices, and offer a *voluntary* premarket *approval* process. In the 21CCA, Congress has already indicated a shift towards reducing the impact upon both the FDA and non-Class III manufacturers.<sup>199</sup> Therefore, eliminating mandatory premarket notification by the FDA would move the needle even further. The bulk of the FDA’s effort in the medical device arena could then be focused on Class III medical devices, which would maintain regulation of devices carrying the greatest risk and eliminate the burden on manufacturers of all other medical devices.

The key to a comprehensive solution is to balance the reduced FDA oversight of non-Class III devices with the deterrent of increased state tort law damages. This system would promote one of two tracks for manufacturers. First, if a manufacturer identifies the possibility of its device seriously injuring an individual, the damages multiplier would incentivize the manufacturer to seek voluntary FDA approval to obtain preemption, or, at the very least, make a safer product. Gray area devices, like a cryotherapy chamber, would be a typical example of this type of analysis because the device’s potential adverse effects carry the potential for considerable damages. The second possibility is that a manufacturer determines that, even in an adverse event, the damages to any consumer would be minimal and it would therefore forego the approval process as an unnecessary burden. An example of this might be the maker of a

<sup>198</sup> O’REILLY & VAN TASSEL, *supra* note 136. Additionally, there is precedent for Class II devices receiving state tort preemption based on FDA promulgated guidelines. Bexis, *Successful Class II Medical Device Preemption Decision*, DRUG & DEVICE L. (Sept. 28, 2011), <https://www.druganddevicelawblog.com/2011/09/successful-class-ii-medical-device.html> [<https://perma.cc/J482-LQEB>]. The preemption landscape is still unclear and an express provision would also alleviate some litigation arising from the ambiguities.

Additionally (although the issues [were] not addressed by the *Lohr* Court), Class II devices have been held to be preempted if device-specific regulations have been promulgated by the FDA. In *Papike v. Tambrands, Inc.*, the Ninth Circuit held that the plaintiff’s state claims were preempted because tampons, although a Class II rather than a Class III device, have been the subject of several specific FDA regulations mandating warnings for toxic shock syndrome.

*Regulatory Preemption of Medical Devices*, FINDLAW, <http://corporate.findlaw.com/litigation-disputes/regulatory-preemption-of-medical-devices.html> [<https://perma.cc/E8GY-FZXX>] (last visited Feb. 27, 2018); *see also* *Papike v. Tambrands, Inc.*, 107 F.3d 737, 737 (9th Cir. 1997).

<sup>199</sup> *See* 21st Century Cures Act, Pub. L. No. 114-255, § 3054(b)(1)(A)(i), 130 Stat. 1033, 1126 (2016).

magnetic bracelet touted to improve healing, where damages for an adverse event would likely be minimal, like treatment for a rash.

These two principles act to place the premarket process in the hands of the manufacturer to determine the best course of action while incentivizing them to create a safe product without overburdening the FDA. Increasing tort liability impacts potentially dangerous products while benign ones may enjoy the reduced burden of getting products to market faster. Reducing the burden of approval to proving only safety further incentivizes manufacturers to obtain approval. This solution reduces oversight by the FDA while expanding the role of the public market for efficacy, and tort litigation for safety. Both the public's and the manufacturer's interests are taken into account. The answer, therefore, lies in contracting regulation while, at the same time, increasing oversight and legal remedies.