

# **FDA Review of Medical Devices: Should Consumers Really Feel Safe?**

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### Should consumers really feel safe?

The Food and Drug Administration (FDA), a federal agency within the Department of Health and Human Services (HHS), is responsible for protecting and promoting the public's health.<sup>1</sup> The mission of the FDA is to protect the well-being of the public by regulating the safety and effectiveness of drugs and medical devices.<sup>2</sup> The Center for Devices and Radiological Health (CDRH) manages the FDA medical device approval process.<sup>3</sup>

A medical device is used to diagnose, treat, or prevent disease.<sup>4</sup> It includes such varied items as hospital gowns, breast implants, and pacemakers. The United States is the largest producer of medical devices in the world.<sup>5</sup> In order to sell a medical device in the United States, a submission must first be filed with the FDA, unless the device is otherwise exempted per the regulations.<sup>6</sup> The FDA review process for a medical device consists of two main routes: premarket approval (PMA) or 510(k) clearance.<sup>7</sup> While both of these methods allow for FDA review and release of a device for sale in the United States, the 510(k) clearance tends to be considered somewhat of a 'fast-track' process.<sup>8</sup> With no requirement for performance or safety data from patient use, the 510(k) allows for comparison of a new device to a similar, previously cleared device.<sup>9</sup> The 510(k) review is by far the preferred pathway for device manufacturers.<sup>10</sup>

The stakes are high for consumers, healthcare professionals, and device manufacturers in the medical device world. Consumers trust the FDA to assure that devices being used are safe and effective and will not cause harm. Healthcare professionals seek to treat patients with confidence. Device manufacturers want a quick, low cost approval system that allows them to sell their products in the United States. The FDA also seeks to provide a process that protects public health and safety, is manageable, and does not stifle innovation. A regulatory review process that closely encompasses the desires of each group will likely improve public health by allowing for new and innovative products to be made available more quickly to consumers. However, a rush to market may actually overlook deficiencies that exist in devices, allowing harmful products to be used in patients.

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<sup>1</sup> INSTITUTE OF MEDICINE, *MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS* xi (The National Academies Press, 2011).

<sup>2</sup> Charles J. Walsh & Alissa Pyrich, *Tort Reform and American Society: A Dialogue: December 15, 1995: Article: Rationalizing the Regulation of Prescription Drugs and Medical Devices: Perspectives on Private Certification and Tort Reform*, 48 Rutgers L. Rev. 883, 886 (1996).

<sup>3</sup> JUDITH A. JOHNSON, CONG. RESEARCH SERV., R42130, *FDA REGULATION OF MEDICAL DEVICES* 1 (2012).

<sup>4</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 17.

<sup>5</sup> THE LAW LIBRARY OF CONG., GLOBAL RESEARCH CENTER, *APPROVAL OF MEDICAL DEVICES* 15 (2014).

<sup>6</sup> 21 C.F.R. § 807.85 (2014).

<sup>7</sup> 21 C.F.R. § 814(b), subpart B (2014); 21 C.F.R. § 807 (2014).

<sup>8</sup> Kyle M. Fargen et al., *The FDA Approval Process for Medical Devices, An Inherently Flawed System or a Valuable Pathway for Innovation*, 5 J NEUROINTERVENT SURG. 269, 270 (2013).

<sup>9</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 91.

<sup>10</sup> INSTITUTE OF MEDICINE, *supra* note 1.

Dr. Stephen Tower was a victim of deficiencies in a system that allows for medical device marketing without prior patient testing.<sup>11</sup> As a renowned orthopedic surgeon who specializes in hip replacement surgery,<sup>12</sup> he was privy to the most up-to-date technology and findings in the field. When he needed a hip replacement, he chose the DePuy hip, which was gaining popularity as a superior device due its composition of metal on metal rather than plastic parts.<sup>13</sup> The DePuy hip was expected to provide better long-term wear for patients over previous hip replacements, which failed due to wear and tear of the plastic socket lining.<sup>14</sup>

Dr. Tower was initially thrilled with his results and started using the DePuy hip on his own patients.<sup>15</sup> A year later, however, Dr. Tower started having significant trouble with his implant, including constant pain, hearing loss and mood swings.<sup>16</sup> When he asked company representatives whether they had received similar complaints, he was essentially brushed off and told they did not know.<sup>17</sup>

These company representatives were most likely telling the truth, as the FDA does not mandate reporting of device problems unless they cause death or require action to prevent serious injury to the public.<sup>18</sup> The FDA only maintains a voluntary reporting system for medical device adverse event reporting,<sup>19</sup> which makes it very difficult for health care professionals and consumers to track problems with medical devices.<sup>20</sup> Such a reporting system may allow issues to go unnoticed.

Promoted to offer great benefits to consumers, but actually resulting in harm, DePuy ultimately issued a voluntarily recall of all 93,000 DePuy hip devices worldwide.<sup>21</sup> Thousands of lawsuits were filed after the device recall when patients realized that their side effects and injuries were actually due to the DePuy hip.<sup>22 23</sup> Without a nationwide mandated reporting system, there was no obvious way for consumers or healthcare professionals to know in advance of the problems with the device.

This scenario is one of many that demonstrate the FDA's potential inadequacy of protecting consumers from unsafe medical devices. Cleared for market with no patient data and

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<sup>11</sup> Consumer Reports, *Dangerous Medical Implants and Devices*, May 2012, <http://www.consumerreports.org/cro/magazine/2012/04/cr-investigates-dangerous-medical-devices/index.htm>

<sup>12</sup> TOWER JOINT REPLACEMENT CLINIC, INC., <http://www.tjrclinic.com> (last visited Mar. 8, 2016)

<sup>13</sup> Consumer Reports, *supra* note 11.

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 124.

<sup>19</sup> *Id.*

<sup>20</sup> Consumer Reports, *supra* note 11.

<sup>21</sup> *Id.*

<sup>22</sup> Mayo B. Alao, *Thirty-Eight Years and Counting: The FDA's Misuse of the 510(k) Notification Process and Consequent Under-Regulation of Implantable Medical Devices*, 8 St. Louis U. J. Health L. & Pol'y 347, 347 (2015).

<sup>23</sup> In March 2013, the first DePuy hip lawsuit was settled in excess of \$8.3 million in California. See *Kransky v. DePuy, Inc.*, No. BC456086 (L.A. Cnty., Cal., Super. Ct. 2013). Additionally, Johnson & Johnson, the parent company of DePuy, agreed to pay at least \$2.5 billion to settle 8,000 lawsuits regarding defective DePuy hips. See Press Release, Johnson & Johnson, DePuy Announces U.S. Settlement Agreement to Compensate ASR™ Hip System Patients Who Had Surgery to Replace Their ASR Hip, (Nov. 19, 2013), <https://www.jnj.com/news/all/DePuy-Announces-US-Settlement-Agreement-to-Compensate-ASR-Hip-System-Patients-Who-Had-Surgery-to-Replace-Their-ASR-Hip>.

allowed to remain on the market due to lack of an effective monitoring system, the device caused serious harm to many consumers.

So how did such a device get to market in the first place? Medical devices are either exempt, cleared, or approved for sale through the FDA.<sup>24</sup> The FDA's 510(k) review process, used for the DePuy hip, is very limited in scope. Specifically, the only evaluation of a device during the 510(k) review is whether a new device is 'substantially equivalent', meaning it performs at least as well, with no more danger, than an earlier or legally marketed device known as the 'predicate'.<sup>25</sup> A device can become a predicate once it receives clearance through the 510(k) process.<sup>26</sup> The FDA neither determines safety nor effectiveness of either the new or predicate device during the 510(k) review.<sup>27</sup> Therefore, a device can receive clearance to market without ever having been used in patients. Because no follow-up data from patient use is required as part of 510(k) clearance,<sup>28</sup> a product can cause serious harm to consumers for some time before any realization of the issue surfaces.

The entire 510(k) process assumes the safety of the device in question due to the likeness to the predicate. Not surprisingly, the DePuy hip 510(k) clearance was based on 'substantial equivalence' to earlier products.<sup>29</sup> In this instance, the predicate devices provided as 'substantially equivalent' to the DePuy hip were seven other devices with 510(k) clearance, the majority of them from the same company, DePuy.<sup>30</sup>

Consumers believe that the FDA conducts a careful review of medical devices and only allows safe products to be marketed. However, upon closer review, this may not always be the case. Ironically, once a manufacturer obtains clearance for a medical device, they may be able to continue to grow their line of marketed products by linking back to their own devices as predicates to show 'substantial equivalence' for new devices.<sup>31</sup> It is not an uncommon occurrence for manufacturers such as Medtronic<sup>32</sup>, Zimmer<sup>33</sup>, Stryker<sup>34</sup>, and Siemens,<sup>35</sup> among others, to reference their own products as predicates. While there is nothing illegal about this, it does raise concern.

Competition and innovation are healthy drivers of continued scientific growth, advancement, and discovery. This should be encouraged and not squelched by a myriad of regulations that bog down the system. However, the 510(k) review process, the route to market

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<sup>24</sup> U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-190, MEDICAL DEVICES, FDA SHOULD TAKE STEPS TO ENSURE THAT HIGH-RISK DEVICE TYPES ARE APPROVED THROUGH THE MOST STRINGENT PREMARKET REVIEW PROCESS 2-3 (2009) [hereinafter *Medical Devices*].

<sup>25</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 89.

<sup>26</sup> *Id.*

<sup>27</sup> *See infra* pp. 21-23.

<sup>28</sup> JOHNSON, *supra* note 3, at 10.

<sup>29</sup> Consumer Reports, *supra* note 11.

<sup>30</sup> DePuy ASR XL Modular Acetabular Cup System, K080991, at 1, [http://www.accessdata.fda.gov/cdrh\\_docs/pdf8/K080991.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf8/K080991.pdf)

<sup>31</sup> *Id.*

<sup>32</sup> Medtronic FUSION Compact™ Navigation System, K153247, at 4, [http://www.accessdata.fda.gov/cdrh\\_docs/pdf15/K153247.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf15/K153247.pdf)

<sup>33</sup> Zimmer Virage OCT Spinal Fixation System, K153631, at 4, [http://www.accessdata.fda.gov/cdrh\\_docs/pdf15/K153631.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf15/K153631.pdf)

<sup>34</sup> Stryker CMF MEDPOR Customized Implant, K153508, at 4, [http://www.accessdata.fda.gov/cdrh\\_docs/pdf15/K153508.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf15/K153508.pdf)

<sup>35</sup> Siemens syngo.CT Single Source Dual Energy (twin beam), K153220, at 4-5 [http://www.accessdata.fda.gov/cdrh\\_docs/pdf15/K153220.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf15/K153220.pdf)

for the majority of medical devices,<sup>36</sup> needs to embody adequate scrutiny and oversight. It is in the public's best interest that the FDA and Congress revise the existing regulations related to the 510(k) review process to require actual safety data, including postmarketing and clinical trial requirements as needed, in addition to the current 'substantial equivalence' standard. Inclusion of such data will reasonably confirm the safe and effective performance of the device under review and not solely allow for clearance on 'substantial equivalence' to a previous device.

This paper will provide an overview of medical device regulation by the FDA and propose legislative changes. First, the FDA background will be reviewed, including a summary of the history of device regulations. Next, this paper will examine the pathways for bringing a medical device to market in the United States. Then the medical device reporting system will be reviewed and cases involving marketed devices, which have resulted in serious harm, will be outlined. Additionally, the 2011 Institute of Medicine report will be reviewed for significant findings. Finally, pending legislation and recommended changes to the regulatory landscape will be detailed.

Congress and the FDA need to take action now to change the regulatory structure that guides medical device review. They must require the inclusion of more clinical use performance data, including postmarketing reporting and a national registry. They must also establish better technology to store such data, resulting in an efficient, searchable database. These changes will provide the assurance of safety and effectiveness in devices currently lacking in the 510(k) review and ultimately mitigate the risk to consumers, as experienced by Dr. Tower.

## I. FDA BACKGROUND

The FDA was created in 1906 under the Pure Food and Drugs Act.<sup>37</sup> The FDA has several missions, one of which is "to promote the public health by... ensuring that... there is reasonable assurance of the safety and effectiveness of devices intended for human use."<sup>38</sup>

Although medical devices have been used for centuries, the FDA did not initially have the authority to regulate devices.<sup>39</sup> Although the FDA began regulating drugs in 1906, the regulation of medical devices did not start until the Food, Drug and Cosmetic Act of 1938 (FDCA) was enacted.<sup>40</sup> During this period of non-regulation, medical devices became more complex and often posed unreasonable risk and severe harm to consumers.<sup>41</sup> Legislators realized that such problems necessitated the need for better regulatory oversight of devices.

Drugs and medical devices must first receive FDA review before they can be legally marketed in the United States.<sup>42</sup> However, drugs and devices go through very different FDA review processes based on their respective regulations.<sup>43</sup> Congress requires one detailed review path for drugs; however, devices may take a path of no review, limited review, or detailed review.<sup>44</sup> The differences between drug and device approvals raise legitimate concerns as to whether the medical device review framework is sufficient to safeguard consumers.

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<sup>36</sup> Kyle Lennox, *Substantially Unequivocal: Reforming FDA Regulation of Medical Devices*, 2014 U. Ill. L. Rev. 1363, 1383 (2014).

<sup>37</sup> Pure Food and Drug Act of 1906. 59 P.L. 384, 34 Stat. 768, 59 Cong. Ch. 3915.

<sup>38</sup> 21 U.S.C § 393 (2010).

<sup>39</sup> Walsh, *supra* note 2, at 902.

<sup>40</sup> Lennox, *supra* note 36, at 1377.

<sup>41</sup> Walsh, *supra* note 2, at 902.

<sup>42</sup> JOHNSON, *supra* note 3.

<sup>43</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 17.

<sup>44</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 208.

However, good reasons do exist for the differences in regulatory structure. Devices typically have a shorter life span than drugs and have frequent changes in technology.<sup>45</sup> Devices are also used in much smaller populations than drugs,<sup>46</sup> which makes it difficult to test devices in the same large clinical trials that occur as part of the drug review process.<sup>47</sup> Notwithstanding these differences, consumers should expect to be protected by thorough FDA review and oversight.

Congress acknowledges that consumers need to be safeguarded from devices “inadequately tested or improperly designed or used”.<sup>48</sup> Over time, they have tried to balance the needs of consumer access to new, improved medical devices, while preventing the sale of devices that are not safe and effective.<sup>49</sup> American consumers expect drugs and medical devices to be thoroughly tested and vetted before being used for treatment. For devices, however, this is a false assumption.<sup>50</sup> Many medical devices are rarely tested for safety and efficacy before they are marketed, but instead gain clearance because they are similar enough to another FDA cleared device.<sup>51</sup> Such regulatory “flaws inherent to the current FDA regulatory processes [are] beginning to undermine the ability of the USA to remain competitive in the medical device industry”<sup>52</sup> and must be changed to allow for continued dominance in the medical device field.

## II. REGULATIONS THAT GOVERN FDA REVIEW AND APPROVAL OF DEVICES

Medical device regulation in the United States has a long history, which has been impacted and hastened by public outcry from tragic events of medical devices gone awry.<sup>53</sup> For instance, problems with faulty pacemakers, heart valves, and silicone breast implants have caused Congress to take notice, ultimately creating new authorities for the FDA or revising regulations governing the device approval process.<sup>54</sup>

### A. FOOD, DRUG AND COSMETIC ACT OF 1938 (FDCA)

In 1938, Congress enacted The Food, Drug and Cosmetic Act (FDCA),<sup>55</sup> as an effort to support the government’s role in regulating medical products for safety and effectiveness.<sup>56</sup> As early devices were less complicated than today, there was a belief that any defects or problems could be easily identified and resolved.<sup>57</sup> The FDCA gave the FDA authority to halt the sale of currently marketed medical devices,<sup>58</sup> but no “authority to review [devices] for safety or

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<sup>45</sup> *Id.* at 17.

<sup>46</sup> *Id.*

<sup>47</sup> *Id.*

<sup>48</sup> Walsh *supra* note 2, at 903.

<sup>49</sup> JOHNSON, *supra* note 3, at 2.

<sup>50</sup> Lennox, *supra* note 36, at 1366.

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

<sup>52</sup> Fargen, *supra* note 8, at 272.

<sup>53</sup> Robert Higgs, *Wrecking Ball: FDA Regulation Of Medical Devices*, CATO POL’Y ANALYSIS 235, 3 (Aug. 7, 1995), <http://www.cato.org/pubs/pas/pa-235.html>

<sup>54</sup> *Id.*

<sup>55</sup> Federal Food, Drug and Cosmetic Act (FDCA), (June 25, 1938, ch. 675, § 1, 52 Stat. 1040.)

<sup>56</sup> Alao, *supra* note 22, at 350.

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

<sup>58</sup> *Two pathways for approval of devices, FDA’s process for allowing medical devices to be sold fails to ensure safety and effectiveness*, SAFE PATIENT PROJECT.ORG 1 (Jan. 18, 2012, 10:15 am),

effectiveness prior to marketing, nor to establish or enforce performance standards." <sup>59</sup> Additionally, the FDCA allowed the FDA to have postmarket oversight and enforcement for devices they found to be misbranded (misabeled) or adulterated (false claims).<sup>60</sup> However, as devices became more complex, it was evident that the government needed more oversight, thus regulatory changes ensued. While FDCA did not provide for regulation of medical devices, it was an important first step for FDA involvement with defective medical devices.

## B. MEDICAL DEVICE AMENDMENTS OF 1976 (MDA)

In 1976, the Secretary of Health, Education and Welfare formed the Cooper Committee to investigate increasing concerns that medical devices were actually causing harm to consumers.<sup>61</sup> The committee found that devices "caused or contributed to over 700 deaths and nearly 10,000 injuries in a ten-year period."<sup>62</sup> This report finally caused legislators to take action in the regulation of medical devices prior to marketing.<sup>63</sup> Congress, industry, engineers, and consumers collaborated for many years<sup>64</sup> to create the review pathways, including the 510(k) notification process,<sup>65</sup> which ultimately reduced the approval process time for low- and moderate-risk devices.<sup>66</sup>

The MDA<sup>67</sup> provided the FDA with jurisdiction over virtually everything that could be used in disease treatment and diagnosis.<sup>68</sup> It granted the FDA greater authority for review and approval of medical devices.<sup>69</sup> Additionally, upon passage of the MDA, devices became known as 'preamendment' (on the market before the MDA) or postamendment (not yet on the market).<sup>70</sup>

Of continued significance, the MDA created a classification system based on the level of risk a device presents to consumers and the "level of controls needed to ensure the safety and effectiveness of that particular device."<sup>71</sup> This valuable system is still utilized today and requires all medical devices intended for human use to be placed into one of three classes.<sup>72</sup> The greater the potential for risk, the higher the classification and the more regulatory oversight needed to ensure the safety and effectiveness of the device.<sup>73</sup>

Class I are the lowest risk devices, including tongue depressors,<sup>74</sup> medical gloves and toothbrushes<sup>75</sup> which inflict little harm, if any, on consumers. 95% of devices in this category are

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<http://safepatientproject.org/document/two-pathways-for-approval-of-devices.pdf> [hereinafter *Two Pathways*].

<sup>59</sup> Lennox, *supra* note 36, at 1377.

<sup>60</sup> *Id.*

<sup>61</sup> Walsh, *supra* note 2, at 902-03.

<sup>62</sup> *Id.* at 903.

<sup>63</sup> *Id.*

<sup>64</sup> Lennox, *supra* note 36, at 1378.

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

<sup>66</sup> *FDA Fast-Track Programs for Drugs and Medical Devices*, DRUGWATCH.COM, (Nov. 3, 2015),

<http://www.drugwatch.com/fda/fast-track/> [hereinafter *FDA Fast-Track*].

<sup>67</sup> Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976).

<sup>68</sup> Walsh, *supra* note 2, at 903.

<sup>69</sup> JOHNSON, *supra* note 3, at 3.

<sup>70</sup> *Medical Devices*, *supra* note 24, at 10.

<sup>71</sup> Alao, *supra* note 22, at 351.

<sup>72</sup> 21 U.S.C. § 360c (2010).

<sup>73</sup> *Medical Devices*, *supra* note 24, at 1-2.

<sup>74</sup> Alao, *supra* note 22, at 351.

<sup>75</sup> Walsh, *supra* note 2, at 919.

exempt from 510(k) review because they are considered minimal risk.<sup>76</sup>

Class II are moderate risk devices, such as powered wheelchairs, hypodermic needles,<sup>77</sup> and daily wear contact lenses.<sup>78</sup> The FDA does not consider the risk great enough to require extensive safety and effectiveness data as part of the approval process.<sup>79</sup> Instead, the review of these devices is based on how similar they are to a previously cleared device.<sup>80</sup> If there are no additional safety or effectiveness concerns, the new device will be found ‘substantially equivalent’ to the previous device.<sup>81</sup>

Class III devices are those of highest risk, such as pacemakers, breast implants,<sup>82</sup> and replacement heart valves.<sup>83</sup> These devices are implantable, life sustaining, or pose a significant risk to the health, safety, or welfare of an individual.<sup>84</sup> Class III devices are intended to be reviewed through the Premarket Approval (PMA) process, the most intensive application process.<sup>85</sup> Additionally, all new devices introduced after the MDA (postamendment) were automatically classified as Class III.<sup>86</sup> Yet, exceptions exist in the MDA regulations to allow for reclassification of a device from one class to another, i.e., a Class III device to be reclassified to either Class I or II or a Class III device to be found ‘substantially equivalent’ to another device, effectively bypassing PMA review.<sup>87</sup>

Critics argue the MDA actually created a standard for reviewing medical devices [i.e. 510(k)], which is lower than the standard for reviewing new drugs.<sup>88</sup> However, the MDA significantly strengthened and improved the medical device regulatory process and remains the basis of the current device review regulatory structure. The MDA was pivotal medical device legislation. The MDA granted FDA the authority to review devices before they entered the market and created much of the current medical device review process framework, such as classification based on risk and the 510(k) review.

### C. SAFE MEDICAL DEVICES ACT OF 1990 (SMDA)

Mounting concerns that the FDA may not receive timely notice of marketed device problems led to heightened regard for patient safety and ultimately the Safe Medical Devices Act.<sup>89</sup> Of significance, the SMDA requires user facilities, such as hospitals and nursing homes, to track and report to the manufacturer and/or FDA adverse events that cause death, serious

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<sup>76</sup> *Medical Devices*, *supra* note 24, at 9.

<sup>77</sup> Alao, *supra* note 22, at 351.

<sup>78</sup> Walsh, *supra* note 2, at 919.

<sup>79</sup> *FDA Fast-Track*, *supra* note 66.

<sup>80</sup> Daniel B. Kramer et al., *Ensuring Medical Device Effectiveness and Safety: A Cross-National Comparison of Approaches to Regulation*, 69 *Food Drug L.J.* 1, 6 (2014).

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

<sup>82</sup> *FDA Fast-Track*, *supra* note 66.

<sup>83</sup> Walsh, *supra* note 2, at 920.

<sup>84</sup> *Medical Devices*, *supra* note 24, at 6.

<sup>85</sup> Alao, *supra* note 22, at 352. The Premarket Approval (PMA) process is one FDA review route for medical devices. See *infra* pp. 20-21.

<sup>86</sup> Walsh, *supra* note 2, at 920.

<sup>87</sup> JOHNSON, *supra* note 3, at 24. The DePuy hip replacement did not undergo the more rigorous premarket review as a Class III implantable device, but was cleared by the FDA with no clinical testing via the substantial equivalence allowance. See Consumer Reports, *supra* note 11.

<sup>88</sup> Alao, *supra* note 22, at 356.

<sup>89</sup> Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (1990) (codified as amended in scattered sections of 26 U.S.C.).



illness or serious injury.<sup>90</sup> The FDA is then mandated to monitor and track such adverse events caused by device use or misuse.<sup>91</sup> Moreover, as a way to reduce the FDA workload,<sup>92</sup> SMDA enlarged the Class II device category to include some devices previously designated as Class III, thereby allowing such devices to be reviewed under 510(k) rather than PMA.<sup>93</sup> The purpose of this reclassification was “to reduce the number of device types that needed PMA review.”<sup>94</sup> Additionally, a new device could now be compared to either a preamendment or a postamendment device as part of the 510(k) review,<sup>95</sup> thus allowing for similarity to a device that may actually never have gone through any FDA review prior to marketing. Finally, the SMDA influenced the 510(k) review process by providing a much-needed definition of ‘substantial equivalence’.<sup>96</sup> While the FDA may request safety and effectiveness data as part of the review, such as that obtained during clinical trials,<sup>97</sup> SMDA allows for clearance even when there are differences in technology between old and new devices.<sup>98</sup> Only new concerns of safety and effectiveness will cause a finding of non-substantial equivalence.<sup>99</sup> This effectively may put consumers at risk when a device can be cleared for market, even in the face of technology differences between old and new. While SMDA provided a definition of ‘substantial equivalence’ and reporting of serious adverse events, it effectively broadened the 510(k) review process by allowing a new device to be compared to pre or postamendment and allowing Class III devices to be reclassified and thus bypass PMA review for the less stringent 510(k) review.

#### **D. FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997 (FDAMA)**

Because Congress believed that medical device innovation was hampered by the regulatory system, they passed the Food and Drug Administration Modernization Act of 1997 (FDAMA).<sup>100</sup> FDAMA allowed some devices to be exempted from review, such as investigational devices and some Class I and II devices,<sup>101</sup> in order to allow the FDA greater focus on review of Class III devices.<sup>102</sup> Under this law, Congress also dictated that the FDA could ask a manufacturer for further safety and effectiveness data as part of 510(k) review, but only in the ‘least burdensome’ way,<sup>103</sup> practically limiting the information which the FDA can

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<sup>90</sup> Higgs, *supra* note 53, at 8.

<sup>91</sup> JOHNSON, *supra* note 3, at 15.

<sup>92</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 34.

<sup>93</sup> Specifically, the SMDA provided a new definition of Class II devices to include some devices previously in Class III, allowing the Secretary to determine if any special controls are necessary. Alao, *supra* note 22, at 366.

<sup>94</sup> INSTITUTE OF MEDICINE, *supra* note 1 at 256.

<sup>95</sup> *Id.* at 2.

<sup>96</sup> The SMDA: Considers a device to be substantially equivalent if it has the same intended use as an earlier device and: (1) has the same technological characteristics; or (2) the application contains information that the device is as safe and effective as a legally marketed device and does not raise different questions of safety and efficacy than the earlier device. Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511, Sec. 12(a) (1990).

<sup>97</sup> INSTITUTE OF MEDICINE, *supra* note 1 at 6.

<sup>98</sup> Alao, *supra* note 22, at 356.

<sup>99</sup> *Id.*

<sup>100</sup> Food & Drug Admin. Modernization Act of 1997 (FDAMA), Pub. L. No. 105-115, 111 Stat. 2296 (1997).

<sup>101</sup> Alao, *supra* note 22, at 354.

<sup>102</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 37.

<sup>103</sup> *Id.*

request.<sup>104</sup> Finally, FDAMA limited some postmarketing surveillance to implantable, life-sustaining Class II or III devices that may cause adverse consequences<sup>105</sup> and to consider how the addition of postmarketing surveillance data may enhance the premarket approval process.<sup>106</sup> Postmarketing surveillance data includes information regarding device performance, such as adverse event reporting, and may confirm whether the device is performing as expected.<sup>107</sup> In effect, FDAMA restricted the safety and effectiveness data the FDA can request as part of 510(k) review, but it did create the Sentinel system<sup>108</sup> as a method to collect serious adverse event data and provided consideration for use of postmarket data during the premarket approval review.

#### **E. THE MEDICAL DEVICE USER FEE AND MODERNIZATION ACT OF 2002 (MDUFMA)**

The Medical Device User Fee and Modernization Act of 2003 (MDUFMA) was enacted to provide additional funding to the FDA via user fees paid by device companies<sup>109</sup> and remains an important way to bolster FDA resources for medical device review.<sup>110</sup> These monies can only be used to supplement costs of PMA and 510(k) review<sup>111</sup> and in 2011 accounted for 15% of the CDRH program.<sup>112</sup> The law expires every 5 years, but was most recently renewed in 2012.<sup>113</sup> In order to continue receiving this support, Congress must continue to appropriate funding<sup>114</sup> and the FDA must meet agreed upon performance standards, such as completion of 90% of 510(k) reviews within 90 days.<sup>115</sup> User fees remain a tenuous source of revenue for the FDA due to the required conditions.<sup>116</sup> MDUFMA was important in the creation of additional monies available to the FDA for medical device review. Certainly, lack of this funding would have a negative impact on the device review process.

#### **F. THE FDA AMENDMENTS ACT OF 2007 (FDAAA)**

The FDA postmarket surveillance of devices, modified by FDAMA,<sup>117</sup> was a model for the postmarket surveillance of drugs enacted by FDAA.<sup>118</sup> Device postmarket review includes such things as labeling requirements and mandatory performance standards<sup>119</sup> and may be required per device classification and level of risk.<sup>120</sup> Because drugs were not subject to such review after approval, FDAAA focused on improving the FDA's management of drug-related

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<sup>104</sup> *Id.* at 38.

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

<sup>106</sup> *Id.* at 37.

<sup>107</sup> *Id.* at 49.

<sup>108</sup> *See infra* p. 18.

<sup>109</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 38.

<sup>110</sup> *Id.* at 39.

<sup>111</sup> JOHNSON, *supra* note 3, at 26.

<sup>112</sup> JOHNSON, *supra* note 3.

<sup>113</sup> *See, Medical Device User Fee Amendments (MDUFA)*, FDA, [http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/?](http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/)

<sup>114</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 38.

<sup>115</sup> *Id.* at 39.

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

<sup>117</sup> *See supra* pp. 16-17.

<sup>118</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 62.

<sup>119</sup> JOHNSON, *supra* note 3, at 5.

<sup>120</sup> *Id.* at 3.

risks with postmarket surveillance.<sup>121</sup> FDAAA added new authorities to the FDA to both evaluate and manage the risks of approved drugs in the market,<sup>122</sup> and required the FDA to establish an active monitoring system for postmarketing data for drugs.<sup>123</sup> The Sentinel system was created under FDAMA as the monitoring system.<sup>124</sup> While only drug data was required, the FDA opted to include medical device data in the Sentinel system via their general authority under the FDCA.<sup>125</sup> Additionally, FDAAA required HHS to establish and implement a unique identification system (UDI) in order to provide “an easily accessible source of device identification information to patients and health care professionals”.<sup>126</sup> Finally, FDAAA required the Government Accountability Office (GAO) to conduct a review of the 510(k) process, which has now been completed and published several times.<sup>127</sup> FDAAA provided for the collection of medical device data into the Sentinel database system, as well as establishing a formal identification system for device tracking via UDI.

Each round of legislative changes has strengthened the medical device review process, yet it remains a process fraught with criticism. Because there are different paths a device may take to market, any regulatory modifications must focus on what is lacking from each pathway and enact appropriate changes.

### III. MEDICAL DEVICE APPROVAL REVIEW PROCESS

#### A. APPROVAL PATHWAYS

As previously noted, there are distinct differences in the regulatory pathways for drugs and devices. The overall review process for drugs is quite lengthy and expensive.<sup>128</sup> It may take as long as 12 years to bring a drug to market and cost about \$800 million.<sup>129</sup> The drug pathway includes sequential review stages with increasing risk: research and development, clinical research and development (including clinical trials), and a new drug application (including post-market data collection).<sup>130</sup>

In contrast, medical devices may make it to market in as little as 3 years, with much less financial commitment.<sup>131</sup> While drugs are expected to be tested in patients with several phases of increasing risk and show positive results through clinical trials,<sup>132</sup> devices may be cleared with no actual clinical use. While the drug review pathway requires successful results in all clinical phases to obtain approval, CDRH is not required to collect such data in the medical device approval process [i.e. 510(k)].<sup>133</sup> As a whole, the drug review process is not suitable to the needs of medical device review. While the drug review process may be more thorough, it is also costly,

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<sup>121</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 62.

<sup>122</sup> *Id.* at 63.

<sup>123</sup> *Id.* at 130-31.

<sup>124</sup> *Id.* at 131

<sup>125</sup> *Id.*

<sup>126</sup> JOHNSON, *supra* note 3, at 18.

<sup>127</sup> *Medical Devices*, *supra* note 24, at 4.

<sup>128</sup> Fargen, *supra* note 8, at 269.

<sup>129</sup> *Id.*

<sup>130</sup> *Id.*

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

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

<sup>133</sup> *Id.*

lengthy, and tailored to the nuances of drugs. The medical device review process is well suited for the differences between drugs and devices, albeit lacking in safety and performance data.

Generally, there are two main routes of FDA review leading to approval or clearance for the sale of a medical device — PMA and 510(k).<sup>134</sup> Unless a product is otherwise exempt per FDA regulations,<sup>135</sup> an application or notification must be made to begin the FDA premarket review process.<sup>136</sup> Devices are then approved or cleared for market, dependent upon the route they take.<sup>137</sup>

#### 1. PREMARKET APPROVAL (PMA) REVIEW PATHWAY

Congress intended the PMA process to provide the most stringent premarket review of the highest risk devices.<sup>138</sup> While this is not as thorough as the drug review process mentioned above, it is the highest level of scrutiny that a new medical device will face in the postmarket review process. To ensure the safety and effectiveness of high-risk devices, PMA applications require a very detailed evaluation, including valid scientific data from bench and animal tests, as well as clinical trials.<sup>139</sup> The manufacturer bears the burden of proving the device is safe and effective<sup>140</sup> and must submit documentation from studies or testing as evidence.<sup>141</sup> PMA approvals also require inspections of manufacturing facilities to confirm compliance with quality regulations.<sup>142</sup> PMA includes review by an advisory panel comprised of scientists, medical and industry experts, and consumer groups who offer recommendations regarding device approval.<sup>143</sup> As a condition of PMA approval, the FDA can require postmarket studies to provide safety, effectiveness and reliability data.<sup>144</sup> However, this rarely happens, and the IOM notes: “The inadequacy of the current postmarketing surveillance system and the resulting lack of data make it impossible to confidently draw broad conclusions about the safety and effectiveness of products that are on the market.”<sup>145</sup> Significantly, since the MDA, all new devices brought to market are deemed Class III and subject to this review process,<sup>146</sup> yet exceptions for reclassification exist.<sup>147</sup> Ultimately, less than 1% of device applications received by CDRH are

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<sup>134</sup> See *Device Approvals, Denials, and Clearances*, FDA, <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/default.htm>

<sup>135</sup> A device is exempt from review if the FDA determines that it presents low risk of illness or injury. See 21 C.F.R. §§ 862 to 892.

<sup>136</sup> *Medical Devices*, *supra* note 24, at 2.

<sup>137</sup> Alao, *supra* note 22, at 353.

<sup>138</sup> *Medical Devices*, *supra* note 24, at 27.

<sup>139</sup> Of interest, FDA policy allows for acceptance of scientifically valid clinical data from foreign clinical studies in support of premarket submissions for devices. Special considerations may apply to such data, including study design, regulatory issues, and differences in patient population. See *Draft Guidance for Industry and FDA Staff on Acceptance of Medical Device - Clinical Data from Studies Conducted Outside the United States*, 80 FR 22205 (FDA April 22, 2015).

<sup>140</sup> Walsh, *supra* note 2, at 922.

<sup>141</sup> *Id.* at 923.

<sup>142</sup> JOHNSON, *supra* note 3, at 12.

<sup>143</sup> Walsh, *supra* note 2, at 923.

<sup>144</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 70.

<sup>145</sup> *Id.* at 129.

<sup>146</sup> Walsh, *supra* note 2, at 920.

<sup>147</sup> See *supra* p. 14.

for Class III devices.<sup>148</sup> Completion of the PMA process can result in FDA approval to market a device in the United States and a reasonable assurance of safety and effectiveness.<sup>149</sup>

## 2. PREMARKET NOTIFICATION; THE 510(K) REVIEW PATHWAY

The 510(k) review process was developed by Congress as a way to “make available to consumers devices that are safe and effective” and “promote innovation in the medical device industry.”<sup>150</sup> This premarket notification is found in Section 510(k) of the regulations<sup>151</sup> and is commonly known as 510(k) notification or 510(k) clearance.<sup>152</sup> Congress initially planned 510(k) review as a short-term way to “facilitate [the backlog in the FDA’s] task of classifying all marketed devices according to risk,”<sup>153</sup> yet 40 years later it is still in use. Most new medical devices are cleared for market via 510(k) review.<sup>154</sup>

As per the 510(k) regulations, ninety days before planning to market a new device, a manufacturer must notify the FDA of their intent.<sup>155</sup> This notification confirms that the manufacturer does not want to proceed through PMA review, but rather believes there is ‘substantial equivalence’ between the new and predicate device.<sup>156</sup> The new device will be assigned to the same Class as the predicate device(s).<sup>157</sup> As long as there are no new concerns of safety or effectiveness,<sup>158</sup> the new device will be found substantially equivalent (SE) and cleared for patient use. If the FDA does not agree, they may issue a finding of not substantially equivalent (NSE), meaning that the new device will be automatically classified as Class III and required to undergo PMA review.<sup>159</sup> The 510(k) process is a relatively quick, economical path to market, which allows for potential innovation and benefits to public health. However, the issue with this pathway, as described below, is the concerning lack of safety and effectiveness data. Additionally, a loophole in FDA regulations allows for some high-risk (Class III) devices to bypass the PMA review for the faster, cheaper 510(k) review.<sup>160</sup>

### B. PMA VERSUS 510(K)

How do these approval pathways compare? First, both review processes are important components of the overall medical device regulatory structure because they allow for premarket review of devices based on risk to consumers.<sup>161</sup> As such, they provide a unique function that

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<sup>148</sup> *Two Pathways*, *supra* note 58.

<sup>149</sup> JOHNSON, *supra* note 3, at 3.

<sup>150</sup> INSTITUTE OF MEDICINE, *supra* note 1, at xii.

<sup>151</sup> See *Federal Food, Drug and Cosmetic Act (FFDCA)*, 21 U.S.C. § 360(k) (1962).

<sup>152</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 1.

<sup>153</sup> *Id.* at 15.

<sup>154</sup> Lennox, *supra* note 36, at 1366.

<sup>155</sup> *Medical Devices*, *supra* note 24, at 12.

<sup>156</sup> Walsh, *supra* note 2, at 925.

<sup>157</sup> *Id.* at 926.

<sup>158</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 34-35.

<sup>159</sup> *Id.* at 88-89.

<sup>160</sup> The loophole allows Class III devices to be reviewed via 510(k) if ‘substantial equivalence’ can be shown, effectively allowing high-risk devices to avoid the more stringent PMA review. See Negah Mouzoon & Michael Carome, *Substantially Unsafe Medical Devices Pose Great Threat to Patients; Safeguards Must be Strengthened, Not Weakened*, PUBLIC CITIZEN, February 2012, at 27.

<sup>161</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 1.

will best serve the overall public need of safe and innovative treatments.

The difference in the processes starts with the initial perspective the FDA takes in its evaluation. For PMA review, the FDA must assess if the device is reasonably safe and effective for its intended use.<sup>162</sup> For 510(k) review, however, the FDA assesses if the device is substantially equivalent to some other device whose safety and effectiveness may never have been assessed.<sup>163</sup> This difference has been the subject of concern and discussion for many years because of the loophole allowing a device to get to market based on similarity to a previous device whose safety may never have been assessed.

Beyond the starting point for evaluation, there are additional differences between the two pathways. The 510(k) process is less stringent as it does not require clinical data (rather ‘substantial equivalence’),<sup>164</sup> is a faster process (90 days versus 180 days), and is less expensive (about \$18,200 versus \$870,000 in 2005).<sup>165</sup> Additionally, a 510(k) review may result in FDA clearance to market, as opposed to FDA approval to market resulting from a PMA.<sup>166</sup> The difference between “clearance to market” and “approval to market” is noteworthy as it is indicative of the level of FDA review, but does not bear on the marketing of the product. Clearance to market indicates that the device has completed the 510(k) process and is ‘substantially equivalent’ to a device already marketed for the same use.<sup>167</sup> Approval to market indicates that the device has completed the more stringent PMA review and provided ‘reasonable assurance of safety and effectiveness’.<sup>168</sup>

Generally, Class III devices are those that must go through the more rigorous PMA review.<sup>169</sup> While it is a longer, more detailed process, PMA does allow for inclusion of public review and feedback via advisory panels,<sup>170</sup> while 510(k) review is completed solely by FDA staff. Also, critics of the PMA process argue that the FDA has not clearly defined the scientific data required for application, leading to confusion and delay during an already time-intensive and expensive process.<sup>171</sup> The 510(k), on the other hand, has become the route of choice because it is fast, relatively cheap, and in effect, plays a ‘gate-keeper’ or mini premarket review function if a more detailed PMA is needed.<sup>172</sup>

Many Class I and II devices are cleared through 510(k),<sup>173</sup> which is a more widely used review process than PMA.<sup>174</sup> This makes sense because Class I and Class II devices are, by definition, low to moderate risk devices which do not require submission of extensive safety and effectiveness data.<sup>175</sup> In general, Class III devices are approved through PMA, yet there are two situations that allow Class III devices to be reviewed through 510(k).<sup>176</sup> First, Class III devices that were already sold in the United States prior to the MDA legislation (referred to as

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<sup>162</sup> *Id.* at 91.

<sup>163</sup> *Id.*

<sup>164</sup> *Two Pathways*, *supra* note 58.

<sup>165</sup> *Medical Devices*, *supra* note 24, at 15.

<sup>166</sup> *Id.* at 2-3.

<sup>167</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 86.

<sup>168</sup> *Medical Devices*, *supra* note 24, at 2.

<sup>169</sup> The PMA review process is required for implantable, lift-sustaining, high-risk Class III devices. *See supra* pp. 20-21.

<sup>170</sup> Walsh, *supra* note 2, at 923.

<sup>171</sup> *Id.* at 946.

<sup>172</sup> *Id.*

<sup>173</sup> *Two Pathways*, *supra* note 58.

<sup>174</sup> Alao, *supra* note 22, at 355.

<sup>175</sup> *See supra* p.13.

<sup>176</sup> *Medical Devices*, *supra* note 24, at 3.

‘grandfathered’ devices) are not required to undergo PMA review.<sup>177</sup> Secondly, Class III devices after enactment of the MDA, which can show substantial equivalence to a grandfathered device, or any Class I or II device, will not be subject to PMA review.<sup>178</sup> Allowing Class III devices to be cleared via the 510(k) pathway is concerning due to the inherent risk of the device and absence of safety and effectiveness data.

Of note, when a device receives clearance through the 510(k) process, it becomes eligible to serve as a predicate.<sup>179</sup> Devices marketed prior to the MDA and approved without safety testing<sup>180</sup> can also serve as predicates to clear new devices.<sup>181</sup> A device only becomes ineligible to serve as a predicate when it has been banned, found to be adulterated or misbranded, or pulled from the market.<sup>182</sup> Yet, due to lack of efficient tracking systems, a device removed from market does not always get removed as a predicate, consequently future devices may still be approved on this recalled device.<sup>183</sup> The bottom line is that a device with no safety or performance data can serve as a predicate device in the 510(k) process and a new device with no such data can still result in FDA clearance to market.

The FDA must provide clearance if a 510(k) notification can find any legally cleared device to show similarity.<sup>184</sup> However, “the FDA has made it clear from the outset that clearance of a 510(k) notification was not a determination that the cleared device was safe or effective”,<sup>185</sup> but just similar to a predicate. United States courts recognize this lack of determination of safety and effectiveness for a device as a shortcoming in the 510(k) review.<sup>186</sup> In Lohr v. Medtronic, Inc., the Court of Appeals for the Eleventh Circuit noted that whether a device is actually safe and effective for public use is a question that cannot be resolved by the 510(k) process.<sup>187</sup> The United States Supreme Court affirmed this interpretation in a 1996 opinion and stated “the 510(k) process is focused on equivalence, not safety, [and] as a result substantial equivalence determinations provide little protection to the public.”<sup>188</sup> Yet, when marketed to the public, consumers are not necessarily aware of this lack of safety testing and manufacturers certainly do not clarify this distinction in their marketing.

While improvements to both pathways are needed, 510(k) is the primary review method preferred by both manufacturers<sup>189</sup> and the FDA and as such, needs immediate attention.

#### IV. MEDICAL DEVICE REPORTING SYSTEM

While manufacturers may not be mandated to report safety and effectiveness data for premarket review, they are required to report some data regarding the use of a marketed device. Medical device manufacturers must maintain product data and report device related adverse

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<sup>177</sup> David C. Vladeck, *Preemption and Regulatory Failure*, 33 Pepp. L. Rev. 95, 102 (2005).

<sup>178</sup> *Id.*

<sup>179</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 89.

<sup>180</sup> *Two Pathways*, *supra* note 58.

<sup>181</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 87-88.

<sup>182</sup> *Id.* at 89.

<sup>183</sup> *Two Pathways*, *supra* note 58.

<sup>184</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 35.

<sup>185</sup> *Id.* at 36.

<sup>186</sup> Diana M. Zuckerman et al., *Medical Device Recalls and the FDA Approval Process*, 171 JAMA Internal Med. 1006, 1010 (2011).

<sup>187</sup> *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1348 (11th Cir. 1995).

<sup>188</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996).

<sup>189</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 73.

events such as malfunctions, serious injuries, and death to the FDA.<sup>190</sup> Yet, they are not required to provide safety data from clinical trials or postmarket surveillance studies for a marketed device.<sup>191</sup>

The FDA's Manufacturer and User Facility Device Experience (MAUDE) database contains data from these mandatory medical device reports (MDR),<sup>192</sup> as well as voluntary reports from health care professionals, patients, and consumers.<sup>193</sup> The reporting system cannot be relied upon to ascertain postmarketing performance of a device because of likely under-reporting and lack of information regarding device use.<sup>194</sup> Additionally, because this reporting is voluntary,<sup>195</sup> the data cannot be confidently used to evaluate devices currently marketed that may serve as future predicates.<sup>196</sup> A passive reporting system, dependent on manufacturers, clinicians, and consumers to file mandatory and voluntary reports, may contain potentially biased data.<sup>197</sup>

The FDA can and should enforce device regulations when collected data identifies a concerning trend or device flaws. The FDA was granted authority via the MDA to penalize manufacturers who produce defective devices.<sup>198</sup> When problems are uncovered, the FDA may seize devices, obtain injunctions or pursue criminal prosecution.<sup>199</sup> However, the FDA does not have an efficient tool to track their own actions in such cases<sup>200</sup> and in reality, rarely take action. If the FDA cannot depend upon a system to track problems with marketed devices, they certainly cannot penalize wrongdoing with any certainty.

## V. PROBLEMATIC DEVICE APPROVALS

The FDA is often criticized for taking too long to approve new medical devices.<sup>201</sup> To resolve this problem, they have tried to speed up the approval process time via 510(k).<sup>202</sup> Device companies, of course, prefer the 510(k) process because they do not have to offer proof of safety and effectiveness for the new device they wish to market. This saves the company time, money, and resources that would be required for a PMA review.<sup>203</sup> The FDA also tends to favor the 510(k) process as a less costly and time-consuming review that can depend on the significant equivalence finding.<sup>204</sup>

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<sup>190</sup> FDA, *Medical Device Reporting (MDR)*, [www.FDA.GOV](http://www.fda.gov), <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> (last visited Mar. 27, 2016) [hereinafter *Medical Device Reporting*].

<sup>191</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 64.

<sup>192</sup> 21 C.F.R. § 803 (2014).

<sup>193</sup> FDA, *MAUDE - Manufacturer and User Facility Device Experience*, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM> (last visited Mar. 15, 2016).

<sup>194</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 126.

<sup>195</sup> *Medical Device Reporting*, *supra* note 190.

<sup>196</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 129.

<sup>197</sup> *Medical Device Reporting*, *supra* note 190.

<sup>198</sup> Walsh, *supra* note 2, at 903.

<sup>199</sup> *Id.* at 896.

<sup>200</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 54.

<sup>201</sup> Walsh, *supra* note 2, at 933.

<sup>202</sup> Lennox, *supra* note 36, at 1366.

<sup>203</sup> *Id.*

<sup>204</sup> Walsh, *supra* note 2, at 946.



Yet, device problems occur and may go unnoticed for some time, causing serious harm for patients. Throughout history, device tragedies have initiated legislative changes to the review system<sup>205</sup> and increased oversight for the FDA.<sup>206</sup> In addition to the DePuy hip previously discussed,<sup>207</sup> some of the more well-known device problems include the Dalkon Shield, Medtronic lead wire, and Axxent Flexishield. Each of these devices eventually caused great harm to patients.

The Dalkon shield was an intrauterine birth-control device with a “distinctively new design that cut risk of intrauterine bleeding, expulsion or pregnancy”.<sup>208</sup> It entered the market in 1971 and was advertised as safe and effective.<sup>209</sup> Notably, the device was marketed without FDA approval.<sup>210</sup> Eventually, in 1975, the device was pulled off the market “due to numerous deaths, miscarriages, and cases of pelvic infection,”<sup>211</sup> but, surprisingly, it was not recalled at that time. Over 10 years later, the company created a \$615 million reserve in order to settle lawsuits filed all across the country.<sup>212</sup> The result of the countless tragedies caused by this device resulted in the MDA legislation.

Another significant malfunction was the Medtronic lead wire failure, which demonstrates the serious life-threatening harm that can occur with a lack of clinical data and FDA premarket review.<sup>213</sup> The lead wire carried electrical current from a pacemaker to the heart.<sup>214</sup> Even though it was an implantable, Class III device, it was found substantially equivalent to a preamendment device<sup>215</sup> and cleared for market via 510(k).<sup>216</sup> The company relied on stress testing, not a clinical trial and 268,000 patients were exposed to a wire that led to multiple deaths.<sup>217</sup> The Court in this 1995 case noted, “we are not convinced that 510(k) approval constitutes a finding of safety and effectiveness.”<sup>218</sup>

Finally, the Axxent Flexishield Mini device allows healthy breast tissue to be shielded from radiation during treatment for breast cancer.<sup>219</sup> This flexible, silicone pad is only used during treatment and then removed.<sup>220</sup> Cleared via 510(k) in 2009,<sup>221</sup> the predicate used for

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<sup>205</sup> Alao, *supra* note 22, at 350.

<sup>206</sup> Walsh, *supra* note 2, at 902.

<sup>207</sup> See *supra* pp. 4-7.

<sup>208</sup> Karen Kenney, *Dalkon Shield Gives Birth To A Generation Of Lawsuits*, L.A. DAILY NEWS, April 30, 1985, [http://articles.chicagotribune.com/1985-04-30/features/8501260779\\_1\\_dalkon-shield-intrauterine-robins](http://articles.chicagotribune.com/1985-04-30/features/8501260779_1_dalkon-shield-intrauterine-robins)

<sup>209</sup> *Id.* The Dalkon Shield entered the market at a time when the FDA had no authority to review devices before sale. See *supra* note 59.

<sup>210</sup> Vladeck, *supra* note 177, at 103.

<sup>211</sup> Lennox, *supra* note 36, at 1378.

<sup>212</sup> Kenney, *supra* note 208.

<sup>213</sup> Vladeck, *supra* note 177, at 106-07.

<sup>214</sup> *Id.* at 106.

<sup>215</sup> *Id.* at 107.

<sup>216</sup> Medtronic Models 4011 & 4511, K822781, [http://www.accessdata.fda.gov/cdrh\\_docs/pdf8/K822781.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf8/K822781.pdf)

<sup>217</sup> Thomas M. Burton, *Do the FDA's Regulations Governing Medical Devices Need to Be Overhauled?*, WALL ST. J., Mar. 23, 2015, <http://www.wsj.com/articles/do-the-fdas-regulations-of-medical-devices-need-to-be-overhauled-1427079649>.

<sup>218</sup> *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1348 (11th Cir. 1995).

<sup>219</sup> Mouzoon, *supra* note 160, at 16.

<sup>220</sup> *Id.* at 17.

<sup>221</sup> Axxent® FlexiShieldMini, K 090417, [http://www.accessdata.fda.gov/cdrh\\_docs/pdf9/K090417.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090417.pdf)

clearance was actually a device with significant technological differences.<sup>222</sup> The device was found to be depositing small pieces of metal in the very breast tissue it was meant to protect, resulting in additional unplanned mastectomies for affected patients.<sup>223</sup> The device was eventually recalled, yet the manufacturer still recommends that those exposed to this device have annual blood and urine tests to check for the metal.<sup>224</sup>

There is no foolproof review process that can assure ultimate safety of a device. Consumers should have confidence, however, that the system will provide significant oversight and protect them from harm. While thousands of devices successfully make it to market each year in the United States, failures like these leave a lasting impression and a demand for change.

## VI. INSTITUTE OF MEDICINE REPORT ON DEVICE REGULATORY FRAMEWORK

The Government Accountability Office (GAO) listed the FDA's medical review process as high-risk area in both 2009 and 2011.<sup>225</sup> The FDA also has taken notice of device failures and has realized that flaws may exist in the regulatory process.<sup>226</sup> Due to concerns surrounding the ability of the 510(k) process to actually protect and promote the public's health, the FDA commissioned the Institute of Medicine (IOM) to conduct a detailed review of the 510(k) clearance process.<sup>227</sup> In their 2011 report, the IOM found that the ability of the FDA to notice problems is so deficient it is 'impossible to confidently draw broad conclusions about the safety and effectiveness of products that are on the market.'<sup>228</sup> They also reported that 510(k) was not meant to be a method to evaluate safety and effectiveness of a medical device and thus cannot be viewed as an evaluation of safety and effectiveness "as long as the standard for clearance is substantial equivalence to any previously cleared device".<sup>229</sup> Equally important, in Medtronic, Inc. v. Lohr, where the Court was faced with the issue of whether the MDA pre-empts a claim of negligence under state common law against a medical device manufacturer, the Supreme Court identified the "logical flaw" in relying on the standard of substantial equivalence:<sup>230</sup>

As the court below noted, "[t]he 510(k) process is focused on equivalence, not safety." . . . As a result, "substantial equivalence determinations provide little protection to the public. These determinations simply compare a post-1976 device to a pre-1976 device to ascertain whether the later device is no more dangerous and no less effective than the earlier device. If the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective."<sup>231</sup>

The IOM found a lack of information about how devices are used and perform once they are on the market, which negatively impacts the FDA's ability to evaluate intended use, indications for use, and whether substantial equivalence exists in a 510(k) review.<sup>232</sup> With no adequate tools to consistently assess quality, consistency and effectiveness of the program,

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<sup>222</sup> Mouzoon, *supra* note 160, at 17.

<sup>223</sup> *Id.*

<sup>224</sup> *Id.* at 18.

<sup>225</sup> JOHNSON, *supra* note 3, at summary.

<sup>226</sup> INSTITUTE OF MEDICINE, *supra* note 1.

<sup>227</sup> *Id.*

<sup>228</sup> *Id.* at 129.

<sup>229</sup> *Id.* at 5.

<sup>230</sup> Mouzoon, *supra* note 160, at 35.

<sup>231</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996).

<sup>232</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 100.

CDRH cannot make needed improvements. IOM recommended that “FDA resources would be put to better use in obtaining information needed to develop a new regulatory framework for Class II medical devices and addressing problems with other components of the medical device regulatory framework.”<sup>233</sup> They concluded their thorough review of the device approval process by stating “further investment in the 510(k) process is [not] a wise use of the FDA’s scarce resources.”<sup>234</sup> While this was a comprehensive look at the FDA’s review of medical devices, many of the problematic issues noted are still in existence today, five years later.

## VII. PENDING LEGISLATION

Those that argue how cumbersome the FDA process is for drug and device approval believe that consumers suffer harm and even death while waiting for approved treatments to make it to market.<sup>235</sup> Legislation attempts to rectify deficiencies within the FDA approval process and offer much needed resources.<sup>236</sup>

The Patient Protection and Affordable Care Act, commonly known as ACA, initially included a proposed National Medical Device Registry to be overseen by HHS.<sup>237</sup> While this was ultimately not part of the final legislation,<sup>238</sup> it confirms the realization of the need for a device registry in the United States.

Reciprocity Ensures Streamlined Use of Lifesaving Treatments Act (RESULT) is a new bill introduced by Republican presidential candidate, Ted Cruz.<sup>239</sup> This bill proposes expedited approvals for lifesaving drugs, gives Congress authority to intervene in FDA decisions, and allows drugs and devices “that are authorized to be lawfully marketed abroad” into the United States market.<sup>240</sup> While finding innovative ways to speed up the overall FDA process could be an improvement, allowing members of Congress to overthrow FDA rulings would be detrimental for citizens.<sup>241</sup> Like other agencies within HHS, the FDA is comprised of professionals who have extensive knowledge in the field. Few Congressional members have this same expertise. Taking regulatory decisions away from those with knowledge and experience in order to simply speed up the review process is a worrisome proposal.<sup>242</sup>

Additional pending legislation includes the 21<sup>st</sup> Century Cures Act which proposes a “\$8.75 billion investment in National Institute of Health (NIH) grants over the next five years, [and] a concentrated effort to streamline the FDA’s approach to the regulatory process by incorporating more modern analytical methods for evaluating drugs and devices.”<sup>243</sup> While many support legislation that will speed up the regulatory approval process, others worry that

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<sup>233</sup> *Id.* at 8.

<sup>234</sup> *Id.* at 7.

<sup>235</sup> Elizabeth C. Price, *Teaching the Elephant to Dance: Privatizing the FDA Review Process*, 51 Food Drug L.J. 651, 654 (1996).

<sup>236</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 29.

<sup>237</sup> H.R. 3200, 111<sup>th</sup> Cong. § 1 (2009).

<sup>238</sup> Patient Protection and Affordable Care Act (PPACA), 42 U.S.C. §18001 (2010).

<sup>239</sup> S. 2388, 114<sup>th</sup> Cong. § 1 (2015).

<sup>240</sup> *Id.*

<sup>241</sup> John LaMattina, *Sen. Ted Cruz Wants To Change The Way The FDA Approves Drugs*, FORBES, Feb. 3, 2016.

<sup>242</sup> *Id.*

<sup>243</sup> Suzanne Hodsdon, *21st Century Cures Act Set To Overhaul FDA Regulatory Process*, MED DEVICE ONLINE, Jul. 10, 2015.

“the bill will weaken the FDA and may jeopardize patient safety”<sup>244</sup> because “the new law would redefine the evidence on which high risk devices can be approved to include case studies, registries, and articles in medical literature, rather than rigorous clinical trials”.<sup>245</sup> Critics worry that medical devices may go through less stringent requirements under this bill, which could lead to overall reduced safety for American consumers. Congress should be looking for ways to positively impact the review structure, not simply searching for a way to speed up the process.

## VIII. RECOMMENDED CHANGES TO THE PROCESS

Without dismantling the current structure and starting over, the regulatory framework must be repaired. Dr. Jeffrey Shuren, Director of CDRH, noted, “Rather than focus on more regulation or less regulation, we [must] focus on ‘smart regulation’.”<sup>246</sup> While the IOM provided a thorough review of the overall device review process, their recommendation of bypassing the current 510(k) process in favor of creating “a new regulatory framework for Class II medical devices”<sup>247</sup> is unreasonable. Distinct problems do lie within this pathway, yet the 510(k) process should not be entirely dismissed. The review process is an adequate pathway that needs to be enhanced and incorporate data needed to confirm safety and effectiveness of the device.

Consistent with the three risk classifications, the current regulatory process allows for exemption, limited, or thorough review by the FDA.<sup>248</sup> At issue is the lack of clinical data required in the limited review process, [i.e. 510k], as well as a robust system to capture, analyze and use data that must be required from device use in order to properly safeguard the public from faulty devices. Five recommendations to enhance the medical device review process are noted below.

First, as discussed in Section I, the classification system created by the MDA assigns a device to Class I, II, or III based on the level of risk and then regulates the class accordingly. However, the classifications need to be more closely aligned with the review pathways. Specifically, Class I devices should be those that are exempt from review, Class II required to go through 510(k) review, and Class III required to go through PMA review. While 510(k) review encompasses mostly Class II devices, there are also some Class I and III devices reviewed via this pathway.<sup>249</sup> Manufacturers are certainly motivated to offer similarities between their device and a predicate in order to market; however, it is not in the best interest of consumers to allow this mixing of Classes within review types to be a common standard.

The PMA pathway is meant to review high-risk devices, yet some Class III devices do not go through this process<sup>250</sup>, for instance when they can show ‘substantial equivalence’ to a predicate device and go through the 510(k) process instead. Because Class III devices are implantable and capable of supporting and sustaining life, they should not be cleared through the 510(k) process with no safety data review.<sup>251</sup> These devices need to be held to similar safety

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<sup>244</sup> *Id.*

<sup>245</sup> *Id.*

<sup>246</sup> *Medical Devices: Protecting Patients and Promoting Innovation*: Statement Before the S Comm. on Health, Educ., Lab, and Pensions, 112th Cong. (2011) (statement of Jeffrey Shuren, Dir., Center for Devices and Radiological Health, FDA) [Hereinafter *Protecting Patients*].

<sup>247</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 8.

<sup>248</sup> *See supra* p. 9.

<sup>249</sup> *See supra* p. 14.

<sup>250</sup> *Id.*

<sup>251</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 13.

requirements as drugs and provide substantial proof of safety and effectiveness, rather than only showing similarity to a current device. Therefore, PMA review must be required for all Class III devices<sup>252</sup>, and the loophole closed allowing for less stringent review.

Class II devices are those of moderate risk. They should complete the 510(k) review and not be exempted from review. The 510(k) review of these devices must provide for inclusion of data regarding the device's clinical performance.

Class I devices are those with the lowest risk. 95% of these devices are exempt from review by the FDA,<sup>253</sup> which is appropriate. However, if a Class I device is determined not to be exempt from FDA, it should accordingly be reclassified to Class II and regulated according to the 510(k) review.

To summarize, implantable, life sustaining devices should be deemed Class III and subject to the more rigorous review [i.e. PMA],<sup>254</sup> while Class II devices must go through 510(k) review with submission of postmarket performance data. Class I devices should be exempted from review.

Second, 510(k) review may be built on a long list of predicate devices dating back to 1976.<sup>255</sup> Although a new device may vary dramatically from a predicate, each new device clearance can, in turn, become a predicate for the next round of new devices.<sup>256</sup> As the cycle continues, the cleared device may look less and less like the initial predicate. This dependence on use of a past device as predicate to show similarity is problematic because it is the crux of the 510(k) process.<sup>257</sup> Ironically, "a 510(k) submission for a new device in 2008 could be compared to the 20<sup>th</sup> iteration of a device type that was on the market before 1976."<sup>258</sup> In order to strengthen the current regulatory framework, the regulations should be changed to exclude pre-1976 amendment devices from serving as a predicate device in the 510(k) process, because such devices were not approved to market by review of safety or effectiveness data.<sup>259</sup> This will place the burden on manufacturers to find newer predicates similar to their new devices. This process will allow for similarity comparisons between more current devices.

Third, performance and safety data must be added to 510(k) in a way that is manageable for both device manufacturers and meaningful for the FDA. The 510(k) review process is a major component of FDA medical device oversight in the United States.<sup>260</sup> As it stands today, it is not a sufficient review pathway because there is no requirement for either pre or postmarket data to confirm device performance. While the FDA's role is to find a 'reasonable assurance of safety and effectiveness' in medical devices premarket, the 510(k) review provides neither of these assurances.<sup>261</sup> Premarket data should be required if available, but mandatory postmarket performance data must be a condition of 510(k) clearance.<sup>262</sup> Use of a cleared or approved device in the clinical setting does provide "at least a level of confidence in the safety and

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<sup>252</sup> *Medical Devices*, *supra* note 24, at 7.

<sup>253</sup> *See supra* p.13.

<sup>254</sup> *Medical Devices*, *supra* note 24, at 28.

<sup>255</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 118.

<sup>256</sup> *Id.* at 33.

<sup>257</sup> *Id.* at 89.

<sup>258</sup> *Medical Devices*, *supra* note 24, at 13.

<sup>259</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 6.

<sup>260</sup> *See supra* p. 8.

<sup>261</sup> Andre Francisco, *FDA Medical Device Approval Process Needs Overhaul*, The Project On Government Oversight (POGO) Blog, Aug. 4, 2011, at 1.

<sup>262</sup> Fargen, *supra* note 8, at 273.

effectiveness<sup>263</sup> and should be required. This data will help to identify risk or long-term effects, as well as provide some assurance that the device is performing as expected.<sup>264</sup> Although manufacturers will argue that postmarket data collection will be costly and time consuming, data can be gathered from clinical use more quickly and with less financial burden than through a clinical trial requirement.

Fourth, while post-market data collection is crucial, a robust database to house critical information is equally important. In order to provide the FDA access to meaningful data, clinical performance data must be reported on a mandatory schedule throughout the life of device usage.<sup>265</sup> The FDA must then proactively monitor the database for any potential safety issues. This recommendation places the burden on a device manufacturer to show that a device does perform as expected. Moving forward, this post marketing data can and should then be used as part of the review process for new devices.<sup>266</sup>

The FDA does not currently have an efficient, searchable database that allows for tracking of decisions made about predicate devices,<sup>267</sup> clinical outcomes, or performance data.<sup>268</sup> With an efficient tracking system in place, the FDA can require a manufacturer to maintain contact information for each patient who receives a device, as well as their physician.<sup>269</sup> Collection of this information will allow the FDA to directly notify consumers and healthcare providers regarding device problems.<sup>270</sup> A tracking database must also include mandatory documentation of adverse device events, device malfunctions, recalls, and enforcement and resolution data to make it dependable and up-to-date.<sup>271</sup> Such a system will allow for review of performance data in predicate devices and prohibit recalled devices from serving as future predicates.<sup>272</sup>

The FDA mission of protecting the public's well-being will be reinforced with the utilization of a vigorous medical device database, as a delay in the notification of a recalled device can only cause harm to consumers.<sup>273</sup> A device registry listing, as is common in many European countries,<sup>274</sup> makes it possible to reach affected consumers with information about device failures. As part of a robust database, the FDA must implement a registry that requires manufacturers to assign and document a device identification number, linking it to the patient who has received it.<sup>275</sup> This will allow for device recalls or problems to be communicated to

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<sup>263</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 32.

<sup>264</sup> *Id.* at 52.

<sup>265</sup> *Id.* at 22.

<sup>266</sup> *Id.*

<sup>267</sup> *Id.* at 118.

<sup>268</sup> *Id.* at 119.

<sup>269</sup> *Id.* at 49.

<sup>270</sup> Lennox, *supra* note 36, at 1399.

<sup>271</sup> Of note, the FDA has noted the establishment of a 'National Evaluation System for Medical Devices' as part of the 2016-2017 Strategic Priorities for CDRH. US Food and Drug Administration, 2016-2017 Strategic Priorities, Center for Disease and Radiological Health (2016).

<sup>272</sup> Mouzoon, *supra* note 160, at 46.

<sup>273</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 142.

<sup>274</sup> Lennox, *supra* note 36, at 1398.

<sup>275</sup> Of note, under FDAAA, the FDA is now required to develop unique device identifiers. On September 24, 2013, FDA published a final rule creating a unique device identification system, including unique device identifier (UDI) labeling and data submission requirements (78 FR 58786) (the UDI Rule). Generally, under 21 C.F.R. § 801.20, the label and device package of a device must bear a UDI; 21 C.F.R. § 801.30 provides exceptions.

individual consumers and healthcare providers.<sup>276</sup> Such a registry can be modeled after the VIN system for cars, which allows a consumer to receive updates from manufacturers or the government regarding recalls. This will potentially become an effective tool to assess device outcomes as well.<sup>277 278</sup>

Finally, the FDA must hold device manufacturers accountable for production of safe, effective devices. The IOM found that the FDA rarely uses their authorities,<sup>279</sup> such as device recall, product seizure, injunction, and criminal penalty<sup>280</sup>, against device manufacturers. However, they must systematically begin to use these tools to best protect the public health and well-being.<sup>281</sup> While a lack of resources is not a sufficient argument as to why these protections are not used, Congress must partner with the FDA to ensure that resources and funding are provided to ensure compliance. Monies collected from device manufacturers via user fees<sup>282</sup> and the medical device excise tax, as enacted by the Patient Protection and Affordable Care Act (PPACA),<sup>283</sup> should be directed towards compliance efforts.

## IX. CONCLUSION

Clearly defining the review process for each device class, mandating the reporting of clinical data and developing a suitable database for collection and tracking of device information are necessary additions to the current structure.

Although the medical device approval process in the United States follows a different path than the approval process for drugs, the desired outcome of both is to provide safe, effective medical treatments to consumers. The regulatory structure of the medical device pathway is sound, but to be effective, needs to be updated. Congress has made attempts to speed up the process through the 510(k), but consumers should not feel confident that this review is sufficient. It is necessary for the public benefit to make improvements in the current medical device review structure that assure that new devices are performing as expected in the clinical setting. A review process that does not require data from actual testing of a product is a flawed system.

Consistent and transparent requirements are needed for both manufacturers and the FDA to increase the efficiency of the review process. The public will benefit from the collection of additional device performance data, allowing both consumers and healthcare providers the ability to make better-informed treatment decisions. Such improvements will also allow for better collaboration between industry, the FDA, and the public.

Legislative changes take time and this will not be a quick fix. However, medical device regulatory history shows a desire to improve the process, thus there is every indication that such improvements are possible. As Dr. Shuren at the CDRH states, “if the United States is to maintain its leadership role in [the global medical device industry], we must continue to

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<sup>276</sup> Lennox, *supra* note 36, at 1400.

<sup>277</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 139.

<sup>278</sup> The aforementioned DePuy hip recall actually stemmed from the device malfunction report data reported to international registries. Regulatory agencies in Australia, England and Wales noticed the increase in complaints regarding serious device problems because they have a shared national registry that allows for tracking of every implant. *See supra* pp. 5-6.

<sup>279</sup> INSTITUTE OF MEDICINE, *supra* note 1, at 10.

<sup>280</sup> *Id.* at 55-56.

<sup>281</sup> *Id.* at 10.

<sup>282</sup> *See supra* p. 17.

<sup>283</sup> Patient Protection and Affordable Care Act (PPACA), 42 U.S.C. §18001, 810 (2010).

streamline and modernize our processes and procedures to make device approval not just scientifically rigorous, but clear, consistent, and predictable without compromising safety.”<sup>284</sup>

### **About the Author**

Kathleen Von Wahlde holds an undergraduate degree in Journalism and a Masters of Jurisprudence in Health Law. For over 19 years, she has worked in social, behavioral and clinical research. She has spent the majority of her career at an academic medical center and loves the collaboration and innovation that flourishes in academia. She lives in Nashville, TN with her husband and enjoys visiting her 3 grown children as often as she can. You can contact her at [kate.vonwahlde@gmail.com](mailto:kate.vonwahlde@gmail.com).

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<sup>284</sup> *Protecting Patients, supra* at 246.