

**ANTICIPATING REGULATORY REFORM:  
THE IMPLICATIONS OF MACHINE-LEARNING  
TECHNOLOGY ON THE U.S. FOOD AND DRUG  
ADMINISTRATION'S REGULATORY APPROVAL PROCESS  
FOR MEDICAL DEVICES**

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I. INTRODUCTION

The ability of technology to extend and improve quality of life continually shapes not only the field of medicine as a whole but also the way in which healthcare is conceptualized and accessed at the individual level.<sup>1</sup> As technological advancements continue to materialize at an exceedingly rapid pace, medical innovations are generally touted as being capable of providing patients with significant benefits and, as a result, the healthcare industry tends to fervently embrace emergent technologies.<sup>2</sup> This tendency is counterbalanced by the U.S. Federal Food and Drug Administration (FDA), which conditions the implementation of medical technology on the satisfaction of high regulatory standards aimed at ensuring an appropriate balance of safety and efficacy.<sup>3</sup> Within this overarching medical landscape, the medical device industry is one facet that mirrors these overall trends and tendencies.<sup>4</sup>

Medical device innovation capitalizes on advances in science and engineering to adapt biotechnology, nanotechnology, and computer technology, among other fields, to medical applications.<sup>5</sup> Initially, medical devices were relied on to work in a discrete manner, and their narrowly tailored range of functionality enabled the FDA to regulate with a relatively

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<sup>1</sup> Susan Bartlett Foote, *Frontiers of Medical Technology: Reflections on the Intersection of Innovation and the Health Care System*, 7 MINN. J.L. SCI. & TECH. 79, 80 (2005-2006).

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

<sup>3</sup> *Id.* at 82–83.

<sup>4</sup> *Id.* at 81.

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

high degree of certainty.<sup>6</sup> Over time, however, technology has progressed to the point where devices are no longer finite but instead are developed to have adaptive functions.<sup>7</sup> The critical question faced at this juncture is how the FDA should anticipate continued evolution in the medical device sector and prepare for the increased need to regulate software-based devices.<sup>8</sup>

This Comment will analyze the inability of the FDA's current regulatory scheme to remain effectual in light of trends evinced by the healthcare industry as a whole. Rather than developing broad-based solutions, the healthcare industry is utilizing technology to target and remediate medical conditions at the individual level and will increasingly rely on measures such as robotic process automation and artificial intelligence to achieve this aim.<sup>9</sup> The current regulatory approval process, which is predicated on the immutability of medical devices, is ill-equipped to evaluate and approve technology-based devices, which are inherently variable.<sup>10</sup> Using this identified deficiency as a framework, this Comment will evaluate and compare the relative merits of implementing a novel regulatory pathway as compared to working within the existing regulatory landscape. This Comment will provide a detailed analysis of the trends in medical technology and the ways in which artificial intelligence has, and will continue to, advance the field of medicine. In many respects, technological innovation will continue to improve lives by redefining the boundaries of what the healthcare industry considers medically feasible.<sup>11</sup> Notwithstanding its innovative potential, technology is imperfect, rendering vigilant oversight and adept regulation not only paramount but indispensable.<sup>12</sup> In anticipation of the imminent and unprecedented surge in the technology-driven medical device sector, the FDA must be equipped to regulate such devices.<sup>13</sup> To successfully achieve the FDA's mandate, this Comment recommends the implementation of a unique framework for vetting the safety and efficacy of algorithm-based medical devices that are

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<sup>6</sup> Suzanne Junod, *Commemorating the 40th Anniversary of the 1976 Medical Device Amendments*, 72 FOOD & DRUG L.J. 26, 26–27 (2017).

<sup>7</sup> *Id.* at 30.

<sup>8</sup> Paul Ohm & Blake Reid, *Regulating Software When Everything Has Software*, 84 GEO. WASH. L. REV. 1672, 1673 (2016).

<sup>9</sup> Junod, *supra* note 6, at 30; *see also* Ohm & Reid, *supra* note 8, at 1673.

<sup>10</sup> Ohm & Reid, *supra* note 8, at 1673.

<sup>11</sup> Elizabeth Kelly, Comment, *FDA Regulation of 3D-Printed Organs and Associated Ethical Challenges*, 166 U. PA. L. REV. 515, 517 (2018).

<sup>12</sup> Anna B. Laakmann, *Customized Medicine and the Limits of Federal Regulatory Power*, 19 VAND. J. ENT. & TECH. L. 285, 325 (2016).

<sup>13</sup> *Id.*

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to some degree indeterminant because of their adaptive functionality.

## II. THE CURRENT REGULATORY FRAMEWORK FOR FDA MEDICAL DEVICE APPROVAL

Section II offers a broad overview of the federal regulation of medical devices.<sup>14</sup> First, the major historical developments resulting in the FDA's authority to regulate medical devices and the ensuing three-tiered device classification system are explained.<sup>15</sup> Second, the general policy goals of the current classification system are explored.<sup>16</sup> Finally, the authority of the FDA to regulate medical devices is contrasted with the definitive prohibition against its regulation of the practice of medicine.<sup>17</sup>

### A. *The Regulation and Classification of Medical Devices*

The authority of the FDA to require advanced approval of new medical products is the result of incremental changes to the statutory regime over time.<sup>18</sup> Before the twentieth century, drug and device manufacturers were under no federal obligation to provide evidence of the safety, efficacy, or quality of the products they produced.<sup>19</sup> Congress passed the Food, Drug and Cosmetic Act (FDCA) in 1938, conferring regulatory control of drugs and medical devices on the FDA.<sup>20</sup> Initially, this grant of authority as it pertained to the medical device sector was limited, allowing the FDA to safeguard against the adulteration and misbranding of medical devices but not to require pre-market regulation.<sup>21</sup> The absence of an express statutory grant of authority to regulate devices

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<sup>14</sup> Spenser F. Powell, *Changing Our Minds: Reforming the FDA Medical Device Reclassification Process*, 73 FOOD & DRUG L.J. 177, 182 (2018).

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

<sup>16</sup> *Id.* at 195.

<sup>17</sup> *FDA's Role in Regulating Medical Devices*, U.S. FOOD & DRUG ADMIN. <https://www.fda.gov/medical-devices/home-use-devices/fdas-role-regulating-medical-devices> (last updated Aug. 31, 2018).

<sup>18</sup> See Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1757–58 (1996).

<sup>19</sup> See generally *id.*; see also Kyle Lennox, *Substantially Unequivalent: Reforming FDA Regulation of Medical Devices*, U. ILL. L. REV. 1363, 1370 (2014) (“Many remedies . . . for various ailments were not actually tested for their safety or effectiveness and were generally sold without guarantee of their safety, quality, or proven benefit.”).

<sup>20</sup> Bonnie Scott, *Oversight Overhaul: Eliminating the Premarket Review of Medical Devices and Implementing a Provider-Centered Postmarket Surveillance Strategy*, 66 FOOD & DRUG L.J. 377, 380 (2011); see also Peter Barton Hutt, *A History of Government Regulation of Adulteration and Misbranding of Medical Devices*, 44 FOOD DRUG COSM. L.J. 99, 104 (1989).

<sup>21</sup> Scott, *supra* note 20, at 380.

prior to market entry resulted in the FDA classifying some devices as drugs under the FDCA.<sup>22</sup>

The FDA did not gain expansive authority over device regulation until 1976 when the enactment of the Medical Device Amendments (MDA) to the FDCA established a new regulatory framework.<sup>23</sup> The MDA nullified the FDA's devices-as-drugs workaround by broadly defining "device" as:

any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man . . . [or] intended to affect the structure or any function of the body . . . .<sup>24</sup>

Further, the MDA created a classification framework predicated on increasing levels of FDA controls and pre-market scrutiny for each device class.<sup>25</sup> Pursuant to the MDA framework, the degree of risk associated with a proposed device dictates the level of pre-market control.<sup>26</sup> The MDA classification system categorizes devices into one of three risk-based categories: Class I, Class II, or Class III.<sup>27</sup> In general, Class III is the default categorization for new, post-1976 devices unless the FDA determines that the device meets one of two exceptions.<sup>28</sup> First, a device may be found to be "substantially equivalent" to a predicate device that the FDA has already classified as either Class I or Class II.<sup>29</sup> Second, the "FDA may make a de novo determination that a device" satisfies the statutory definition of either Class I or Class II.<sup>30</sup>

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<sup>22</sup> Powell, *supra* note 14, at 183; *see* Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 116-22 §§ 505(a)–(b), 52 Stat. 1052 (amended 2019) (Under the FDCA, drug manufacturers were prohibited from introducing new drugs into interstate commerce without first filing an application with the FDA. Pursuant to this requirement, drug manufacturers had to provide "full reports of investigations which have been made to show whether or not such drug is safe for use." If the FDA determined that the proffered evidence was insufficient to establish the drug's safety, it was able to deny the application.).

<sup>23</sup> Scott, *supra* note 20, at 380; Hutt, *supra* note 20, at 112; 21 U.S.C. § 360c(a)(1) (2012).

<sup>24</sup> Medical Device Amendments of 1976, 21 U.S.C. § 321(h) (2012).

<sup>25</sup> Powell, *supra* note 14, at 184.

<sup>26</sup> Scott, *supra* note 20, at 380; Hutt, *supra* note 20, at 112; 21 U.S.C. § 360c(a)(1).

<sup>27</sup> 21 U.S.C. § 360c(a)(1).

<sup>28</sup> Powell, *supra* note 14, at 186.

<sup>29</sup> *Id.*; 21 U.S.C. §§ 360c(f)(1)(A)(i)–(ii).

<sup>30</sup> Powell, *supra* note 14, at 186; 21 U.S.C. §§ 360c(f)(2)–(3).

### 1. Class I: General Controls

Class I devices fall at the lowest end of the risk spectrum.<sup>31</sup> Accordingly, the FDA considers adherence to general regulatory controls, which apply to all medical devices, sufficient to provide reasonable assurance of safety and efficacy.<sup>32</sup> General controls require compliance with the statutory protections pertaining to adulteration, misbranding, FDA registration and listing requirements, FDA labeling regulations, and good manufacturing practices.<sup>33</sup> Examples of Class I devices include dental floss, adhesive bandages, surgical gloves, and other similar, low risk products.<sup>34</sup>

Initially, all Class I devices were subject to pre-market notification under section 510(k) of the FDCA.<sup>35</sup> Pre-market notification requires device manufacturers to file notification with the FDA at least ninety days prior to introducing a medical device into interstate commerce.<sup>36</sup> Based on the understanding that Class I devices present minimal health or safety risks, the FDA has exempted the majority of Class I and select Class II devices from the pre-market notification requirement.<sup>37</sup>

### 2. Class II: Special Controls

Class II devices occupy the midrange of the risk spectrum and are subject to both general and special controls.<sup>38</sup> Special controls tend to be device-specific and include, among other things, compliance with performance standards, post-market surveillance, and patient registries.<sup>39</sup>

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<sup>31</sup> 21 U.S.C. § 360c(a)(1)(A).

<sup>32</sup> *Id.*; see *Regulatory Controls*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls> (last updated Mar. 27, 2018).

<sup>33</sup> 21 C.F.R. § 860.3(c)(1) (2016); Scott, *supra* note 20, at 380; *Regulatory Controls*, *supra* note 32.

<sup>34</sup> Powell, *supra* note 14, at 186.

<sup>35</sup> Powell, *supra* note 14, at 187 n.83 (Despite the fact that the requirements for pre-market notification are now codified at 21 U.S.C. § 360(k) (2012), this form of review is commonly referred to as the “510(k) process,” in reference to section 510(k) of the original MDA.).

<sup>36</sup> 21 C.F.R. § 807.81(a) (2016); see also 21 C.F.R. § 807.87 (2016) (specifying the requirements of a premarket notification submission, which include device name, owner’s establishment registration number, device class and classification panel, actions taken to comply with any performance standards, proposed labeling, and information supporting any claim of substantial equivalence to a predicate device).

<sup>37</sup> Scott, *supra* note 20, at 377–78.

<sup>38</sup> 21 U.S.C. § 360c (a)(1)(B); Scott, *supra* note 20, at 377–78; Powell, *supra* note 14, at 187.

<sup>39</sup> 21 U.S.C. § 360c (a)(1)(B); Scott, *supra* note 20, at 377–78; Powell, *supra* note 14,

Examples of Class II devices include contact lenses, infusion pumps, and CT scanners.<sup>40</sup>

Unlike the vast majority of Class I devices, almost all Class II devices must comply with the FDA's general pre-market notification requirement.<sup>41</sup> Post-amendment devices, namely those that were not on the market when the MDA were enacted, must establish that they are "substantially equivalent" to a predicate device already on the market through a 510(k) submission.<sup>42</sup> If a proposed device "has the same intended use as the predicate . . . [and] the same technological characteristics . . . or has the same intended use[,] . . . different technological characteristics . . . [that do] not raise different questions of safety and effectiveness, and . . . is at least as safe and effective as the legally marketed device[,]" then it may be deemed substantially equivalent and bypass the need for clinical testing.<sup>43</sup>

Although the 510(k) provision was initially intended to be temporary, it has not only endured but has become the principal pathway to market for many new devices.<sup>44</sup> Device manufacturers are obligated to submit a pre-market notification submission upon first introducing a new device into the market, modifying the device in a manner that could significantly affect its safety or effectiveness, or proposing a new intended use for a device that is already on the market.<sup>45</sup> Government agencies, such as the Institute of Medicine, and commentators alike have suggested that the prevalence and relative ease of satisfying pre-market notification requirements increases the risk that unsafe or ineffective devices reach the market.<sup>46</sup>

### 3. Class III: Pre-Market Approval

Class III devices comprise the highest range of the risk spectrum.<sup>47</sup>

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<sup>40</sup> Powell, *supra* note 14, at 187.

<sup>41</sup> *Id.*; Scott, *supra* note 20, at 380–81.

<sup>42</sup> COMMITTEE ON THE PUB. HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS, INST. OF MED. OF THE NAT'L ACADS., MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 86–87 (2011); Scott, *supra* note 20, at 381; *Premarket Notification 510(k)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k> (last updated Sept. 27, 2018).

<sup>43</sup> Scott, *supra* note 20, at 381; *Premarket Notification 510(k)*, *supra* note 42.

<sup>44</sup> Junod, *supra* note 6, at 27.

<sup>45</sup> 21 C.F.R. § 807.81 (2012); Scott, *supra* note 20, at 381.

<sup>46</sup> Powell, *supra* note 14, at 188; *see* COMMITTEE ON THE PUB. HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS, *supra* note 42, at 193.

<sup>47</sup> Scott, *supra* note 20, at 381; *see Premarket Approval (PMA)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval->

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Such devices are used in “supporting or sustaining human life or for . . . preventing impairment of human health, or . . . [possess] a potential unreasonable risk of illness or injury.”<sup>48</sup> Examples of Class III devices include pacemakers, cochlear implants, and some surgical meshes.<sup>49</sup>

In general, Class III devices must be vetted through the FDA’s rigorous pre-market approval (PMA) process, unless substantial equivalence allows for use of the alternative 510(k) process.<sup>50</sup> The PMA process, which imposes greater demands and is more time intensive than the 510(k) process, is aimed at ensuring device safety and effectiveness.<sup>51</sup> To establish these aims, device manufacturers are required to submit extensive information and data derived from both nonclinical laboratory studies and clinical human subjects investigations.<sup>52</sup> Prior to initiating these studies, manufacturers must first obtain investigational device exemption (IDE) approval from the FDA.<sup>53</sup> IDE approval permits investigational devices to be used in studies for purposes of generating safety and effectiveness data in support of the PMA.<sup>54</sup>

The relative burdens imposed on both the FDA and device manufacturers pursuant to the PMA process are significantly greater than under the 510(k) pre-market notification pathway.<sup>55</sup> The average amount of time the FDA spends reviewing a 510(k) submission is twenty hours, as compared to an average of twelve hundred hours for a PMA submission.<sup>56</sup> Additionally, the cost for manufacturers to complete the PMA process is three times more than the 510(k) process.<sup>57</sup> Accordingly, manufacturers are strongly incentivized to establish 510(k) substantial equivalence in

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pma (last updated May 16, 2019).

<sup>48</sup> 21 U.S.C. § 360c(a)(1)(C) (2012).

<sup>49</sup> Powell, *supra* note 14, at 188.

<sup>50</sup> 21 U.S.C. § 360c(a)(1)(C); 21 C.F.R. § 860.3(c)(3) (2019); Powell, *supra* note 14, at 188.

<sup>51</sup> 21 C.F.R. § 860.7(c); Scott, *supra* note 20, at 381.

<sup>52</sup> See 21 C.F.R. § 814.20 (2019).

<sup>53</sup> *Device Advice: Investigational Device Exemption (IDE)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-advice-investigational-device-exemption-ide> (last updated Sept. 27, 2018); Scott, *supra* note 20, at 381–82.

<sup>54</sup> *Device Advice: Investigational Device Exemption (IDE)*, *supra* note 53; Scott, *supra* note 20, at 382.

<sup>55</sup> Powell, *supra* note 14, at 188.

<sup>56</sup> *Id.* (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478–79 (1996) (citing *Hearings before the Subcomm. on Health and the Env’t of the H. Comm. on Energy & Commerce*, 100th Cong. 384 (1987))).

<sup>57</sup> Powell, *supra* note 14, at 189.

order to avoid the onerous PMA process.<sup>58</sup>

*B. The Policy Goals of the Medical Device Classification System*

According to the MDA, the main objective of the device classification system is to “provide reasonable assurance of the safety and effectiveness” of the devices that the FDA allows to enter into the market.<sup>59</sup> Devices are considered safe if the “probable benefits to health” outweigh the “probable risks.”<sup>60</sup> Devices are considered effective if “clinically significant results” are achieved in a “significant portion of the target population.”<sup>61</sup> The Center for Devices and Radiological Health (CDRH) is the division within the FDA that is primarily responsible for device regulation.<sup>62</sup> CDRH’s identified mission is “to protect and promote the public health” by assuring that “patients and providers have timely and continued access to safe, effective, and high-quality medical devices.”<sup>63</sup> Accordingly, to fulfill its mission of ensuring the safety and effectiveness of medical devices, the FDA must ensure that its regulatory review process is capable of accurately predicting the future impact of devices on human health in a wide range of circumstances.<sup>64</sup>

The time required to ensure product safety and efficacy is in direct tension with the medical device industry’s goal of getting innovative new devices to market within a reasonably efficient timeframe.<sup>65</sup> This conflicting consideration highlights some of the criticisms that skeptics often levy against the American regulatory system.<sup>66</sup> As compared to the more expedited European Union model, device regulation in the United States is commonly considered to be “too slow, risk adverse, and

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

<sup>59</sup> 21 U.S.C. §§ 360c (a)(1)(A)(i)–(ii), (a)(1)(B), (a)(1)(C)(i), (e)(2)(A)–(B) (2012); Powell, *supra* note 14, at 195.

<sup>60</sup> 21 C.F.R. § 860.7(d)(1) (2016).

<sup>61</sup> 21 C.F.R. § 860.7(e)(1).

<sup>62</sup> *CDRH Mission, Vision and Shared Values*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/center-devices-and-radiological-health/cdrh-mission-vision-and-shared-values> (last updated Oct. 23, 2017).

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

<sup>64</sup> Powell, *supra* note 14, at 196; *see also* 21 C.F.R. § 860.7(c)–(e) (2016).

<sup>65</sup> Powell, *supra* note 14, at 197; *see* Letter from Jeffrey Shuren, Director, FDA’s Center for Devices and Radiological Health, to the American Public (2010) (“[T]he FDA’s medical device center has been hearing major concerns about the 510(k) program . . . [namely that it] stifles innovation . . . [and that it] isn’t sufficiently robust to assure that some devices cleared under the program are safe and effective”).

<sup>66</sup> Powell, *supra* note 14, at 198–99.



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expensive.”<sup>67</sup> In light of this viewpoint, commentators have argued that the FDA should bring new devices to market more quickly by reallocating all or a portion of the required pre-market review to the post-market period.<sup>68</sup>

It is crucial for the FDA to protect the public through regulation while simultaneously fostering an environment that promotes innovation.<sup>69</sup> Protection is essential because the public is vulnerable to medical product manufacturers.<sup>70</sup> Manufacturers are privy to considerably more information about their products, which results in information asymmetry.<sup>71</sup> As medical devices continue to become more complex, the degree of information asymmetry likewise continues to expand.<sup>72</sup> For example, there is little, if any, information asymmetry associated with the tongue depressor, meaning that the public can readily ascertain relevant product information.<sup>73</sup> Conversely, it is unfeasible for the general public to evaluate the safety and efficacy of pacemakers, for instance.<sup>74</sup> Encouraging innovation enables manufacturers to capitalize on advances in technology to create safer, more effective, well-regulated medical products for the public.<sup>75</sup>

### C. The Legislative History of the FDA

Despite the complementary policy goals of ensuring safety and efficacy while simultaneously fostering industry advancement, the FDA’s legislative history reveals that it perpetually lags behind technological innovation.<sup>76</sup> In short, the FDA’s legislative history is characterized by reactionary measures rather than comprehensive foresight.<sup>77</sup> Congress has historically reacted to high profile catastrophes by passing legislation in an

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<sup>67</sup> Powell, *supra* note 14, at 198 (citing Corinna Sorenson & Michael Drummond, *Improving Medical Device Regulation: The United States and Europe in Perspective*, 92 MILBANK Q. 114, 115 (2014)); *see also* Scott, *supra* note 20, at 378 (“U.S. patients must wait months, and sometimes even years, before the latest American-developed device technologies are available in the U.S.”).

<sup>68</sup> Powell, *supra* note 14, at 199; *see id.* at n.189.

<sup>69</sup> Marilyn Uzdavines, *Dying for a Solution: The Regulation of Medical Devices Falls Short in the 21st Century Cures Act*, 18 NEV. L.J. 629, 630 (2018).

<sup>70</sup> *Id.* at 630–31.

<sup>71</sup> *Id.* at 631.

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

<sup>73</sup> *Id.* at n.9.

<sup>74</sup> *Id.*

<sup>75</sup> Uzdavines, *supra* note 69, at 630.

<sup>76</sup> Uzdavines, *supra* note 69, at 631.

<sup>77</sup> *Id.*

attempt to correct the disconnect between technology and legislation.<sup>78</sup> The shortcoming of such legislation, however, is that it imposes too great of a burden on the FDA in regulating medical devices without accounting for the agency's resource limitations.<sup>79</sup> Accordingly, there has been inconsistent regulation of potentially harmful medical devices.<sup>80</sup>

Legislation enacted to increase the safety and efficacy of medical devices has historically taken a myopic view of the FDA's duty to the public.<sup>81</sup> This approach has resulted in an unfortunate oscillation between excessive regulation and insufficient regulation.<sup>82</sup> More specifically, legislative reform can be characterized as taking one of two approaches.<sup>83</sup> Some amendments have sought to protect the public by increasing "the scope of FDA regulation, thereby increasing the burden on manufacturers to bring products to market."<sup>84</sup> Alternatively, other amendments have focused "on fostering innovation and the public's access to drugs and devices, thereby reducing the burden on manufacturers without accounting for impact on safety to the public."<sup>85</sup> As technology continues to advance and algorithm-based medical innovations become more commonplace, there will be an increased need for comprehensive approaches.<sup>86</sup>

#### *D. The Division Between Federal Regulation and the Practice of Medicine*

Despite the FDA's seemingly straightforward three-tiered device classification system and corresponding pre-market controls, the regulatory landscape it governs is inherently complex.<sup>87</sup> Despite such complexity, one conclusive fact is that the FDA does not have the authority to regulate the practice of medicine.<sup>88</sup> Accordingly, there is an acute distinction between product manufacturers that are within the ambit of FDA regulation and

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

<sup>79</sup> *Id.* at 632.

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

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

<sup>82</sup> Uzdevins, *supra* note 69, at 632.

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

<sup>84</sup> *Id.*

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

<sup>86</sup> *See id.*

<sup>87</sup> Scott, *supra* note 20, at 382.

<sup>88</sup> *FDA's Role in Regulating Medical Devices*, U.S. FOOD & DRUG ADMIN. (last updated Aug. 31, 2018) ("The FDA does not have the authority to: . . . tell providers what to do when running their business or what they can or cannot tell their patients[,] [m]ake recommendations for individual doctors, . . . [or] [c]onduct or provide a rating system on any regulated medical devices.").

healthcare service providers who are beyond the scope of the FDA's purview.<sup>89</sup> Nevertheless, identifying precisely where the dividing line between these distinct entities falls is both crucial and contested.<sup>90</sup> As emerging technologies continue to transform the field of medicine, such advancements are effectuating a shift from mass-market distribution models to customized, individual-oriented approaches, such as 3D-printed devices and individually-tailored software.<sup>91</sup> Consequently, the distinction between regulated product manufacturers and non-regulated healthcare providers is becoming increasingly distorted, raising profound questions about the appropriate function of the FDA within the evolving regulatory landscape.<sup>92</sup>

When enacting the FDCA, Congress made it abundantly clear that federal regulation was not intended to interfere with the practice of medicine.<sup>93</sup> Although subsequent amendments to the FDCA expanded the scope of the FDA's regulatory authority, this fundamental restriction has never been impinged upon.<sup>94</sup> From the time of the original statute's enactment, the FDA has never claimed the authority to prohibit physicians from prescribing approved products for unapproved, off-label uses.<sup>95</sup> After medical devices receive FDA approval, states regulate their use in the context of the practice of medicine pursuant to state-based plenary police powers.<sup>96</sup> Accordingly, the scope of the FDA's regulatory authority encompasses the manufacture, promotion, and dissemination of medical devices, but does not extend to practitioners' delivery of medical services utilizing those devices.<sup>97</sup>

If technology-based medical devices incorporate algorithms to direct patient care, then FDA regulation of medical software may be construed as

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<sup>89</sup> Laakmann, *supra* note 12, at 287.

<sup>90</sup> *Id.*

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

<sup>92</sup> *Id.*

<sup>93</sup> Laakmann, *supra* note 12, at 294.

<sup>94</sup> *Id.*

<sup>95</sup> 21 U.S.C. § 396 (2018) ("Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship."); *see also* Laakmann, *supra* note 12, at 295.

<sup>96</sup> Laakmann, *supra* note 12, at 295; *see also* Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 U. KAN. L. REV. 149, 159 (2004) ("The Supreme Court long ago recognized that the police powers of the states justified their regulation of the practice of medicine.").

<sup>97</sup> Laakmann, *supra* note 12, at 295.

infringing on the practice of medicine.<sup>98</sup> Irrespective of this possibility, the FDA has clearly asserted its jurisdiction over the regulation of standalone software products.<sup>99</sup>

### III. THE IMPACT OF TECHNOLOGY ON THE FIELD OF MEDICINE

#### A. *The Trend Toward Personalized Medicine*

The entire field of medicine has been impacted by advances in medical technology, which have enabled practitioners to offer unique treatment options to their patients.<sup>100</sup> Not only do these innovative treatment alternatives reflect the latest medical standards, but collectively they also represent the industry-wide trend toward customized medicine.<sup>101</sup> Although most devices are not yet patient-specific, technology is progressing towards this becoming a reality.<sup>102</sup>

With the advent of data collection and aggregation, large datasets can be analyzed using artificial intelligence.<sup>103</sup> When implemented in the context of medical devices, such devices can process vast quantities of collected data to generate insights in the form of individually-tailored outputs.<sup>104</sup> For example, technology-based devices that interface with mobile applications are capable of accumulating an unquantifiable amount of health and wellness data about users.<sup>105</sup> Accordingly, algorithm-based medical devices, unlike mass-produced unitary devices that consistently perform in the same predetermined manner for all patients, achieve personalized results by adapting to the unique aspects of the individual.<sup>106</sup>

#### B. *Emerging Technology in Robotics and Artificial Intelligence*

With increasing frequency, individuals in the field of medicine turn to algorithms to assist in solving complex health problems.<sup>107</sup> Devices that

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<sup>98</sup> W. Nicholson Price II, *Regulating Black-Box Medicine*, 116 MICH. L. REV. 421, 441–42 (2017).

<sup>99</sup> *Id.* at 442.

<sup>100</sup> Junod, *supra* note 6, at 27.

<sup>101</sup> Laakmann, *supra* note 12, at 325.

<sup>102</sup> Kelly, *supra* note 11, at 520–21.

<sup>103</sup> Drew Simshaw, Nicolas Terry, Kris Hauser & M.L. Cummings, *Regulating Healthcare Robots: Maximizing Opportunities While Minimizing Risks*, 22 RICH. J.L. & TECH. 1, 11 (2016).

<sup>104</sup> *See id.*

<sup>105</sup> *Id.* at 13.

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

<sup>107</sup> Price, *supra* note 98, at 474.

incorporate artificial intelligence have the capacity to analyze and respond to data by changing over time.<sup>108</sup> In general, algorithms are derived from sophisticated machine-learning techniques that analyze large datasets of health information.<sup>109</sup> Developers of such algorithms are inclined to “keep information about [them] secret [in order to] preserve competitive advantage.”<sup>110</sup>

Since their inception, implanted devices have served a wide range of functions, including physical, such as pacemakers and artificial limbs; chemical, such as insulin pumps; and sensory, such as cochlear and retinal implants.<sup>111</sup> As technology has progressed over time, medical devices have advanced to incorporate machine learning technology and thus, have become exponentially more complex.<sup>112</sup> This complexity stems from the adaptive nature of artificial intelligence, which by definition does not produce predetermined outcomes.<sup>113</sup> Accordingly, there is some degree of agency that is ascribed to such systems, which is neither fully predictable by the device manufacturer nor fully controllable by the human agents interacting with such devices.<sup>114</sup> The inherently independent, adaptive quality of artificial intelligence systems results in medical devices that, to some degree, “make autonomous decisions and . . . [act on] their own initiative.”<sup>115</sup> The degree of device autonomy ranges from a “supervisory control paradigm, in which certain functions are automated with a human supervising the system, all the way to fully autonomous robots.”<sup>116</sup>

Once medical devices are software-based, there are essentially limitless variations for the ways in which technology may impact their functioning.<sup>117</sup> This inherent variability is the driving force behind the

<sup>108</sup> Jessica S. Allain, *From Jeopardy! to Jaundice: The Medical Liability Implications of Dr. Watson and Other Artificial Intelligence Systems*, 73 LA. L. REV. 1049, 1078 (2013).

<sup>109</sup> Price, *supra* note 98, at 430.

<sup>110</sup> Price, *supra* note 98, at 436; *see also id.* at 436 n.73.

<sup>111</sup> Courtney S. Campbell, Lauren A. Clark, David Loy, James F. Keenan, Kathleen Matthews, Terry Winograd & Laurie Zoloth, *The Bodily Incorporation of Mechanical Devices: Ethical and Religious Issues (Part 1)*, 16 CAMBRIDGE Q. HEALTHCARE ETHICS 229, 233 (2007).

<sup>112</sup> *See* Philipp Kellmeyer, Thomas Cochrane, Oliver Muller, Christine Mitchell, Tonio Ball, Joseph J. Fins & Nikola Biller-Andorno, *The Effects of Closed-Loop Medical Devices on the Autonomy and Accountability of Persons and Systems*, 25 CAMBRIDGE Q. HEALTHCARE ETHICS 623, 625 (2016).

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

<sup>114</sup> *Id.*

<sup>115</sup> Allain, *supra* note 108, at 1078.

<sup>116</sup> Simshaw et al., *supra* note 103, at 3.

<sup>117</sup> *See* Roland Knight, *Additive Manufacturing of Medical Devices: Maintaining Innovation, Protecting Patients and Avoiding Regulatory Duplication*, 9 FED. CTS. L. REV.

regulatory challenges faced by the FDA, which is charged with ensuring the safety and effectiveness of medical devices.<sup>118</sup> To achieve its mandate, the FDA must proactively confront the regulation of medical devices that incorporate machine-based learning, which can be characterized as moving targets.<sup>119</sup>

*C. Oversight and Cost of Care Challenges Associated with Emerging Technologies*

It is irrefutable that the United States is the global leader in healthcare expenditures, spending more money on healthcare than any other nation.<sup>120</sup> A significant driver of healthcare spending is technology, which presents a host of regulatory oversight challenges.<sup>121</sup> Additionally, the vast complexity of the American healthcare system is partially attributable to the amalgam of applicable federal and state laws and regulations.<sup>122</sup> Accordingly, medical device technology is both “directly and indirectly affected by” a robust body of laws and regulations.<sup>123</sup> This reality underscores the need for a nuanced regulatory framework that is predicated on an understanding of these vastly complex dynamics.

*D. Challenges Associated with the Regulation of Software*

Sophisticated medical software, robotics, and machine-based learning are rapidly evolving and contributing to the changing medical device landscape.<sup>124</sup> With the advent of software-based biomedical devices, code is supplementing physical functionality.<sup>125</sup> Consequently, the FDA must confront new challenges associated with the regulation of not only new devices, but also their accompanying software and digital output.<sup>126</sup> For example, software increasingly controls the operation of medical devices such as insulin pumps and pacemakers, which means that the safety features of such devices are also dependent upon programming.<sup>127</sup> The incorporation of digital features adds an additional layer of regulatory

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125, 129 (2016).

<sup>118</sup> Hutt, *supra* note 20, at 106.

<sup>119</sup> See Knight, *supra* note 117, at 129.

<sup>120</sup> Foote, *supra* note 1, at 85.

<sup>121</sup> Foote, *supra* note 1, at 85–86.

<sup>122</sup> Foote, *supra* note 1, at 82.

<sup>123</sup> *Id.*

<sup>124</sup> Junod, *supra* note 6, at 30.

<sup>125</sup> Ohm & Reid, *supra* note 8, at 1673.

<sup>126</sup> Ohm & Reid, *supra* note 8, at 1675.

<sup>127</sup> Ohm & Reid, *supra* note 8, at 1677.

complexity because software can be easily manipulated, allowing its evolution to outpace that of the devices it accompanies.<sup>128</sup> Accordingly, software cannot be regulated in the same manner as devices because verifying the operation of digital code presents unique theoretical and practical challenges.<sup>129</sup>

The FDA has long exercised regulatory authority over medical software.<sup>130</sup> Despite its longstanding control, the FDA has promulgated few regulations specifically tailored to software or algorithms.<sup>131</sup> The agency has instead chosen to issue nonbinding guidance documents and to regulate via case-specific adjudication.<sup>132</sup> Notably, algorithm-based medical devices are typically approved through the 510(k) pathway.<sup>133</sup> Pursuant to this regulatory approval process, the “FDA has often determined that software applications are equivalent to nonsoftware precedents, even though they perform tasks in a markedly different manner.”<sup>134</sup> This current disconnect between the implementation and regulation of medical software necessitates a narrowly tailored regulatory response.

#### IV. INSIGHTS GAINED FROM ANALOGOUS INDUSTRIES

##### A. *The Regulation of 3D Printing*

Like artificial intelligence, additive manufacturing, commonly referred to as 3D printing, is a technological innovation that raises interesting questions about the scope of the FDA’s regulatory authority.<sup>135</sup> Within the healthcare industry, 3D printing has the potential to significantly disrupt conventional supply chain procedures and thus warrants close consideration.<sup>136</sup> Customized medical devices, such as joints and spinal implants, can be created based on individual patient scans with relative ease.<sup>137</sup> Consistent with the general departure from mass-market

<sup>128</sup> Ohm & Reid, *supra* note 8, at 1688.

<sup>129</sup> Ohm & Reid, *supra* note 8, at 1689.

<sup>130</sup> Price, *supra* note 98, at 443; *see also id.* at 438 n.85.

<sup>131</sup> Price, *supra* note 98, at 443; *see also* Ohm & Reid, *supra* note 8, at n.111 (citing 17 U.S.C. § 512 (2012)).

<sup>132</sup> Price, *supra* note 98, at 443.

<sup>133</sup> Price, *supra* note 98, at 444; *see* Nathan Cortez, *The Mobile Health Revolution?*, 47 U.C. DAVIS L. REV. 1173, 1219 (2014).

<sup>134</sup> Price, *supra* note 98, at 444; *see* Cortez, *supra* note 133, at 1219.

<sup>135</sup> Laakmann, *supra* note 12, at 317.

<sup>136</sup> Laakmann, *supra* note 12, at 318.

<sup>137</sup> Janet Morrissey, *The Instant, Custom, Connected Future of Medical Devices*, N.Y.

distribution to individually-targeted approaches, physicians and surgeons can use 3D printers to create customized products on-site.<sup>138</sup> The ability to self-manufacture individualized products represents a marked departure from the traditional model whereby conventional suppliers mass produce and distribute identical items.<sup>139</sup> The FDA has begun to address 3D printing, even though some critics claim that such localized production may fall outside the scope of the agency's statutory authority.<sup>140</sup> To date, the full extent of the regulatory implications of 3D printing technology remains unexamined.<sup>141</sup>

Within the realm of medical devices, the primary consideration is whether the FDA will classify 3D printed items as custom devices.<sup>142</sup> Section 520(b) of the FDCA, as amended in 2012, states that the performance standard requirements of section 314 and the pre-market approval requirements of section 515 are not applicable to devices that, in order to comply with the orders of a physician differ from an otherwise applicable performance standard or PMA application.<sup>143</sup> The custom device exemption is only applicable to devices that are "not generally available for commercial distribution," are designed to treat a unique condition, and are manufactured on an individualized basis to accommodate the unique needs of individual patients or providers.<sup>144</sup> Although 3D printed products may satisfy the elements of the custom device exemption, it remains unclear if this pathway is a viable regulatory strategy for manufacturers seeking to circumvent federal regulatory requirements.<sup>145</sup> Notably, the FDCA limits production of custom devices to a maximum of five units per year of a distinct device type.<sup>146</sup> Accordingly, the extent to which manufacturers of 3D printed devices may rely on the custom device exception depends on whether the FDA

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TIMES (Feb. 14, 2019), <https://www.nytimes.com/2019/02/14/business/smart-medical-devices-implants.html>.

<sup>138</sup> Laakmann, *supra* note 12, at 319.

<sup>139</sup> *Id.*

<sup>140</sup> *Id.*

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

<sup>142</sup> *Id.*

<sup>143</sup> 21 U.S.C. § 360j(b)(1)(A)–(B) (2012); Laakmann, *supra* note 12, at 319–20.

<sup>144</sup> 21 U.S.C. § 360j(b)(1)(C)–(G); Laakmann, *supra* note 12, at 320.

<sup>145</sup> Laakmann, *supra* note 12, at 320; *see* Laakmann, *supra* note 12, at 318 n.240 (“[A]lmost all of the legally marketed 3D-printed medical devices were cleared by the FDA via the 510(k) pathway and a small number were authorized for emergency use, compassionate use, or via the custom device exemption pathway.”).

<sup>146</sup> 21 U.S.C. § 360j(b)(2)(B); Laakmann, *supra* note 12, at 320.



determines that such products comprise their own unique device types.<sup>147</sup>

Insights gleaned from additive manufacturing may prove to be informative in seeking to determine the appropriate regulatory pathway for AI-based medical devices. Despite statutory amendments implemented since the enactment of the FDCA, the FDA's existing regulatory framework is not optimally suited to vet and approve emerging technology-driven medical innovations.<sup>148</sup> Like 3D printed products, AI-based devices are perpetually advancing, and as such, represent a dramatically different landscape than what the industry originally contemplated.<sup>149</sup>

#### B. *The Regulation of Mobile Health Applications*

Technology has led to the proliferation of mobile health applications that perform a wide range of functions.<sup>150</sup> Digital psychiatric therapies represent a growing segment of the digital health landscape and allow for a range of approaches to mental health care aimed at different populations and conditions.<sup>151</sup> The FDA has the authority “to regulate digital psychiatric therapies as medical devices” if the applicable statutory requirements are met.<sup>152</sup> Given that the science supporting the use of apps for mental health is only just beginning to emerge, it is currently unclear whether and how such mobile apps should be regulated.<sup>153</sup> The FDA has claimed regulatory authority over mobile health apps and approved the first digital psychiatric therapy for the treatment of substance use disorder.<sup>154</sup>

It is evident that the “current regulatory framework is inadequate” as applied to mobile health applications because it does not specifically address this treatment modality and, therefore, may not ensure safety and efficacy.<sup>155</sup> The FDA has recognized that its “traditional relatively rigid regulatory approaches may interact poorly with the fluid and fast-moving

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<sup>147</sup> Laakmann, *supra* note 12, at 320.

<sup>148</sup> Kelly, *supra* note 11, at 544.

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

<sup>150</sup> Theodore T. Lee, *Recommendations for Regulating Software-Based Medical Treatments: Learning from Therapies for Psychiatric Conditions*, 73 FOOD & DRUG L.J. 66, 66–67 (2018); see Cortez, *supra* note 133, at 1181–90 (providing a taxonomy of mobile health technologies).

<sup>151</sup> Lee, *supra* note 150, at 71.

<sup>152</sup> Lee, *supra* note 150, at 76.

<sup>153</sup> Lee, *supra* note 150, at 70; see also *id.* at n.26.

<sup>154</sup> Lee, *supra* note 150, at 68; see also *id.* at n.11 (citing *FDA Permits Marketing of Mobile Medical Application for Substance Use Disorder*, FOOD & DRUG ADMIN. (Sept. 14, 2017), <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-mobile-medical-application-substance-use-disorder>).

<sup>155</sup> Lee, *supra* note 150, at 91.

structure of the mobile-health industry.”<sup>156</sup> Notwithstanding this recognition, the majority of mobile health applications appear to be subject to the FDA’s oversight as medical devices and are subject to traditional regulatory requirements.<sup>157</sup> Guidance documents issued by the FDA fail to clearly address whether the agency will enforce FDCA requirements for mobile health applications and related software-based treatments.<sup>158</sup> Similarly, it is unknown how the FDA will choose to apply the 510(k) pathway.<sup>159</sup> Due to their intended function, there are safety and effectiveness-related concerns regarding the use of digital psychiatric therapies.<sup>160</sup> Counterbalanced against this concern, however, is the worry that increasing FDA clearance or approval standards could stifle innovation.<sup>161</sup> It is possible that some software-based treatments may evade the FDA’s regulatory authority by not manifesting “an intent to treat or mitigate the symptoms” associated with a specific disease or condition.<sup>162</sup> For the software-based treatments that do fall within the scope of the FDCA, there is a need for the FDA to articulate whether it will enforce its requirements when evaluating them.<sup>163</sup>

#### V. RECOMMENDATION FOR REGULATING ADAPTIVE, TECHNOLOGY-DRIVEN MEDICAL DEVICES

This Section explores the criticisms levied against the current regulatory framework as well as measures the FDA can implement to achieve a comprehensive regulatory approach that is specifically tailored to software-based medical devices.

##### A. Criticism of the Current Regulatory Standard

There is a general consensus among courts, commentators, and the FDA itself that the current regulatory approval process for medical devices is too slow,<sup>164</sup> too costly,<sup>165</sup> and too unpredictable.<sup>166</sup> Given that software-based medical devices can be developed quickly and are highly

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<sup>156</sup> Price, *supra* note 98, at 449.

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

<sup>158</sup> Lee, *supra* note 150, at 91.

<sup>159</sup> *Id.*

<sup>160</sup> *Id.*

<sup>161</sup> *Id.*

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

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

<sup>164</sup> See Powell, *supra* note 14, at 201 n.202.

<sup>165</sup> Powell, *supra* note 14, at 201 n.203.

<sup>166</sup> Powell, *supra* note 14, at 201.

customizable, the current regulatory scheme warrants supplementation.<sup>167</sup> Some algorithms change and progress as new data are incorporated, rendering them incompatible with regulatory approval measures predicated on the unchangeability of devices.<sup>168</sup> Accordingly, rigid adherence to existing regulatory standards would hinder the development and implementation of innovative and potentially groundbreaking new medical devices.<sup>169</sup>

If the incorporation of algorithm-based software necessitates Class III categorization, then medical device innovation will likely be severely impeded.<sup>170</sup> First, automatically employing this classification will result in substantially greater obstacles getting devices to market.<sup>171</sup> Second, it will significantly limit the flexibility of algorithms to change and evolve as manufacturers continue to gather and incorporate additional data.<sup>172</sup>

As the preeminent public health agency, the FDA is charged with preventing unsafe and ineffective therapies from entering the market and reaching the public.<sup>173</sup> FDA regulation shapes innovation within the healthcare industry by establishing the standards that drug and device manufacturers must satisfy before marketing their products.<sup>174</sup> Some scholars have argued that FDA regulatory measures intended to protect patients unnecessarily hinder innovation and prevent patients from accessing potentially helpful therapies.<sup>175</sup> Some have leveled this criticism within the context of the FDA's regulation of emerging health technologies as well.<sup>176</sup> Other scholars, however, "have noted the role FDA regulation plays in incentivizing the production of valuable information about regulated products."<sup>177</sup>

#### B. Constructing a Comprehensive and Consistent Regulatory Scheme

It is incumbent on the FDA to evaluate and respond to concerns regarding safety and effectiveness standards, the risk of stifling innovation,

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<sup>167</sup> Price, *supra* note 98, at 423.

<sup>168</sup> Price, *supra* note 98, at 423–24.

<sup>169</sup> Price, *supra* note 98, at 424.

<sup>170</sup> Price, *supra* note 98, at 452–53.

<sup>171</sup> Price, *supra* note 98, at 453.

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

<sup>173</sup> Lee, *supra* note 150, at 70.

<sup>174</sup> See Lee, *supra* note 150, at 70 n.27.

<sup>175</sup> Lee, *supra* note 150, at 70; see *id.* at n.28.

<sup>176</sup> Lee, *supra* note 150, at 70; see *id.* at n.29.

<sup>177</sup> Lee, *supra* note 150, at 70; see *id.* at n.30.

and existing regulatory uncertainty.<sup>178</sup> To this end, the federal government should develop a separate regulatory framework for algorithm-based medical devices. An optimal regulatory approach must be sufficiently flexible to accommodate the highly variable nature of technological innovation.<sup>179</sup> The first step towards designing such a framework is understanding that pre-market controls are necessarily limited in their ability to fully vet algorithms that cannot be predicted to an absolute degree of certainty.<sup>180</sup> Achieving a framework that comports with the FDA's safety and efficacy standards in light of ever-changing technological considerations poses significant challenges.<sup>181</sup> Despite such obstacles, the FDA can seek to ameliorate this shortcoming by enhancing post-market surveillance in the form of real-world quality markers to provide for more robust regulation following market entry.<sup>182</sup>

Considering the scope of this endeavor, the FDA should seek to employ a collaborative approach that involves multiple entities.<sup>183</sup> More specifically, the FDA should maintain centralized regulatory oversight but incorporate other entities in the healthcare industry, such as physicians and hospitals, to construct a more robust and elaborate post-market surveillance system.<sup>184</sup> By diversifying the responsibility for post-market surveillance and oversight, the FDA can then implement an incremental, adaptive regulatory framework that has the flexibility to respond to new information as technology develops and new data is acquired.<sup>185</sup> Such an approach is ideal because depending solely on pre-market regulation for medical algorithms will not achieve the optimal balance between fostering innovation and ensuring safety and effectiveness.<sup>186</sup> Technology-based medical devices derive their value from their ability to interface with patients and amass data that can then be integrated into their functionality.<sup>187</sup> Post-market surveillance measures would complement these algorithmic features in a way that overly burdensome pre-market approvals do not because of the time and resources required.<sup>188</sup> This notion

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<sup>178</sup> Lee, *supra* note 150, at 97.

<sup>179</sup> Price, *supra* note 98, at 423.

<sup>180</sup> *Id.*

<sup>181</sup> *Id.*

<sup>182</sup> Price, *supra* note 98, at 424.

<sup>183</sup> Price, *supra* note 98, at 458.

<sup>184</sup> Price, *supra* note 98, at 458–59.

<sup>185</sup> Price, *supra* note 98, at 460.

<sup>186</sup> Price, *supra* note 98, at 462.

<sup>187</sup> *Id.*

<sup>188</sup> *Id.*

is similar to incremental physical changes made to medical devices over the course of their lifespan, rendering a pre-market review of each iteration infeasible.<sup>189</sup>

The FDA has already demonstrated a willingness to merge pre-market and post-market review in some contexts.<sup>190</sup> When the FDA engages in pre-market approval review it considers what clinical data would be necessary to establish safety and effectiveness prior to approval, as compared to what data can be collected during the post-market phase.<sup>191</sup> There are, however, significant challenges associated with relying on post-market surveillance.<sup>192</sup> Most significantly, the FDA has long overseen post-market surveillance programs without much success.<sup>193</sup> Compliance tends to be low because such measures are often voluntary and the FDA does not have adequate enforcement resources to compel adherence.<sup>194</sup> Despite this reality, there are three distinct measures that the FDA can implement to make post-market surveillance better suited to regulate algorithm-based medical devices.<sup>195</sup> First, if Congress were to allocate additional authority and resources to the FDA it may be possible to implement and enforce surveillance requirements.<sup>196</sup> Second, monitoring will likely become easier as health information systems continue to become more integrated, allowing data to be more easily shared.<sup>197</sup> Third, if post-market surveillance involves other entities in the healthcare industry beyond the FDA, then surveillance will be more comprehensive.<sup>198</sup>

One feature that the FDA can incorporate into a new, algorithm-based framework is a backup regulatory program.<sup>199</sup> Accordingly, the risks

<sup>189</sup> Price, *supra* note 98, at 462 n.236; see Frederic S. Resnic & Sharon-Lise T. Normand, *Postmarketing Surveillance of Medical Devices—Filling in the Gaps*, 366 N. ENGL. J. MED. 875 (2012) (advocating for comprehensive review of postmarket surveillance systems given the realities of device development and evolution).

<sup>190</sup> Price, *supra* note 98, at 463; U.S. FOOD & DRUG ADMIN., BALANCING PREMARKET AND POSTMARKET DATA COLLECTION FOR DEVICES SUBJECT TO PREMARKET APPROVAL: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2015); see also 21 U.S.C. § 360c(a)(2)(C), (a)(3)(D)(ii) (2012) (enabling such balancing).

<sup>191</sup> 21 U.S.C. § 360c(a)(3)(D)(ii) (2012).

<sup>192</sup> Price, *supra* note 98, at 464.

<sup>193</sup> *Id.*; see generally Phil B. Fontanarosa et al., *Postmarketing Surveillance—Lack of Vigilance, Lack of Trust*, 292 JAMA 2647 (2004) (discussing problems with the postmarket surveillance system).

<sup>194</sup> Fontanarosa et al., *supra* note 193, at 2649.

<sup>195</sup> Price, *supra* note 98, at 464.

<sup>196</sup> *Id.*; see Resnic & Normand, *supra* note 189, at 877.

<sup>197</sup> Price, *supra* note 98, at 464.

<sup>198</sup> Price, *supra* note 98, at 465.

<sup>199</sup> Gary E. Marchant & Yvonne A. Stevens, *Resilience: A New Tool in the Risk*

associated with lessened pre-market approval could be counterbalanced through the construction and implementation of a backup program that would be automatically deployed if software adaptations are determined to be less safe or efficacious than permissible under current FDA standards.<sup>200</sup> This approach would accord new technologies greater regulatory freedom at the outset by permitting them to function without first submitting to the full range of costly, time-intensive pre-market restrictions.<sup>201</sup> Under this type of hybrid regulatory scheme, software-based medical devices would be able to capitalize on the fast-paced nature of technological advancements while the FDA simultaneously safeguards against potential risk through more traditional, risk-based controls.<sup>202</sup>

## VI. CONCLUSION

Algorithm-based medical devices represent the culmination of advances in both technology and medicine. The industry is currently at the threshold of what is poised to be an exponential growth in medical devices that incorporate features of machine learning and artificial intelligence to enhance their therapeutic effects. Although adaptability is the key feature of such devices, it is also the driving force behind the associated regulatory challenges. To capitalize on the immense potential for unprecedented medical breakthroughs associated with improving duration and quality of life, it is critical that the FDA take affirmative steps to implement an appropriate regulatory framework. Unlike devices that perform discrete and immutable functions, technology-based medical devices are inherently variable. Given the impending proliferation of such devices, the FDA will face immense challenges if it relies on the current regulatory framework, which cannot keep pace with the rapid evolution of technology. The optimal regulatory approach is to create a separate pathway for software-based medical devices that enables the FDA to maintain flexible oversight over their safety and effectiveness without stifling technological innovation.

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*Governance Toolbox for Emerging Technologies*, 51 U.C.D. L. REV. 233, 264 (2017).

<sup>200</sup> *Id.*

<sup>201</sup> *Id.* at 265.

<sup>202</sup> *Id.* at 265–66.