

## THE NEED FOR FEDERAL PREEMPTION OF STATE TORT CLAIMS IN THE CONTEXT OF “NEW DRUGS” AND PREMARKET-APPROVED MEDICAL DEVICES

*Lisa M. Mottes\**

### I. INTRODUCTION

Consumers have a dual expectation when it comes to drugs and medical devices. First, consumers hope and expect for the development and distribution of helpful and life-saving drugs and medical devices.<sup>1</sup> Second, consumers want to be protected from the potential dangers associated with such drugs and medical devices.<sup>2</sup> The problem arises, however, in the fact that “the most important drugs and devices . . . both . . . save lives, and . . . cost lives.”<sup>3</sup> The approval process of the Food and Drug Administration (FDA) for drugs and medical devices in conjunction with federal preemption allow for consumers’ dual expectation—the availability of life-saving products and protection from dangers associated with these products—to be met.

The FDA, a federal administrative agency within the Department of Health and Human Services, is responsible for protecting and

---

\* J.D. Candidate, 2011, Seton Hall University School of Law; B.S., 2008, University of Maryland. I wish to thank Professor Jordan Paradise and Andrew Boulay for all of their guidance throughout the writing process. I would also like to thank my family and friends for all of their support.

<sup>1</sup> See Gerald Ford, President of the United States, Statement on Signing the Medical Device Amendments of 1976 (May 28, 1976), *available at* <http://www.presidency.ucsb.edu/ws/index.php?pid=6069> (explaining consumers’ hopes and expectations for life-saving drugs and devices); see also *Medical Device Safety Act of 2009: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 111th Cong. 1–2 (2009) (statement of Michael Kinsley) [hereinafter Kinsley Statement], *available at* [http://energycommerce.house.gov/Press\\_111/20090512/testimony\\_kinsley.pdf](http://energycommerce.house.gov/Press_111/20090512/testimony_kinsley.pdf)

(testifying against the Medical Device Safety Act of 2009 because he suffers from Parkinson’s disease and has benefited from drugs and medical devices and because he is a journalist who has written “about the damage done to our economy and country by excessive litigation . . . over medical care”).

<sup>2</sup> Kinsley Statement, *supra* note 1, at 1 (describing consumers’ desires for drugs and medical devices).

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

promoting public health by ensuring that drugs and medical devices are safe and effective.<sup>4</sup> To ensure safety and efficacy, the Federal Food, Drug, and Cosmetic Act (“FDCA”) grants the FDA the authority to oversee the introduction and approval of both new drugs and high-risk Class II and Class III medical devices.<sup>5</sup> Before a new drug or medical device subject to approval can be distributed to the public, the FDA determines whether the benefits of the drug or medical device outweigh the risks associated with that drug or medical device.<sup>6</sup> As former President Gerald Ford explained,

[The FDA] daily faces a most difficult task—preventing threats to the public health in a way that is not onerous, but fully consonant with the principles of competitive economic development on which this Nation was built. It is a task that requires determination, scientific skill, judgment, and most of all, compassion for the hopes and needs of our fellow man.<sup>7</sup>

The FDCA also gives the FDA the responsibility to promote public health and to ensure that new drugs and medical devices are developed and distributed.<sup>8</sup>

Despite the FDA’s important role, there is an ongoing dispute as to whether the FDA’s approval of a drug or medical device should preempt a state tort claim that challenges the safety or effectiveness of that drug or device. Federal preemption is a legal theory that permits federal law to override state law when that state law conflicts with federal law; the result is that the state law is preempted and “without effect.”<sup>9</sup> The issue of federal preemption is relevant in the context of new drugs and medical devices as a result of two Supreme Court decisions. In 2008, in *Riegel v. Medtronic, Inc.*, the Supreme Court held that an express preemption provision in the FDCA preempts state tort claims that challenge FDA premarket-approved

---

<sup>4</sup> 21 U.S.C. § 393(b)(2)(B)–(C) (2006). The FDA is also responsible for overseeing food and cosmetic products. § 393(b)(2)(A), (D).

<sup>5</sup> *Id.* § 355 (drugs); *id.* § 360c (devices). See discussion of approval processes *infra* Parts II.B, II.C.2. Drugs and Devices are found in Chapter 5 of the FDCA and include sections 501–73. These sections of the FDCA correspond to 21 U.S.C. §§ 351–60.

<sup>6</sup> See *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 142 (2000) (“The FDA must determine that there is a reasonable assurance that the product’s therapeutic benefits outweigh the risk of harm to the consumer.”).

<sup>7</sup> Ford, *supra* note 1.

<sup>8</sup> § 393(b)(1). The FDA ensures that new drugs and medical devices are reviewed and marketed “promptly and efficiently.” *Id.*

<sup>9</sup> *Cipollone v. Liggett Grp.*, 505 U.S. 504, 516 (1992) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)).

medical devices.<sup>10</sup> In 2009, in *Wyeth v. Levine*, the Supreme Court held, in the absence of an express preemption provision, that FDA approval of a new drug does not preempt state tort failure-to-warn and defective-product claims.<sup>11</sup> The distinct holdings in these two cases create a disparity between new drugs and medical devices. Although new drugs and devices are both subject to FDA approval and a finding of safety and efficacy, premarket-approved medical-device manufacturers are immune from state tort claims and new-drug manufacturers are not. The main reason for this disparity is the lack of an express preemption provision for new drugs within the FDCA.

As a result of the discord of *Riegel* and *Wyeth*, a call for safety and efficacy has been initiated, and Congress has indicated that change is necessary.<sup>12</sup> Select members of Congress have expressed their view that the advantages of the state tort system and the dangers associated with drugs and devices indicate that there should be a uniform standard of no preemption for both new drugs and premarket-approved devices.<sup>13</sup> The late Senator Edward Kennedy and Representative Frank Pallone introduced bills into both the Senate and House of Representatives in 2008 and 2009 that would effectually overturn the *Riegel* decision, amend the FDCA, and remove the express preemption provision for premarket-approved medical devices.<sup>14</sup> Enactment of either iteration would resolve the current disparity, and neither premarket-approved medical-device manufacturers nor new-drug manufacturers would be able to argue federal preemption as a defense to state law products liability claims.

This proposed legislation, the Medical Device Safety Act (“MDSA”), has initiated a debate as to whether the current preemption provided in § 360k is beneficial or detrimental in the context of

---

<sup>10</sup> See 552 U.S. 312, 330 (2008); see also *id.* at 333 (Ginsburg, J., dissenting) (stating the majority’s holding). The express preemption provision is in § 360k of the FDCA.

<sup>11</sup> See 129 S. Ct. 1187, 1204 (2009). A failure-to-warn claim alleges that the seller of the product is liable for harm that is caused as the result of failing to provide a warning where a reasonable person would have included a warning. RESTATEMENT (SECOND) OF TORTS: PRODUCTS LIABILITY § 10(a) (1998). A reasonable person would provide a warning if the product “poses a substantial risk of harm.” *Id.* § 10(b)(1). Defective-product claims allege that the seller of a defective product is liable for harms caused as a result of the defect. *Id.* § 1.

<sup>12</sup> See Medical Device Safety Act of 2009, S. 540, 111th Cong. (2009); Medical Device Safety Act of 2009, H.R. 1346, 111th Cong. (2009); Medical Device Safety Act of 2008, S. 3398, 110th Cong. (2008); Medical Device Safety Act of 2008, H.R. 6381, 110th Cong. (2008).

<sup>13</sup> S. 540; H.R. 1346; S. 3398; H.R. 6381.

<sup>14</sup> S. 540; H.R. 1346; S. 3398; H.R. 6381.

medical devices.<sup>15</sup> This debate raised by the proposed legislation also exposes the same arguments for federal preemption in the context of new drugs.<sup>16</sup> Opponents of federal preemption argue that preemption denies injured patients the opportunity to bring state tort claims that provide a means of compensation and relief.<sup>17</sup> Proponents of preemption argue that preemption is necessary to promote innovation and the development of risky yet beneficial drugs and devices because without preemption, manufacturers will be reluctant to produce drugs or devices if subject to state tort claims.<sup>18</sup>

This Comment will argue that the FDCA should be amended to include an express preemption provision for new drugs so that new-drug manufacturers and premarket-approved device manufactures will be treated uniformly. The FDA's approval process serves as support for this recommended action because it ensures the safety and efficacy of new drugs and premarket-approved medical devices. Preemption helps promote innovation and development by encouraging manufacturers to develop new products and keep products on the market. Finally, the approval process for new drugs is even more rigorous than the rigorous premarket-approval process for medical devices. Therefore, preemption should continue to be recognized for premarket-approved devices and should be extended to new drugs.

Part II of this Comment will analyze the legislative history of the FDA, the approval process of new drugs under § 505 of the FDCA, and the approval process of medical devices under § 513 of the FDCA. Part III will discuss preemption generally, will summarize *Medtronic v. Lohr*, *Riegel*, and *Wyeth*, which are the Supreme Court cases addressing preemption for medical devices and new drugs, will indicate the effect of these cases, and will explain the disparity that has resulted. Part IV will argue for federal preemption after weighing

---

<sup>15</sup> 21 U.S.C. § 360k (2006); S. 540; H.R. 1346.

<sup>16</sup> See, e.g., Press Release, Comm. on Energy and Commerce, Health Leaders Introduce Legislation Reversing Supreme Court's Medical Device Decision (Mar. 5, 2009) [hereinafter Committee on Energy and Commerce], available at [http://energycommerce.house.gov/index.php?option=com\\_content&task=view&id=1518](http://energycommerce.house.gov/index.php?option=com_content&task=view&id=1518) (describing the positive outcomes of the decision against federal preemption in *Wyeth* and describing how the same benefits would result from passage of the MDSA); see also *The Medical Device Safety Act of 2009: Hearing on S. 540, Before the Comm. on Health, Educ., Labor and Pensions*, 111th Cong. 10 (2009) (statement of Peter Barton Hutt, former chief counsel of FDA) [hereinafter Hutt Statement], available at <http://help.senate.gov/imo/media/doc/hutt.pdf> (describing the advantages of federal preemption).

<sup>17</sup> See *infra* Part IV.A.2.

<sup>18</sup> See *infra* Part IV.B.

the advantages and disadvantages of preemption and concluding that FDA approval is a sufficient substitute for state tort claims. Part V will suggest a remedy for the disparity between medical devices and new drugs and will set forth the steps Congress should take to preserve the express preemption of medical devices and create an express preemption provision for new drugs.

## II. LEGISLATIVE HISTORY OF THE FDA & AN OVERVIEW OF FDA APPROVAL OF NEW DRUGS AND MEDICAL DEVICES

Congress and the FDA have indicated that the FDA has two principal responsibilities: to protect public health and to promote public health.<sup>19</sup> In the last century, the FDA has been an important mechanism in protecting public health by assuring that drugs, medical devices, and other medical products and foods are safe, effective, and secure.<sup>20</sup> The FDA has also been an important mechanism of promoting public health by allowing for the development and approval of new technology and innovations that “make medicines and foods more effective, safer, and more affordable.”<sup>21</sup>

### A. *History of the FDA’s Legislative Provisions*

The first significant step towards safety and efficacy occurred in 1906 when Congress enacted the Federal Food and Drug Act that prevented adulterated or misbranded foods, drugs, medicines, and liquors from being manufactured, sold, or transported.<sup>22</sup> Because this act only reached adulteration and misbranding, further regulation soon became necessary, and on June 25, 1938, President Franklin De-

---

<sup>19</sup> 21 U.S.C. § 393 (2006).

The [FDA] shall promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner; . . . [The FDA shall] protect the public health by ensuring that . . . drugs are safe and effective . . . [and] there is [a] reasonable assurance of the safety and effectiveness of devices intended for human use[.]

§ 393(b)(1), (2)(B)–(C).

<sup>20</sup> See *What We Do*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last visited Sept. 1, 2010) [hereinafter *What We Do*] (describing the FDA’s mission); see also *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (explaining the government’s role in protecting “the health of our people”).

<sup>21</sup> *What We Do*, *supra* note 20.

<sup>22</sup> Federal Food and Drugs Act of 1906, 59 Pub. L. No. 384, 34 Stat. 768 (1906) (codified as amended at 21 U.S.C. § 301 (2006)). Adulterated products are poisonous, unsanitary, and overall unsafe. § 351(a). Misbranded products contain misleading advertising or labeling. *Id.* § 321(n).

lano Roosevelt signed the Federal Food, Drug, and Cosmetic Act (“FDCA”).<sup>23</sup> A significant effect of the FDCA was that the FDA’s regulatory authority expanded to include medical devices and cosmetics.

<sup>24</sup> The Act also gave the FDA the authority to regulate adulterated or misbranded medical devices and required all “new drug” manufacturers to submit a premarket notification, which included safety assurances, to the FDA.<sup>25</sup> Section 201 of the FDCA defines a “new drug” as follows:

Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof[.]<sup>26</sup>

In 1962, the Kefauver Drug Amendments were enacted “to strengthen the new drug regulatory system.”<sup>27</sup> The amendments required new drugs to undergo premarket approval instead of premarket notification and required that new drugs be found to be both safe and effective before being approved.<sup>28</sup>

Although devices were subject to federal regulatory control as to adulteration<sup>29</sup> and misbranding,<sup>30</sup> devices were not subject to a pre-

<sup>23</sup> *FDA History, Part II: The 1938 Food, Drug, and Cosmetic Act*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054826.htm> (last visited Sept. 1, 2010).

<sup>24</sup> *Id.* Devices were covered because at this time drugs were defined to include medical devices. Peter Barton Hutt, *A History of Government Regulation of Adulteration and Misbranding of Medical Devices*, 44 FOOD DRUG COSM. L.J. 99, 102 (1989).

<sup>25</sup> Hutt, *supra* note 24, at 104. At this time, the FDA only had regulatory authority to control the adulteration and misbranding of medical devices. *Id.*

<sup>26</sup> 21 U.S.C. § 321 (p) (1) (2006). The FDCA defines a “drug” as:

[A]rticles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and . . . articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and . . . articles (other than food) intended to affect the structure or any function of the body of man or other animals . . .

§ 321 (g) (1) (A)–(C).

<sup>27</sup> Hutt, *supra* note 24, at 106.

<sup>28</sup> *Id.* A companion bill that would have required a similar premarket approval method for medical devices was also considered but was never passed. *Id.* See Part II.C.2 *infra* for a description of the premarket notification and premarket approval processes.

<sup>29</sup> A drug or device is considered adulterated when it contains poisonous or unsanitary components or if it was manufactured, processed, packaged, etc., under unsanitary conditions. 21 U.S.C. § 351 (a).

market-review process like new drugs.<sup>31</sup> Medical technology was progressively advancing and new, more complex and potentially dangerous devices were being developed.<sup>32</sup> The FDCA was in need of an amendment to expand its regulatory authority over medical devices.<sup>33</sup> This need was especially evidenced by the fact that there were conflicting state regulations for medical devices, and many states had created their own premarket regulations for medical devices.<sup>34</sup>

In response, President Richard Nixon instructed the Department of Health, Education, and Welfare (“HEW”) to establish a study group.<sup>35</sup> Dr. Theodore Cooper chaired this group, the Study Group on Medical Devices (“Cooper Committee”).<sup>36</sup> In September 1970, the Cooper Committee issued its report and concluded that medical devices required a distinctive regulatory approach and that medical devices should be classified and subject to different approval methods based on the classification assigned to the device.<sup>37</sup> The recommendations of the Cooper Committee became the basis for the Medical Device Amendments of 1976 (“MDA”).<sup>38</sup> The MDA categorizes medical devices into classes based on their level of perceived risk: some devices undergo premarket notification, some undergo premarket approval, and some undergo neither.<sup>39</sup>

#### B. FDA Approval of New Drugs

Every year, the FDA approves approximately one-hundred new drugs.<sup>40</sup> Section 505 of the FDCA regulates the approval of new drugs

---

<sup>30</sup> A drug or device is considered misbranded when it is in any way false or misleading. *Id.* § 352(a).

<sup>31</sup> Hutt, *supra* note 24, at 117.

<sup>32</sup> Ford, *supra* note 1.

<sup>33</sup> See SHARON FRANK, A NEW MODEL FOR EUROPEAN MEDICAL DEVICE REGULATION 152 (2003).

<sup>34</sup> *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 333 (2008) (Ginsburg, J., dissenting). For example, California had its own premarket approval (“PMA”) process for medical devices. *Id.*

<sup>35</sup> FRANK, *supra* note 33, at 154.

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

<sup>37</sup> Hutt, *supra* note 24, at 109–10.

<sup>38</sup> FRANK, *supra* note 33, at 154.

<sup>39</sup> 21 U.S.C. § 360c (2006).

<sup>40</sup> See Lawrence O. Gostin, *Regulating the Safety of Pharmaceuticals: The FDA, Preemption, and the Public’s Health*, 301 J. AM. MED. ASS’N 2036, 2036 (2009) (describing the number of drugs approved each year); *Drug Approval Reports*, U.S. FOOD AND DRUG ADMIN.: CENTER FOR DRUG EVALUATION AND RESEARCH, <http://www.accessdata.fda.gov/Scripts/cder/DrugsatFDA/index.cfm?fuseaction=Re>

and requires new-drug sponsors to file a New Drug Application (“NDA”) before the drug can be introduced into the market.<sup>41</sup> Before filing the NDA, non-clinical and clinical testing must be conducted by the sponsor to “demonstrate the safety and effectiveness of the [new] drug.”<sup>42</sup> Prior to conducting clinical tests, however, the sponsor must file an Investigational New Drug Application (“IND”),<sup>43</sup> which allows the new drug to be lawfully shipped across state lines and undergo clinical testing in various states.<sup>44</sup>

Once the IND is approved and clinical testing is complete, the drug’s sponsor can file a NDA with the FDA. The NDA must include, among other things, all of the following: investigation reports that indicate whether or not the drug is safe and effective in its use; a list of the drug’s components; a statement of the drug’s composition; a description of how the drug is manufactured, processed, and packaged; samples of the drug; and a proposed label.<sup>45</sup> The NDA enables the FDA to review whether the drug is safe—that is, whether its benefits outweigh its risks—and whether “substantial evidence” exists to demonstrate that the drug is effective, as based on adequate and well-controlled studies.<sup>46</sup> This “substantial evidence” standard for effectiveness is defined as follows:

[E]vidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the

---

ports.ReportsMenu (last visited Sept. 1, 2010) (reporting the drug applications that are approved each month).

<sup>41</sup> § 355(a).

<sup>42</sup> PETER BARTON HUTT, *The Regulation of Drug Products by the United States Food and Drug Administration*, in TEXTBOOK OF PHARMACEUTICAL MEDICINE (John P. Griffin & John O’Grady, eds. 2006), reprinted in PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW: CASES AND MATERIALS 676 (3rd ed. 2007).

<sup>43</sup> 21 C.F.R. § 312.20(b) (2010).

<sup>44</sup> § 312.1(a). The IND includes, among other things, the investigational plan, which may include the rationale for the study, what will be studied, the types of clinical trials to be done, and the approach used to evaluate the drug. § 312.23(a)(3)(iv).

<sup>45</sup> 21 U.S.C. § 355(b)(1)(A)–(F) (2006). The sponsor must also provide the patent number and patent expiration date. *Id.*

<sup>46</sup> See 21 C.F.R. § 314.126 (2010) (“Reports of adequate and well-controlled investigations provide the primary basis for determining whether there is ‘substantial evidence’ to support the claims of effectiveness for new drugs.”). Only one adequate and well-controlled study is needed to provide substantial evidence of effectiveness. 21 U.S.C. § 355(d) (2006).



effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the [label].<sup>47</sup>

The NDA also allows the FDA to determine whether the drug is safe for use as the proposed label prescribes, recommends, and suggests and allows the FDA to determine whether the “methods used in manufacturing the drug and the controls used to maintain the drug’s quality are adequate to preserve the drug’s identity, strength, and purity,”<sup>48</sup> (i.e., that there are current good manufacturing practices (“CGMP”)).<sup>49</sup> If the NDA demonstrates that the new drug is safe and effective, the application will be approved.<sup>50</sup>

Conversely, if the application in some way demonstrates that the new drug will be unsafe or ineffective, the FDA will not approve the application. If a new drug application demonstrates that the drug is unsafe “under the conditions prescribed, recommended, or suggested in the proposed label,” the FDA will not approve the application.<sup>51</sup> If “there is a lack of substantial evidence that the drug will have the effect” it is said to have under the “conditions of use prescribed, recommended, or suggested in the proposed [label],” the FDA will not approve the application because the drug is deemed ineffective.<sup>52</sup> Finally, if the proposed label is false or misleading, the FDA will not approve the application.<sup>53</sup>

### C. FDA Approval of Medical Devices

The approval process for medical devices is found within the FDCA and was enacted as part of the Medical Device Amendments (“MDA”). As the preamble to the MDA states, the MDA was enacted to ensure that medical devices are safe and effective by providing a process for premarket approval based in part on the drug approval

---

<sup>47</sup> § 355(d).

<sup>48</sup> § 355(b); *see also* *New Drug Application (NDA)*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm> (last visited Sept. 1, 2010) (describing the requirements of the NDA).

<sup>49</sup> *See* 21 C.F.R. 210.1(a) (2010) (describing the CGMP used to ensure drugs meet the requirements for “manufactur[ing], processing, packing, or holding” that assure the drug’s safety).

<sup>50</sup> § 355(d).

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

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

<sup>53</sup> *Id.*

process.<sup>54</sup> The legislation achieves this purpose by classifying medical devices into three different classes based on their risk and by requiring the approval decision be based on whether there is “reasonable assurance” that the device is safe and effective.<sup>55</sup> As the regulations explain,

There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.<sup>56</sup>

Thus, the “reasonable assurances” standard for medical devices is similar to the standard of safety for drugs, as both define safety to mean that the benefits outweigh the risks.<sup>57</sup>

#### 1. Classes of Medical Devices

Class I medical devices pose the least risk and include devices that are not used to support or sustain life and “do not present a potential unreasonable risk of illness or injury.”<sup>58</sup> Class I medical devices are only subject to “general controls” contained within various statutory provisions of the FDCA and FDA regulations promulgated under the authority set out in the FDCA.<sup>59</sup> The provisions include adulteration in § 501 of the FDCA, misbranding in § 502, registration in § 510, banned devices in § 516, notification and other remedies in § 518, records and reports in § 510, and other general provisions in § 520.<sup>60</sup> These statutory provisions are used to provide “reasonable assurance” that the device is safe and effective and thus that the products are not adulterated, misbranded, or banned.<sup>61</sup> Unless exempt,

---

<sup>54</sup> See Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976) (“An act to amend the Federal Food, Drug, and Cosmetic Act to provide for the safety and effectiveness of medical devices intended for human use.”).

<sup>55</sup> § 360c.

<sup>56</sup> 21 C.F.R. § 860.7(d)(1) (2010).

<sup>57</sup> See discussion *supra* Part II.B.

<sup>58</sup> 21 U.S.C. § 360c(a)(1)(A)(ii)(I)–(II).

<sup>59</sup> 21 C.F.R. § 860.3(c)(1) (2010).

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

<sup>61</sup> 21 U.S.C. § 360c(a)(1)(A)(i). “General controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.” 21 C.F.R. § 860.3(c)(1).

Class I medical devices are also subject to the 510(k)-approval process.<sup>62</sup>

Class II medical devices are devices that require more than general controls to provide “reasonable assurance” that the device is safe and effective and instead require special controls in addition to the general controls.<sup>63</sup> Special controls include:

promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidance documents (including guidance on the submission of clinical data in premarket notification in accordance with section 510(k) of the act), recommendations, and other appropriate actions.<sup>64</sup>

Similar to Class I devices, unless exempt, Class II medical devices are also subject to the 510(k)-approval process.<sup>65</sup>

When a device is considered high-risk or insufficient information exists to prove safety and effectiveness based only on general or special controls, the device is classified as Class III.<sup>66</sup> Class III medical devices are devices “purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or [ . . . ] presents a potential unreasonable risk of illness or injury[.]”<sup>67</sup> Class III medical devices represent the riskiest devices, and because they require more than general or special controls to provide a “reasonable assurance” of safety and efficacy, some Class III medical devices are subject to premarket approval (“PMA”).<sup>68</sup>

## 2. PMA & Its Exceptions

Similar to the new-drug-approval process, PMA-medical devices undergo clinical investigations to determine safety and effectiveness; as with the IND application for new drugs, PMA-medical devices must

---

<sup>62</sup> See § 360c(f)(1); discussion *infra* Part II.C.2.

<sup>63</sup> § 360c(a)(1)(B).

<sup>64</sup> 21 C.F.R. § 860.3(c)(2).

<sup>65</sup> See § 360c(f)(1); discussion *infra* Part II.C.2.

<sup>66</sup> § 860.3(c)(3).

<sup>67</sup> § 360c(a)(1)(C)(ii)(I)–(II).

<sup>68</sup> § 360c(a)(1)(C). Some Class II medical devices also undergo PMA. The FDA regulations do not require all Class III medical devices to be approved by PMA, and from 2003 to 2007, most Class III medical devices were approved through the 510(k) process. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-190, MEDICAL DEVICES: FDA SHOULD TAKE STEPS TO ENSURE HIGH-RISK DEVICE TYPES ARE APPROVED THROUGH THE MOST STRINGENT PREMARKET REVIEW PROCESS 16 (2009), *available at* <http://www.gao.gov/new.items/d09190.pdf>; see *infra* notes 75–78 and accompanying text.

get an Investigation-Device Exemption (“IDE”) approved to allow for lawful shipping of the device across state lines and clinical testing in various states.<sup>69</sup> Once clinical testing is complete, the PMA process requires a device sponsor to submit an application that contains, among other things, the investigational reports from the clinical tests that demonstrate “whether or not [the] device is safe and effective”; a statement of the “components, ingredients, and properties, and of the [principle(s)] of operation” of the device; a description of the device’s manufacture, processing, packaging, and installation; samples of the device; and a proposed label.<sup>70</sup> The FDA determines whether a PMA device is safe and effective based on the target individuals who will use the device and the “conditions of use prescribed, recommended, or suggested” in the label, as well as by comparing the benefits of the device with the risk of any injury or illness.<sup>71</sup> Regulators will deny a PMA application if, among other reasons, the information in the application demonstrates a “lack of showing of reasonable assurance that such device is safe,” “a lack of showing of reasonable assurance that the device is effective,” or that the proposed label is “false or misleading.”<sup>72</sup>

Most Class III medical devices are not subject to PMA. Through a “grandfather clause,” Class III medical devices that were introduced into the market before Congress enacted the MDA and Class III medical devices that are “substantially equivalent” to another already-approved predicate device do not require PMA.<sup>73</sup> A device is “substantially equivalent” if it “has the same intended use . . . and has the same technological characteristics as the predicate device or . . . has different technological characteristics” but the information showing that the device is substantially equivalent “demonstrates that the device is as safe and effective as a legally marketed device and . . . does

---

<sup>69</sup> 21 C.F.R. § 812.1(a) (2010); see also *Device Advice: Investigational Device Exemption (IDE)*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm> (last visited Sept. 1, 2010) (describing the IDE process and requirements). IDEs are also used for clinical testing for devices approved by the 510(k) premarket-notification process. *Id.* While testing is being conducted, a PMA or 510(k) premarket notification does not need to be submitted. *Id.*

<sup>70</sup> 21 U.S.C. § 360e(c)(1)(A)–(C), (E)–(F).

<sup>71</sup> *Id.* § 360c(a)(2)(A)–(C).

<sup>72</sup> *Id.* § 360e(d)(2)(A)–(B), (D).

<sup>73</sup> § 360e(b)(1)(A)–(B).

not raise different questions of safety and effectiveness than the predicate device.”<sup>74</sup>

Instead of PMA, substantially equivalent devices, new Class I devices, new Class II devices, and some Class III devices are subject to the 510(k)-approval process, which requires the submission of premarket notification (“PMN”) to the FDA.<sup>75</sup> The PMN must include, among other things, the name and class of the device, a 510(k) summary that shows the basis for determining substantial equivalence, and the proposed label.<sup>76</sup> Moreover, for devices claiming to be substantially equivalent to a predicate-Class III device, the PMN must also include “a summary of the types of safety and effectiveness problems associated with the type of devices being compared.”<sup>77</sup>

Compared with PMA, obtaining FDA approval of a medical device through the 510(k) process is much easier and faster because essentially all that is needed for 510(k) approval is a demonstration of “substantial equivalence,” as “safety and effectiveness data are not explicitly required.”<sup>78</sup> For 510(k) clearance, a medical-device manufacturer only needs to give the FDA ninety days’ notice of its intent to market a device,<sup>79</sup> and the standard fee for review is approximately \$4,000.<sup>80</sup> Conversely, the FDA approves or denies PMA-device appli-

---

<sup>74</sup> *Id.* § 360c(i)(1)(A)(i)–(ii).

<sup>75</sup> *Premarket Notification (510k)*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyoudevice/premarketnotifications/premarketnotification510k/default.htm#se> (last visited Nov. 1, 2010); *see also* 21 C.F.R. § 807.81 (2010). As long as it is not exempt, a Class I or Class II medical device will be subject to the 510(k) process. 21 U.S.C. 360c(f)(1). The exempt devices include, among other things, anesthesiology devices, cardiovascular devices, dental devices, neurological devices, and orthopedic devices. 21 C.F.R. §§ 862–92 (2010).

<sup>76</sup> 21 C.F.R. § 807.92.

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

<sup>78</sup> *See* Jonathan S. Kahan, *Premarket Approval Versus Premarket Notification: Different Routes to the Same Market*, 39 FOOD DRUG COSM. L.J. 510, 515–16 (1984) (comparing the PMA and 510(k) processes). For example, in December 2009, the 510(k) process approved more than 200 devices; however, no devices received PMA original approval. *See December 2009 510(k) Clearances*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm196259.htm> (last visited Sept. 1, 2010); *December 2009 PMA Approvals*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm198613.htm> (last visited May 20, 2010).

<sup>79</sup> 21 U.S.C. § 360(k).

<sup>80</sup> *Premarket Notification [510(k)] Review Fees*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketY>

cations after 180 days,<sup>81</sup> and the standard fee for review of a PMA application is approximately \$240,000.<sup>82</sup> Furthermore, the 510(k) process is currently under review by the Institute of Medicine to determine whether it “sufficiently protects patients and promotes public health.”<sup>83</sup>

### III. THE SUPREME COURT’S VIEW ON FDA APPROVAL AND PREEMPTION

#### A. *Preemption Generally*

Defendants use preemption as a defense to argue that federal law conflicts with, and thus supersedes, the state law that is the basis for the plaintiff’s claim.<sup>84</sup> In state tort suits in which defendants argue preemption, the plaintiff is usually putting forth a common-law claim of strict liability or negligence and is seeking compensation for injury or other harm.<sup>85</sup> When a court finds a state law preempted, the defendant essentially receives immunity from the state tort claims and the plaintiff is left without compensation for his injury or harm.<sup>86</sup>

The source of federal preemption is the Supremacy Clause in Article VI of the Constitution, which states that federal law “shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the contrary notwithstanding.”<sup>87</sup> The Supreme Court clarified this constitutional provision by explaining that “state

---

ourDevice/PremarketSubmissions/PremarketNotification510k/ucm134566.htm (last visited Sept. 1, 2010).

<sup>81</sup> 21 U.S.C. § 360e(d)(1)(A).

<sup>82</sup> *PMA Review Fees*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm048161.htm#fees> (last visited Sept. 1, 2010).

<sup>83</sup> *Public Health Effectiveness of the FDA 510(k) Clearance Process*, INSTITUTE OF MEDICINE, <http://www.iom.edu/Activities/PublicHealth/510KProcess.aspx> (last visited Sept. 1, 2010).

<sup>84</sup> *See* *Wyeth v. Levine*, 129 S. Ct. 1187, 1192 (2009) (describing Wyeth’s preemption defense). Preemption is defined as “the principle that a federal law can supersede or supplant any inconsistent state law or regulation.” BLACK’S LAW DICTIONARY 1197 (7th ed. 1999).

<sup>85</sup> *See, e.g., Wyeth*, 129 S. Ct. at 1191–92 (describing Ms. Levine’s common law claims of strict liability and negligence and the initiation of her lawsuit to seek damages); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 320–21 (2008) (describing the Riegels’ common law claims of strict liability and negligence); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 481 (1996) (describing the Lohrs’ state common law claims of strict liability and negligence).

<sup>86</sup> *See infra* notes 93–94 and accompanying text. *But see infra* note 99 and accompanying text.

<sup>87</sup> U.S. CONST. art. VI, cl. 2.

law that conflicts with federal law is ‘without effect.’”<sup>88</sup> When analyzing preemption, the Supreme Court explained that there is an “assumption that the historic police powers of the States [are] not to be superseded by [a] Federal Act unless that [is] the clear and manifest purpose of Congress.”<sup>89</sup> This “clear and manifest purpose” is present when Congress has indicated through either express, implied, or conflict preemption that federal law will regulate a specific area, and, as a result, any state law covering that area will be preempted.<sup>90</sup>

Express preemption occurs when Congress’s indication for preemption is “explicitly stated” in a statute.<sup>91</sup> In *Cipollone v. Liggett Group*, the Supreme Court analyzed two statutes with expressly preemptive language: the Federal Cigarette Labeling and Advertising Act of 1965 and the Public Health Cigarette Smoking Act of 1969.<sup>92</sup> The court found that these two federal statutes regulating cigarettes expressly preempted some of the petitioner’s state tort claims,<sup>93</sup> and the defendant was thus immune from liability stemming from these claims.<sup>94</sup>

Implied preemption occurs when preemption is implied in the statute’s “structure and purpose.”<sup>95</sup> More specifically, implied preemption occurs, in the absence of an express provision, “if federal law so thoroughly occupies a legislative field ‘as to make reasonable the inference that Congress left no room for the states to supplement it.’”<sup>96</sup> The Supreme Court analyzed implied preemption in *Silkwood v. Kerr-McGee Corp.*, holding that a federal law on nuclear safety did not

---

<sup>88</sup> *Cipollone v. Liggett Grp.*, 505 U.S. 504, 516 (1992) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)).

<sup>89</sup> *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (internal citations omitted).

<sup>90</sup> *See Jones v. Rath Packing Co.*, 430 U.S. 519, 525–26 (1977).

<sup>91</sup> *Id.* at 525.

<sup>92</sup> 505 U.S. 504, 514–15 (1992).

<sup>93</sup> *Id.* at 530–31.

The 1965 Act did not pre-empt state law damages actions; the 1969 Act pre-empts petitioner’s claims based on a failure to warn and the neutralization of federally mandated warnings to the extent that those claims rely on omissions or inclusions in respondents’ advertising or promotions; the 1969 Act does not pre-empt petitioner’s claims based on express warranty, intentional fraud and misrepresentation, or conspiracy.

*Id.*

<sup>94</sup> *Id.* at 504.

<sup>95</sup> *Id.* at 516 (quoting *Jones*, 430 U.S. at 525).

<sup>96</sup> *Id.* (quoting *Fidelity Fed. Sav. & Loan Assn. v. De la Cuesta*, 458 U.S. 141, 153 (1982)).

preempt a state's award of punitive damages to an individual harmed by plutonium that had leaked from a nuclear facility where the individual worked.<sup>97</sup> Despite a previous Supreme Court holding that Congress "occupied the entire field of nuclear safety concerns,"<sup>98</sup> the Court in *Silkwood* found no preemption; thus, the defendant was not immune from liability, and the injured party was entitled to compensation.<sup>99</sup>

Finally, in the absence of an express provision and even when Congress has not entirely occupied the field, conflict preemption occurs if the state law "conflicts with federal law."<sup>100</sup> The Supreme Court has identified two situations in which conflict preemption arises:<sup>101</sup> when a manufacturer could not possibly follow both the federal and state regulations<sup>102</sup> or when "[state] law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."<sup>103</sup>

#### B. Preemption in the Context of Medical Devices and Drugs

As of 2009, the Supreme Court has held that PMA-medical devices are subject to preemption but that new drugs are not.<sup>104</sup> One of the main reasons for this distinction is that the MDA includes an express preemption provision for medical devices that are subject to review for safety and efficacy.<sup>105</sup> The express preemption provision, in § 521 of the FDCA, states that

no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act [21 U.S.C. §§ 301 et seq.].<sup>106</sup>

<sup>97</sup> 464 U.S. 238, 241, 249 (1984).

<sup>98</sup> See *id.* (quoting *Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 212 (1983)).

<sup>99</sup> *Id.* at 258.

<sup>100</sup> *Id.* at 248. Wyeth argued conflict preemption as a defense in *Wyeth v. Levine*. See *infra* notes 140–42 and accompanying text.

<sup>101</sup> *Wyeth v. Levine*, 129 S. Ct. 1187, 1208 (2009) (Thomas, J., concurring).

<sup>102</sup> *Id.* (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963)).

<sup>103</sup> *Id.* (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

<sup>104</sup> See *infra* Parts III.B.2–3.

<sup>105</sup> See 21 U.S.C. § 360k(a) (2006).

<sup>106</sup> Medical Device Amendments of 1976 § 521, 21 U.S.C. § 360k(a)(1)–(2).



One of the main reasons that the MDA express preemption provision was added to the FDCA was that there were conflicting state regulations for medical devices, and many states had created their own regulations for approval.<sup>107</sup> The 1962 amendments did not require devices to be subject to a premarket-review process for safety and efficacy,<sup>108</sup> and because the FDA did not regulate safety and efficacy, the states did. Therefore, a purpose of the express preemption provision was to coordinate device approval.

1. *Medtronic, Inc. v. Lohr*

One of the first cases to interpret the MDA express preemption provision was *Medtronic, Inc. v. Lohr*.<sup>109</sup> The case involved a pacemaker that was a Class III substantially equivalent medical device that had obtained approval in the 510(k) process.<sup>110</sup> In *Medtronic*, the Supreme Court found that the 510(k)-approval process, which requires premarket notification and a finding of substantial equivalence, only provides minimal protection and, consequently, does not preempt state tort claims.<sup>111</sup> In other words, the 510(k) process does not focus on safety or effectiveness but only focuses on equivalence; therefore, the Court explained that a finding of substantial equivalence “provide[s] little protection to the public.”<sup>112</sup>

The Court found that the MDA preempts state requirements that are specifically developed “with respect to” medical devices and are different from or additional to an FDA requirement specific to the device; the state requirements at issue and the minimal protections of 510(k) were only general requirements and were not specific to the device at issue.<sup>113</sup> Thus, the express preemption provision in the MDA did not preempt the plaintiff’s state tort claims against Medtronic. Because the 510(k) process approved the device in *Medtronic*, the Supreme Court only analyzed the MDA’s preemption pro-

---

<sup>107</sup> See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 333 (2008) (Ginsburg, J., dissenting) (describing regulations of states, including California, which had its own PMA process for medical devices).

<sup>108</sup> Hutt, *supra* note 24, at 106.

<sup>109</sup> 518 U.S. 470 (1996).

<sup>110</sup> See *id.* at 477.

<sup>111</sup> See *id.* at 493–94 (explaining that the § 510(k) process “did not ‘require’ Medtronic’s pacemaker to take any particular form for any particular reason”).

<sup>112</sup> *Id.* at 493 (quoting Robert Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 FOOD DRUG COSM. L.J. 511, 516 (1988)).

<sup>113</sup> *Id.* at 501.

vision in the context of that process.<sup>114</sup> The Court did not consider the express preemption provision in the context of the PMA process until *Riegel*.

2. *Riegel v. Medtronic, Inc.*

Twelve years later, the Supreme Court again interpreted the express preemption provision in the MDA in a case that involved a Class III catheter that had received PMA.<sup>115</sup> The plaintiff, Mr. Riegel, had a Medtronic Evergreen Balloon Catheter inserted into his coronary artery.<sup>116</sup> During the surgery, his doctor inflated the catheter to a level beyond the maximum indicated on the label.<sup>117</sup> Mr. Riegel's coronary artery was both diffusely diseased and heavily calcified, two conditions that the device's label warned were symptoms for which use of the catheter was contraindicated.<sup>118</sup> As a result, the catheter ruptured, and Mr. Riegel was forced to undergo emergency coronary-bypass surgery.<sup>119</sup> Although the doctor's negligence played a significant role in Mr. Riegel's injuries, Mr. Riegel also initiated a lawsuit against Medtronic in the United States District Court for the Northern District of New York.<sup>120</sup> Mr. Riegel alleged that the catheter was "designed, labeled, and manufactured in a manner that violated New York common law."<sup>121</sup>

The Supreme Court held that the MDA in § 360k preempts "common-law claims challenging the safety and effectiveness" of devices that received PMA.<sup>122</sup> Accordingly, the express preemption provision acts as a defense for the manufacturers of Class III PMA devices from conflicting state-law claims and provides immunity to these manufacturers based on the fact that they complied with and were

---

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

<sup>115</sup> *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 320 (2008). Unlike the pacemaker in *Medtronic*, which was approved through the grandfather clause because it was substantially equivalent, the catheter in *Riegel* was approved through PMA. See *supra* note 110 and accompanying text. As of 1996, when the Court decided *Medtronic*, "the FDA [had] not yet initiated nor suggested the initiation of a PMA process for pacemakers or most other grandfathered devices." *Medtronic*, 518 U.S. at 478 n.3.

<sup>116</sup> *Riegel*, 552 U.S. at 320.

<sup>117</sup> *Id.*

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

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

<sup>120</sup> *Id.* Mr. Riegel's common law claims were negligence, breach of warranty, and strict liability. *Id.*

<sup>121</sup> *Id.*

<sup>122</sup> *Riegel*, 552 U.S. at 315.

approved by the FDA's PMA.<sup>123</sup> Unlike *Medtronic*, the Supreme Court held that PMA is a specific requirement relating to safety and efficacy and thus has a preemptive effect.<sup>124</sup> Therefore, after *Medtronic* and *Riegel*, the 510(k) process, which focuses on equivalence and not safety, does not have a preemptive effect, but the PMA process, which focuses on safety and not equivalence, does have a preemptive effect.<sup>125</sup>

The Court emphasized that the MDA-preemption provision only preempts state requirements that are "different from, or in addition to" federal requirements.<sup>126</sup> The Court explained that federal law does not preempt state requirements that parallel FDA requirements, such as those that provide damages for a manufacturer's violation of FDA regulations.<sup>127</sup> *Riegel's* holding in favor of preemption only applies to the limited number of Class III medical devices that have met PMA.<sup>128</sup> Therefore, the preemption provision does not apply to Class I devices, Class II devices, or Class III devices that are found to be substantially equivalent and approved under the § 510(k)-approval process.<sup>129</sup>

### 3. *Wyeth v. Levine*

A year later, in *Wyeth v. Levine*, the Supreme Court addressed whether the FDA's drug-labeling requirements and approval preempt state tort claims regarding the adequacy of the label, and more specifically, failure-to-warn claims.<sup>130</sup> The Court held that the FDA's approval of the drug, which in effect approves the label that the sponsor provides as part of the NDA, does not preempt a state tort claim.<sup>131</sup> Because no express preemption provision relating to drugs exists, the Court analyzed whether implied preemption applied.<sup>132</sup>

The case involved the Wyeth-manufactured drug Phenergan, which the FDA initially approved in 1955, and which is used to treat nausea and can be administered intravenously through either an "IV-

---

<sup>123</sup> See *id.*; see also *id.* at 333 (Ginsburg, J., dissenting) (stating the majority's holding).

<sup>124</sup> *Id.* at 322–23 (majority opinion).

<sup>125</sup> *Id.* at 323.

<sup>126</sup> 21 U.S.C. § 360k(a)(1) (2006); *Riegel*, 552 U.S. at 328.

<sup>127</sup> *Riegel*, 552 U.S. at 329–30.

<sup>128</sup> *Id.*

<sup>129</sup> See *supra* Part II.A.

<sup>130</sup> *Wyeth v. Levine*, 129 S. Ct. 1187, 1193 (2009).

<sup>131</sup> *Id.* at 1191.

<sup>132</sup> *Id.* at 1199–1200.

push” or “IV-drip” method.<sup>133</sup> Diana Levine was suffering from a migraine headache and nausea, and she initially received an intramuscular injection of Phenergan.<sup>134</sup> The first injection did not ease her suffering, and although Phenergan’s label warned that extreme care should be used to avoid the IV-push method because gangrene and amputation could result,<sup>135</sup> Ms. Levine was given another injection of Phenergan through the IV-push method.<sup>136</sup> The second IV-push injection caused Phenergan to enter her artery; as a result, Ms. Levine developed gangrene, and consequently, her entire right forearm was amputated.<sup>137</sup>

Ms. Levine sued Wyeth based on a failure-to-warn claim arguing that Phenergan’s label was defective because it did not specifically give instructions to use the IV-drip method as opposed to the IV-push method.<sup>138</sup> Ms. Levine also argued that the IV-push method was unsafe as its risks far outweighed its benefits.<sup>139</sup> Wyeth argued that both types of conflict preemption preempted Ms. Levine’s claim, i.e., that it was impossible to follow the state’s label requirements “without violating federal law” and that Ms. Levine’s state tort action was an “obstacle to the accomplishment and execution of the full purposes and objectives of Congress because it substitutes a lay jury’s decision about drug labeling for the expert judgment of the FDA.”<sup>140</sup>

In response to Wyeth’s first argument, the Court held that Wyeth could have complied with the state requirements of adding a stronger label without violating federal law.<sup>141</sup> To the second argu-

---

<sup>133</sup> *Id.* at 1191. The “IV-push” method injects the drug “directly into a patient’s vein.” *Id.* The “IV-drip” method first injects the drug into a hanging intravenous bag containing saline solution, and then the drug is injected from the bag and through a catheter into the patient’s vein. *Id.*

<sup>134</sup> *Id.* Specifically, the Phenergan was administered to treat her nausea, and Ms. Levine received Demerol to treat her headache. *Id.*

<sup>135</sup> *Id.* at 1191 & n.1.

<sup>136</sup> *Wyeth*, 129 S. Ct. at 1191.

<sup>137</sup> *Id.* Phenergan entered her artery either because intra-arterial injection occurred, where the needle entered the artery, or because perivascular extravasation occurred, where Phenergan entered the tissue surrounding her veins. *Id.*

<sup>138</sup> *Id.* at 1191–92. Ms. Levine’s claims were based on common-law strict liability and negligence. *Id.* at 1191.

<sup>139</sup> *Id.* at 1192.

<sup>140</sup> *Id.* at 1193–94 (internal citation omitted) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). As to the first argument, the state requirements would have required Wyeth to modify the label and warn of the IV-push method’s hazards. *Id.* at 1193. The federal law, the “changes being effected” regulation, would have allowed Wyeth to strengthen its warning without receiving FDA approvals through a supplemental application. *Id.* at 1196–97; 21 C.F.R. § 314.70(c)(6)(iii)(A) (2010).

<sup>141</sup> *Wyeth*, 129 S. Ct. at 1198.

ment, the Court concluded “from silence that Congress believed state lawsuits pose no obstacle to federal drug-approval objectives.”<sup>142</sup> Thus, the Court held that no implied preemption applied to Ms. Levine’s state tort claim.

In reaching its decision, the Court also considered the FDA’s position on preemption at the time of the case. In 2006, in the preamble to a drug-label regulation, the FDA voiced its position in favor of preemption by indicating that its approval is preemptive; the FDA stated that “FDA approval of labeling . . . preempts conflicting or contrary State law” and that the FDA’s approval is now both a floor and a ceiling.<sup>143</sup> The Court ultimately decided that the FDA’s position was inherently suspect and that no deference should be given to this new position because the FDA had changed its position without giving anyone notice or an opportunity to comment.<sup>144</sup>

### C. *Effects of Riegel and Wyeth*

#### 1. Lack of Uniformity Between Medical Devices and New Drugs

As a result of the *Riegel* and *Wyeth* decisions, there is a lack of uniformity as to preemption. The manufacturers of premarket-approved Class III medical devices can utilize the express preemption provision as a defense and are immune from state tort liability, but the manufacturers of new drugs cannot take advantage of any preemption defense and will still be subject to state tort liability. Interestingly, both cases analyzed the FDA’s approval process in deciding the issue of preemption but came to conflicting conclusions.<sup>145</sup> The *Riegel* decision indicated that the FDA’s approval process is sufficient to shield the PMA-medical-device manufacturer from liability, but the *Wyeth* decision seemed to suggest that the state tort system is still needed to supplement the FDA’s new-drug-approval process.<sup>146</sup> These conflicting Supreme Court decisions raise questions as to whether FDA approval is sufficient to protect and make whole a plaintiff without state tort actions and whether courts should contin-

---

<sup>142</sup> See *id.* at 1216 (Thomas, J., concurring) (describing the majority’s holding).

<sup>143</sup> Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934–35 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, and 601) [hereinafter Requirements I]. See *infra* notes 163–68 and accompanying text.

<sup>144</sup> *Wyeth*, 129 S. Ct. at 1201; see *infra* notes 163–68 and accompanying text.

<sup>145</sup> See *supra* Parts III.B.2–3.

<sup>146</sup> See *id.*

ue to treat PMA-medical devices and new drugs differently with regard to federal preemption. These issues will be analyzed in Parts IV and V.

## 2. Why the Issues of Preemption, FDA Approval, State Tort Actions, and Uniformity are Important Now

The preemption and uniformity issues surrounding PMA medical devices and new drugs are especially relevant now. As a result of *Riegel* and *Wyeth*, a call for safety and efficacy has been initiated, and Congress has indicated that change is necessary.<sup>147</sup> In both 2008, following *Riegel*, and 2009, following *Wyeth*, legislation was introduced that would effectively overrule *Riegel* and amend the MDA to remove preemption for Class III medical devices.<sup>148</sup> Select members of Congress indicated their view that the protections of the state tort system and a uniform standard of no preemption for both new drugs and PMA devices are superior to allowing preemption.<sup>149</sup>

On March 5, 2009, the day following the decision in *Wyeth*, the Medical Device Safety Act of 2009 (“MDSA”) was introduced into both the House of Representatives and the Senate.<sup>150</sup> The MDSA would amend § 521 of the FDCA, which is the MDA express preemption provision relating to PMA medical devices, by adding the following: “nothing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State.”<sup>151</sup> The MDSA would prevent device manufacturers from using the express preemption provision as a defense to argue that the MDA preempts state tort claims even if their Class III device

---

<sup>147</sup> See Medical Device Safety Act of 2009, S. 540, 111th Cong. (2009); Medical Device Safety Act of 2009, H.R. 1346, 111th Cong. (2009); Medical Device Safety Act of 2008, S. 3398, 110th Cong. (2008); Medical Device Safety Act of 2008, H.R. 6381, 110th Cong. (2008). When introducing the Medical Device Safety Act into the House of Representatives, Frank Pallone of New Jersey stated:

[T]he Supreme Court rightfully upheld a patient’s right to legal recourse after sustaining an injury from a pharmaceutical product. Today, we introduce legislation that gives patients that same right when injured by a medical device. This legislation puts safety first and eliminates the blanket immunity that medical device companies currently enjoy thanks to an unfortunate Supreme Court decision last year.

Committee on Energy and Commerce, *supra* note 16.

<sup>148</sup> See S. 540; H.R. 1346; S. 3398; H.R. 6381. The legislation has not been passed as of the date of publication.

<sup>149</sup> See *supra* note 14 and accompanying text.

<sup>150</sup> S. 540; H.R. 1346. The sponsor of the bill in the Senate was the late Senator Edward Kennedy, and the sponsor of the bill in the House of Representatives was Representative Frank Pallone. S. 540; H.R. 1346.

<sup>151</sup> S. 540; H.R. 1346.

was approved through the PMA process and even if the state imposed additional or different requirements.<sup>152</sup> This proposed legislation and the *Riegel* and *Wyeth* decisions have sparked a debate as to whether preemption is beneficial or detrimental in the context of PMA medical devices and whether preemption should continue for PMA devices. Although the only legislation that has been proposed is in regard to medical devices, the same arguments for and against the legislation are also relevant in the context of federal preemption of new drug approvals.

Opponents of preemption argue that preemption denies injured patients the opportunity to bring state tort claims that provide a means of compensation and relief.<sup>153</sup> One such opponent is President Barack Obama, and although the MDSA has not been approved,<sup>154</sup> the MDSA or similar legislation may have a better chance of being approved in the future because of changes initiated by President Obama's administration.<sup>155</sup> On May 20, 2009, President Obama issued a memorandum regarding preemption to the heads of the executive departments and agencies.<sup>156</sup> In the memorandum, President Obama stressed the importance of balance between the federal government and the states and indicated that in many instances, states have protected the public's health and safety "more aggressively" than the federal government.<sup>157</sup> President Obama stated, "[P]reemption of State law by executive departments and agencies should be undertaken only with full consideration of the legitimate prerogatives of the States and with a sufficient legal basis for preemption."<sup>158</sup> Additionally, President Obama indicated that preemption provisions or language should not be added to regulatory preambles or codified regulations and that such preemption provisions that have been added in the last ten years should be reevaluated.<sup>159</sup>

---

<sup>152</sup> See Gregory J. Wartman, *Life After Riegel: A Fresh Look at Medical Device Preemption One Year After Riegel v. Medtronic, Inc.*, 64 FOOD & DRUG L.J. 291, 311 (2009) (explaining the possible consequences that would result if the MDSA is passed).

<sup>153</sup> See *infra* Part IV.A.2.

<sup>154</sup> S. 3398, 110th Cong. (2008); H.R. 6381, 110th Cong. (2008).

<sup>155</sup> See Memorandum from the White House Office of the Press Sec'y to the Heads of Exec. Dep'ts and Agencies (May 20, 2009) [hereinafter Memorandum], available at [http://www.whitehouse.gov/the\\_press\\_office/Presidential-Memorandum-Regarding-Preemption/](http://www.whitehouse.gov/the_press_office/Presidential-Memorandum-Regarding-Preemption/).

<sup>156</sup> *Id.*

<sup>157</sup> See *id.* (describing the effects of preemption).

<sup>158</sup> *Id.*

<sup>159</sup> See *id.* (explaining what the heads of departments and agencies should avoid with regard to preemption).

On the other hand, many proponents of preemption argue that it is necessary to promote innovation and the development of risky yet beneficial medical devices because, without preemption, manufacturers will be reluctant to produce new devices knowing they could be subject to state tort claims.<sup>160</sup> Such proponents in favor of preemption include the FDA during President George W. Bush's term and the Bush Administration.<sup>161</sup> During his administration, President Bush appointed officials who supported preemption.<sup>162</sup> These appointments were especially evident in the FDA, which changed its position on preemption during the Bush Presidency.<sup>163</sup> For many years, the FDA believed that "Congress wanted federal approval and tort liability to operate simultaneously, 'each providing a significant, yet distinct, layer of consumer protection.'"<sup>164</sup> For example, prior to Bush's administration, the FDA indicated that a proposed rule amending drug-label regulations "[did] not preempt State law."<sup>165</sup> During this time, the government indicated that the FDA's approval was a floor and that "states could provide 'additional protection to consumers.'"<sup>166</sup> But in 2006, the FDA changed its position to favor preemption.<sup>167</sup> The FDA stated that "FDA approval of labeling . . .

---

<sup>160</sup> See *infra* Part IV.B and accompanying text.

<sup>161</sup> See Requirements I, 71 Fed. Reg. 3922, 3922 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, and 601) (describing the FDA's position on preemption during the Bush Administration); Richard L. Cupp Jr., *Preemption's Rise (and a Bit of a Fall) as Products Liability Reform* Wyeth, Riegel, Altria, and *The Restatement (Third)'s Prescription Product Design Defect Standard*, 74 BROOK. L. REV. 727, 746 (2009) (describing President Bush's actions regarding preemption).

<sup>162</sup> See Cupp, *supra* note 161, at 746 (explaining the steps Bush took during his administration in dealing with preemption).

<sup>163</sup> Compare Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81082 (Dec. 22, 2000) (to be codified at 21 C.F.R. pt. 201) [hereinafter Requirements II] (describing the FDA's position that their approval did not preempt state tort claims), with Requirements I, 71 Fed. Reg. 3922 (describing the FDA's position that their approval did preempt).

<sup>164</sup> Lawrence O. Gostin, *The Deregulatory Effects of Preempting Tort Litigation: FDA Regulation of Medical Devices*, 299 J. AM. MED. ASS'N 2313, 2314 (2008) (quoting Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7 (1997)).

<sup>165</sup> Requirements II, 65 Fed. Reg. at 81103.

<sup>166</sup> Robert Pear, *In a Shift, Bush Moves to Block Medical Suits*, N.Y. TIMES, July 25, 2004, at N18, available at <http://www.nytimes.com/2004/07/25/politics/25DRUG.html> (citing the views of "the government" as of 1997).

<sup>167</sup> Requirements I, 71 Fed. Reg. at 3934–35; see *supra* notes 143–44.



preempts conflicting or contrary State law” and that the FDA’s approval is now both a floor and a ceiling.<sup>168</sup>

The transition from the Bush Administration in 2008 to the Obama Administration in 2009, the change in the FDA’s position during Bush’s Administration, and the introduction of the MDSA or future similar legislation could have a significant effect on preemption now and in the future. The changes could potentially eliminate preemption completely for FDA approved medical devices and new drugs. This is because *Wyeth* indicated a resistance to finding implied preemption and Congress is attempting to eliminate express preemption. But the potential consequences of Obama’s administration and the MDSA—no preemption—may not be the most beneficial solution. Instead, the advantages of preemption should be given more consideration in determining what position the executive, legislative, and judicial branches should take on the issue of preemption.<sup>169</sup>

#### IV. THE ADVANTAGES OF PREEMPTION IN THE CONTEXT OF MEDICAL DEVICES AND NEW DRUGS

##### A. *Is FDA Approval a Sufficient Substitute for the State Tort System?*

If the current discord is remedied in the FDCA, preemption in the context of PMA medical devices and new drugs would afford a manufacturer who has received FDA approval of a PMA medical device or a new drug immunity from state tort liability. The FDA’s approval process for both medical devices and drugs would preempt the conflicting state law that is the basis of the state tort claim.<sup>170</sup> The fact that a new drug or PMA device received FDA approval would prevent an injured individual from seeking recourse through the state tort system. These injured individuals want access to new drugs and devices, but they also want to be protected from such drugs and devices. Based on these considerations, the issue is whether or not FDA approval and preemption is a sufficient substitute for the state tort system.

---

<sup>168</sup> Requirements I, 71 Fed. Reg. at 3934–35; *see supra* notes 143–44. But, the 2006 preamble is not the first time the FDA has expressed a preemptive view, and the FDA has “previously preempted State law requirements relating to drugs in rulemaking proceedings.” *See* Requirements I, 71 Fed. Reg. at 3935. For example, the FDA has included preemptive statements in regulations for over-the-counter drugs in 1982, for aspirin manufacturers in 1986, and for the “disclosure of adverse event-related [confidential] information.” *Id.*

<sup>169</sup> *See infra* Part IV.

<sup>170</sup> *See supra* notes 87–88 and accompanying text.

### 1. Advantages of FDA Approval

Although the FDA-approval processes for new drugs and PMA devices are distinct, both processes are rigorous.<sup>171</sup> When Congress gave the FDA the authority to oversee the introduction and approval of new drugs and medical devices, Congress' goal was to ensure that public health would be protected and that new drugs and medical devices would be safe and effective.<sup>172</sup> As indicated in *Medtronic*, the FDA is the government administrative agency given the authority to carry out the approval process and the other provisions of the FDCA.<sup>173</sup> As a result, many argue that the FDA is in a better position to determine the safety and efficacy of a new drug or PMA medical device than a jury.<sup>174</sup>

The FDA has been overseeing the approval of new drugs since 1938 and the approval of medical devices since 1976.<sup>175</sup> This makes the FDA uniquely qualified to determine whether a particular form of state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" and whether it should be pre-empted.<sup>176</sup> The FDA is "the expert Federal [public health] agency,"<sup>177</sup> and as an expert, the FDA looks at the effects of a medical product as a "whole instead of focusing on a few individuals, which occurs in many jury trials."<sup>178</sup> The "FDA is in a better position"

---

<sup>171</sup> See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475–77 (1996) (noting that the PMA process "is a rigorous one."); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 343 (2008) (Ginsburg, J., dissenting) ("[T]he process for approving new drugs is at least as rigorous as the premarket approval process for medical devices.").

<sup>172</sup> See 21 U.S.C. § 393(b)(2)(B) (2006); see also *Medtronic*, 518 U.S. at 474–75 (describing the FDA's mission).

<sup>173</sup> *Medtronic*, 518 U.S. at 496.

<sup>174</sup> See Hutt Statement, *supra* note 16, at 11 (comparing the FDA as an expert agency and a jury as a group of random individuals); *The Safety of Medical Products Regulated by the FDA: Hearing Before the H. Comm. on Oversight and Government Reform*, 111th Cong. (2009) (statement of Randall Luther, Ph.D., FDA) [hereinafter Luther Statement], available at <http://www.fda.gov/NewsEvents/Testimony/ucm101513.htm>.

<sup>175</sup> See *supra* Part II.A.

<sup>176</sup> *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

<sup>177</sup> Timothy Ardizzone, *The FDA: Advocate or Regulator of the Pharmaceutical Industry? The Attempted Preemption by the FDA of State Tort Claims for Failure-to-Warn on Pharmaceutical Labeling*, 75 U. CIN. L. REV. 763, 786 (2006) (quoting Requirements I, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, and 601)).

<sup>178</sup> See *id.* (describing the FDA's arguments in Requirements I, 71 Fed. Reg. at 3934).

than a jury to make determinations of safety and efficacy.<sup>179</sup> As Justice Breyer declared,

[W]ho would you rather have make the decision that this [product] is, on balance, going to save people or, on balance, is going to hurt people? An expert agency, on one hand, or 12 people pulled randomly for a jury role, who see before them only the people whom the [product] hurt and don't see the people who need the [product] to cure them?<sup>180</sup>

Juries are not capable of balancing the risks and benefits of a drug or device the way that the FDA can because a jury is only concerned with the risks and dangers of a product rather than its benefits.<sup>181</sup> The jury views only the injured, suffering patient and is persuaded by his tragedy while the FDA considers the possible risks and considers the patients who require the device or drug and would suffer without it.<sup>182</sup>

## 2. Advantages of the State Tort System and Concerns with the FDA

In the absence of preemption, state tort suits can be helpful for individuals injured by a new drug or PMA device, and many argue that preemption is detrimental because it removes the advantages of these suits.<sup>183</sup> As the late Senator Edward Kennedy stated, “Congress never intended that FDA approval would give blanket immunity to manufacturers from liability for injuries caused by faulty devices.”<sup>184</sup> State tort suits allow individuals injured by a new drug or device to seek compensation for their injuries and to impose liability on the manufacturer.<sup>185</sup> These suits can reveal the dangers associated with the drug or device because the injured plaintiff must explain how

---

<sup>179</sup> See Hutt Statement, *supra* note 16, at 10 (comparing the FDA as an expert agency and a jury as a group of random individuals).

<sup>180</sup> See *id.* (quoting Justice Breyer); see also Transcript of Oral Argument at 30–31, *Warner Lambert v. Kent*, 552 U.S. 440 (2008) (No. 06-1948).

<sup>181</sup> *Wyeth v. Levine*, 129 S. Ct. 1187, 1229 (2009) (Alito, J., dissenting); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008).

<sup>182</sup> *Wyeth*, 129 S. Ct. at 1230 (2009) (Alito, J., dissenting).

<sup>183</sup> See *id.* at 1202 (majority opinion) (explaining the advantages of the state tort system for the injured); Brief for NEJM Editors and Authors as Amici Curiae Supporting Respondents, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249), 2008 WL 3851616 at \*38–39 (describing the benefits of the state tort system); *Kennedy, Pallone Eye Legislation to Undo Preemption Ruling*, FDA Wk., Feb. 29, 2008, available at 2008 WLNR 4025500 (describing Senator Kennedy’s view in opposition of preemption).

<sup>184</sup> *Kennedy, Pallone Eye Legislation to Undo Preemption Ruling*, *supra* note 183.

<sup>185</sup> See *Wyeth*, 129 S. Ct. at 1202 (explaining the advantages of the state tort system).

and why he was injured to initiate the state tort suit.<sup>186</sup> An injured plaintiff's revelation can expose previously unknown dangers related to the use or misuse of the drug or device and can incentivize manufacturers to disclose such risks.<sup>187</sup> Manufacturers are motivated to provide adequate warnings and to insure that their products are safe and effective because they want to avoid future liability and compensation to the injured party.<sup>188</sup> In sum, the state tort system holds manufacturers responsible and protects consumers.

The state tort system also acts as a backup for plaintiffs to ensure safety and efficacy because the FDA's approval may not always be sufficient.<sup>189</sup> In a brief in support of Ms. Levine in *Wyeth*, editors of the *New England Journal of Medicine* argued that because the FDA must depend on the manufacturer for the information used in determining safety and efficacy in the application for approval and for information post-approval, the FDA is limited in knowing what the possible risks are; acting alone, they argued, the FDA is unable to ensure completely that products are safe and effective.<sup>190</sup> Conversely, the state tort system, through the discovery process, requires manufacturers to "disclose everything they know or reasonably should know" regarding the safety and efficacy of their products.<sup>191</sup>

Moreover, just because the FDA has approved a PMA device or drug does not ensure that it will remain safe because many risks do not become apparent until after the product has entered the market and been used for many years.<sup>192</sup> The FDA cannot "anticipate and protect against all safety risks," and no matter how rigorous the ap-

---

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

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

<sup>188</sup> *Id.* at 1200; see also William P. Gunnar, *Is There an Acceptable Answer to Rising Medical Malpractice Premiums?*, 13 ANN. HEALTH L. 465, 478 (2004) ("An essential element of the United States tort system is a requirement that the injured party be returned to whole, best achieved through a pecuniary award.").

<sup>189</sup> See Brief for NEJM Editors and Authors as Amici Curiae Supporting Respondents, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249), 2008 WL 3851616 at \*3-4.

<sup>190</sup> See *id.* ("[T]he FDA alone simply lacks the ability to serve as the sole guarantor of drug safety.").

<sup>191</sup> Gostin, *supra* note 164, at 2315.

<sup>192</sup> See Gregory D. Curfman, Stephen Morrissey & Jeffrey M. Drazen, *Why Doctors Should Worry About Preemption*, 359 NEW ENG. J. MED. 1, 1 (2008) (analyzing the dangerous side effects of various drugs that were uncovered after they were approved). For example, four drugs (Aprotinin, Dexfenfluramine, Rofecoxib, and Rosiglitazone) were all approved by the FDA, but then years later, each of these drugs demonstrated life-threatening risks and some were subsequently removed from the market. *Id.*

proval process, safety issues could still be present.<sup>193</sup> Thus, the state tort system acts as a backup and can expose risks where the FDA is unable to do so.<sup>194</sup>

The FDA may also be unable to continue to meet its mission of protecting the public and ensuring safety and efficacy.<sup>195</sup> Recently, the FDA's demands have increased, but its resources have not increased in proportion to these demands.<sup>196</sup> In a 2008 study, the FDA Science Board's Subcommittee on Science and Technology submitted a report concluding that because of inadequate funding and resources, the FDA has faced numerous "inadequacies that threaten our society" and that the "FDA can no longer fulfill its mission without substantial and sustained additional appropriations."<sup>197</sup> The Institute of Medicine also found that the FDA "lacks the resources needed to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future."<sup>198</sup>

### 3. Why FDA Approval Is Superior to State Tort Claims

Despite the arguments in favor of state tort claims, the only real advantage of the state tort system is the compensation it can give to injured individuals. Although preemption does not provide compensation to those injured, its other advantages balance the lack of compensation. For example, the FDA has its own methods of exposing risks and ensuring safety after the product has been approved.<sup>199</sup>

---

<sup>193</sup> See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 337 (2008) (Ginsburg, J., dissenting) (quoting the former chief counsel to the FDA).

<sup>194</sup> See Gostin, *supra* note 164, at 2314 (describing the advantages of the state tort system).

<sup>195</sup> See *id.*; see also *Medical Devices: Shortcomings in FDA's Premarket Review, Postmarket Surveillance, and Inspections of Device Manufacturing Establishment: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 111th Cong. 1 (2009) (statement of Marcia Crosse, Director, Health Care, U.S. Gov't. Accountability Office), available at <http://www.gao.gov/new.items/d09370t.pdf> ("Recently, concerns have been expressed about FDA's ongoing ability to fulfill its mission of ensuring the safety and efficacy of medical products, including drugs . . . and devices.").

<sup>196</sup> GAIL CASSELL, FDA SCI. BD.'S SUBCOMM. ON SCI. AND TECH., FDA SCIENCE AND MISSION AT RISK: ESTIMATED RESOURCES REQUIRED FOR IMPLEMENTATION 3 (2008), available at [http://energycommerce.house.gov/Press\\_110/022508.ScienceBoardReport.EstimatedResources.pdf](http://energycommerce.house.gov/Press_110/022508.ScienceBoardReport.EstimatedResources.pdf).

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

<sup>198</sup> INST. OF MED., THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 193 (National Academies Press 2007), available at [http://www.nap.edu/openbook.php?record\\_id=11750&page=193](http://www.nap.edu/openbook.php?record_id=11750&page=193).

<sup>199</sup> 21 U.S.C. §§ 355(k), (e), § 360e(e) (2006). The state tort system may also be helpful in exposing injuries that result from the drug or medical device but only after someone has been injured. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1202 (2009).

Post-approval, new drug and PMA device manufacturers must report any new information discovered that may affect the safety or efficiency of the drug or device, and once the FDA becomes aware of this new information, it can withdraw its approval of the drug or device or amend the label.<sup>200</sup>

With respect to new drugs, the sponsor must maintain records of clinical data and other information received relating to the drugs, and the sponsor must report these findings to the FDA.<sup>201</sup> If these records, new clinical evidence, or new information demonstrate that a particular new drug is unsafe for use or if new information demonstrates that substantial evidence of the drug's effectiveness no longer exists, the FDA can withdraw its approval of the drug.<sup>202</sup> If the FDA finds that an "imminent hazard to public health" is present, the FDA can also suspend the drug's approval.<sup>203</sup> Moreover, the FDA has an Adverse Event Reporting System (AERS) that monitors for "new adverse events" of drugs as reported by healthcare professionals and consumers to either the FDA or the manufacturer, who then reports to the FDA.<sup>204</sup> If the AERS shows a potential safety concern, the FDA "may take regulatory action(s) to improve product safety and protect the public health."<sup>205</sup>

Additional post-approval measures were taken in 2007 when the Food and Drug Administration Amendments Act of 2007 ("FDAAA") was added to the FDCA.<sup>206</sup> Specifically, § 505 of the FDCA was amended to add provisions for "active postmarket risk identification," which would create a "postmarket risk identification and analysis sys-

---

<sup>200</sup> § 355(k), (e).

<sup>201</sup> § 355(k), (e). If records are not maintained, the FDA could withdraw approval. *Id.*

<sup>202</sup> § 355(e).

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

<sup>204</sup> *Adverse Event Reporting System (AERS)*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm> (last visited Nov. 16., 2010). Healthcare professionals include doctors, pharmacists, nurses, etc., and consumers include patients, family members, lawyers, etc. *Id.*

<sup>205</sup> *Id.*

<sup>206</sup> Food and Drug Amendments Act of 2007, H.R. 3580, 110th Cong. (2007). As the preamble explains, the FDAAA was added:

[T]o amend the [FDCA] to revise and extend the user-fee programs for prescription drugs and for medical devices, to enhance the post-market authorities of the Food and Drug Administration with respect to the safety of drugs, and for other purposes.

*Id.*

tem,”<sup>207</sup> and for “postmarket drug safety information for patients and providers,” which would create a website containing information about drug safety, labeling, and other materials.<sup>208</sup> As part of the FDAAA, the FDA was also granted the express authority to ensure the safety of new drugs by imposing Risk Evaluation and Mitigation Strategies (“REMS”).<sup>209</sup> REMS are required plans that ensure “the benefits of the [new] drug outweigh the risks.”<sup>210</sup>

With respect to medical devices, device sponsors cannot make any changes to PMA approved devices that would affect safety or effectiveness without first receiving the FDA’s permission.<sup>211</sup> If the device sponsor wants to change the device, the sponsor must submit a supplemental application that is subject to a similar review process as the initial PMA.<sup>212</sup> Approved devices are also subject to further post-approval protections. PMA can be withdrawn if, among other things, the device is found to be unsafe or ineffective, if new information demonstrates that a reasonable assurance of safety and efficacy no longer exists, if false statements were made in the PMA application, or if the methods for manufacturing the device were nonconforming.<sup>213</sup> Moreover, one can research the safety of medical devices on the Manufacturer and User Facility Device Experience Database (“MAUDE”), which contains voluntary, facility, distributor, and manufacturer “reports of adverse events involving medical devices,” and provides a searchable online database that contains information about medical devices that have “malfunctioned or caused a death or serious injury.”<sup>214</sup>

Despite the recent difficulties that the FDA has experienced in achieving its mission due to financial constraints, the FDA has taken action to correct this problem. More specifically, through its 2010 budget request, the FDA took initiatives to make sure that it could

---

<sup>207</sup> 21 U.S.C. § 355(k)(3)(B)(ii) (LexisNexis 2010).

<sup>208</sup> § 355(r).

<sup>209</sup> See Gerald F. Masoudi, *Legal Developments in the Enforcement of Food and Drug Law*, 63 FOOD & DRUG L.J. 585, 586–87 (2008) (describing how the FDAAA through REMS expands the FDA’s authority to ensure the “benefits of the drug outweigh the risks”).

<sup>210</sup> *Id.* at 586.

<sup>211</sup> § 360e(d)(6)(A)(i).

<sup>212</sup> *Id.*

<sup>213</sup> § 360e(e).

<sup>214</sup> *Manufacturer and User Facility Device Experience Database—(MAUDE)*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm> (last visited Sept. 1, 2010).

fulfill its mission in the future.<sup>215</sup> In 2010, the FDA requested 3.2 billion dollars to better enable it to protect and promote health; this amount was nineteen percent more than what was requested in 2009.<sup>216</sup> Specifically, the FDA denoted that 166.4 million dollars would be allocated to improving the safety of medical products, including devices and drugs.<sup>217</sup> The FDA also requested 67.5 million dollars for drugs and 4.5 million dollars for medical devices to fund the review process of each.<sup>218</sup> This funding for 2010 allowed the FDA to initiate “a distributed network of electronic health data that can track the safety of [drugs] . . . once they reach the market and quickly investigate potential safety signals,” and the funding allowed the FDA to “release[] key guidance defining a path for more efficient and effective clinical trials” for medical devices.<sup>219</sup>

For 2011, the FDA requested 4 billion dollars to protect and promote public health.<sup>220</sup> The FDA is also planning on hiring 215 full-time staff members “for programs that protect patients and support the safety and effectiveness of medical devices” and drugs.<sup>221</sup> Additionally, the FDA is taking initiatives to protect Americans from high-risk drugs and medical devices; for example, the FDA plans to create a National Medical Device Registry that would “link unique identifiers for medical devices with electronic health data.”<sup>222</sup>

While the FDA is not perfect, neither are manufacturers or members of a jury.<sup>223</sup> The FDA has doctors and other scientific experts reviewing the applications for approval and is far more qualified than lay juries to ensure that public health is protected and that

---

<sup>215</sup> See Press Release, U.S. Food and Drug Admin., President’s FY 2010 Budget for FDA Invests Substantially in Food and Medical Product Safety: \$3.2 billion request reflects a 19 percent increase from FY 2009 (May 7, 2009) available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm152276.htm>.

<sup>216</sup> *Id.*

<sup>217</sup> *Id.*

<sup>218</sup> *Id.*

<sup>219</sup> *The President’s Fiscal Year 2011 Budget Request for FDA: Hearing Before the Subcomm. on Agric., Rural Dev., Food and Drug Admin., and Related Agencies of the S. Comm. on Appropriations* (March 9, 2010) (statement of Margaret A. Hamburg, Comm’r of Food and Drugs), available at <http://www.fda.gov/NewsEvents/Testimony/ucm204379.htm>.

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

<sup>221</sup> *Id.*

<sup>222</sup> *Id.*

<sup>223</sup> See Hutt Statement, *supra* note 16, at 10–11 (comparing the FDA as an expert agency and a jury as a group of random individuals).



drugs and devices are safe and effective.<sup>224</sup> In the context of preemption, “the purpose of Congress is the ultimate touchstone,”<sup>225</sup> and Congress “made its ‘purpose’ plain” when it gave the FDA authority to regulate the approval of drugs and devices.<sup>226</sup> Nothing in the FDCA indicates that the FDA should be second-guessed by juries, and preemption by its very nature allows the FDA to achieve its mission because it prevents state tort juries from questioning the FDA’s approval of a drug or device.<sup>227</sup> The FDA should not be second-guessed, and the FDA should be the only entity with the ability to impose requirements to determine and ensure the safety and efficacy of products. If too many entities evaluate the safety and efficacy of new drugs and medical devices and question the FDA’s determination of approval, the public health may be endangered. No one will really know whether a drug or device is safe and effective because the FDA will not have the last word. Consequently, preemption is a beneficial legal principle in the context of medical devices and drugs based on the FDA’s expertise and rigor in the pre and post-approval processes. This expertise and rigor makes preemption the method that poses the least amount of danger to public health.

A further argument in favor of preemption is the fact that the FDA has indicated its position in favor of preemption.<sup>228</sup> Historically, the Supreme Court has deferred to the FDA’s interpretation of its authority.<sup>229</sup> In *United States v. Bacto-Unidisk*, the Supreme Court noted that “remedial legislation such as the [FDCA] is to be given liberal construction consistent with the Act’s overriding purpose to protect the public health[.]”<sup>230</sup> In *Bacto-Unidisk*, the Court deferred to the FDA and upheld its construction of the FDCA because it was enough for the Court that the expert agency, the FDA, had determined that the regulation in question was desirable for public health.<sup>231</sup> The

---

<sup>224</sup> See *id.*; see also Luther Statement, *supra* note 174.

<sup>225</sup> *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)).

<sup>226</sup> *Wyeth v. Levine*, 129 S. Ct. 1187, 1219 (2009); see also *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 474–75 (1996).

<sup>227</sup> See *Horn v. Thoratec Corp.*, 376 F.3d 163, 178 (3d Cir. 2004).

<sup>228</sup> See *supra* note 168 and accompanying text.

<sup>229</sup> See James T. O’Reilly, *Losing Deference in the FDA’s Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939, 947 (2008) (describing the types of deference given to the FDA and explaining that one type is deference “to Agency interpretations of its statutory delegation of authority over foods, drugs, medical devices, and related products”).

<sup>230</sup> *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969).

<sup>231</sup> *Id.* at 791–92. In this pre-MDA case, the Court followed the FDA’s determination and held that the FDCA’s drug provisions covered sensitivity discs. *Id.* at 800.

Court also emphasized that it was “hardly qualified” to second-guess the FDA’s approval.<sup>232</sup> Currently, the FDA contends that its regulations should preempt conflicting state laws and that its approval represents both a floor and a ceiling;<sup>233</sup> therefore, deference should be given to this position.

*B. Is FDA Approval Sufficient to Promote the Public Health?*

FDA approval and preemption are not only superior to state tort claims when it comes to protecting the public health but also when it comes to promoting the public health. The FDA has been an important mechanism in promoting public health by allowing for the development and approval of new technology and innovations<sup>234</sup> that make medical devices and drugs “more effective, safe[], and . . . affordable.”<sup>235</sup> The FDA’s approval process ensures that innovation is not stifled,<sup>236</sup> and preemption can also encourage innovation by preempting state tort claims<sup>237</sup> because the threat of liability and expensive litigation arguably deter the development of new technology.<sup>238</sup> Both the pharmaceutical industry and the FDA have supported this argument. The pharmaceutical industry believes that the possibility of tort liability would deter the creation of new beneficial drugs.<sup>239</sup> The FDA has indicated that state and common law tort claims can lead to large damage awards that may influence manufacturers to remove FDA approved products from the market, even though the products have been found safe and effective by the FDA,

---

<sup>232</sup> *Id.* at 791–92.

<sup>233</sup> See Requirements I, 71 Fed. Reg. 3922, 3934–35 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, and 601).

<sup>234</sup> See 21 U.S.C. § 393(b)(1) (2006) (describing the FDA’s mission to promote and protect).

<sup>235</sup> See also *What We Do*, *supra* note 20 (describing the FDA’s mission).

<sup>236</sup> See *Contact Lens Mfrs. Ass’n. v. Food & Drug Admin. of Dep’t of Health & Human Servs.*, 766 F.2d 592, 594 (D.C. Cir. 1985) (describing the FDA’s approval process).

<sup>237</sup> Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL’Y L. & ETHICS 587, 655 (2005).

<sup>238</sup> Wartman, *supra* note 152, at 310–11; *Device Industry Says Anti-Preemption Bill Would Hurt Innovation*, FDA WEEK, Apr. 17, 2009 (quoting Stephen Ubi, the president and CEO of AdvaGMed).

<sup>239</sup> Brief for PhRMA and BIO as Amici Curiae Supporting Petitioner, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249), 2008 WL 2322236 at \*3.

or to refrain from researching and developing new drugs or devices in the future.<sup>240</sup>

Without preemption, manufacturers must comply with both the FDA's regulations and different state regulations, which may also compel manufacturers to remove their products from the market or refrain from researching and developing new products.<sup>241</sup> This is especially possible if states impose additional requirements that were not originally required by the FDA for approval.<sup>242</sup> As explained in Justice Scalia's majority opinion in *Riegel*, the inclusion of an express preemption provision in the MDA indicates that concern over the risks of devices and the injuries they could cause was outweighed by "Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations."<sup>243</sup> Preemption is beneficial because it aids not only those who would potentially be helped but also those who would consequently be harmed if the device or drug is no longer available or was not available in the first place.<sup>244</sup>

### C. Other Advantages of Preemption

As indicated by *Riegel* and *Wyeth*, preemption is also beneficial because it protects manufacturers from liability when a doctor's negligence is the reason for the risk.<sup>245</sup> In *Riegel*, although preemption applied and the manufacturer was shielded from liability, the adverse

---

<sup>240</sup> See *Horn v. Thoratec Corp.*, 376 F.3d 163, 178 (3d Cir. 2004); see also Catherine T. Struve, *Greater and Lesser Powers of Tort Reform: The Primary Jurisdiction Doctrine and State-Law Claims Concerning FDA-Approved Products*, 93 CORNELL L. REV. 1039, 1039–40 (2008). Thus, state tort suits limit access to these beneficial drugs and devices. See Luther Statement, *supra* note 174 (explaining that state tort suits might "limit[] patient and doctor choices and decrease[] patient access to beneficial products").

<sup>241</sup> *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 351 (2001).

<sup>242</sup> See Bruce Patsner, *Riegel v. Medtronic, Inc.: Revisiting Preemption from Medical Devices*, 37 J.L. MED. & ETHICS 305, 311 (2009) (quoting Ted Olson, Medtronic Inc.'s counsel); see Wartman, *supra* note 152, at 310–11 (quoting Steven Ubi, "A patchwork approach to medical device approvals where state courts effectively review and regulate medical devices would likely result in a dizzying array of conflicting labeling and indications for use and ultimately may result in life-saving, life-enhancing technologies simply not being available for patients."); see, e.g., *Horn*, 376 F.3d at 178 (discussing the FDA's argument that "[s]tate common law tort actions threaten the statutory framework for the regulation of medical devices"); see also Gilbert Ross, *FDA Supreme, For Now*, WASH. TIMES, March 5, 2008, at A14 ("[D]anger of suits in state after state can create a disincentive to put drugs through the centralized FDA approval in the first place.").

<sup>243</sup> *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 326 (2008).

<sup>244</sup> See Hutt Statement, *supra* note 16, at 12.

<sup>245</sup> This argument is beyond the scope of this Comment, but it is still important considering the facts of *Riegel* and *Wyeth*.

reaction was the result of Mr. Riegel's surgeon taking actions specifically warned against in the device's label.<sup>246</sup> During Mr. Riegel's surgery, his surgeon inflated the catheter to a level beyond the maximum indicated on the label.<sup>247</sup> Additionally, the device's label warned against using the catheter in a patient with a diffusely diseased and heavily calcified coronary artery; because Mr. Riegel's coronary artery was both, the catheter ruptured, and he was forced to undergo emergency coronary bypass surgery.<sup>248</sup>

Conversely, in *Wyeth*, no preemption was found and the manufacturer was not shielded from liability.<sup>249</sup> Phenergan's label warned that extreme care should be used because injections were in close proximity to arteries and veins.<sup>250</sup> The warning indicated that a potential risk of the drug was both gangrene and amputation.<sup>251</sup> The warning also stated that the use of an IV-drip was preferable and that the injection should be stopped as soon as the patient complained of pain.<sup>252</sup> In Ms. Levine's case, a physician's assistant, not a doctor, administered more of the drug than the label prescribed and may have injected the drug directly into an artery.<sup>253</sup> Moreover, the physician's assistant did not stop the injection when Ms. Levine indicated that she was in pain; in her testimony, the physician's assistant stated that she never thought "an antecubital injection of Phenergan could hit an artery," and when asked why she did not stop when Ms. Levine complained of pain, she said that it would have been "just crazy" to be concerned about an intra-arterial injection.<sup>254</sup> The physician's assistant clearly disregarded or never read Phenergan's label warnings.

In such professional channels, an "upstream player should never be held accountable for the mistakes of downstream players."<sup>255</sup> If manufacturers of drugs or devices will be liable for the mistakes of doctors without preemption, this possible liability may also deter them from creating new products. A manufacturer, who would be liable based on claims that the FDA approved label is faulty, would not

---

<sup>246</sup> *Riegel*, 552 U.S. at 320 (2008).

<sup>247</sup> *Id.*

<sup>248</sup> *Id.*

<sup>249</sup> *Wyeth v. Levine*, 129 S. Ct. 1187, 1191 (2009).

<sup>250</sup> *Id.* at 1192 n.1.

<sup>251</sup> *Id.*

<sup>252</sup> *Id.* at 1192.

<sup>253</sup> *Id.* at 1194.

<sup>254</sup> *Id.* at 1226–27 (Alito, J., dissenting).

<sup>255</sup> Richard A. Epstein, *The Case for Field Preemption of State Laws in Drug Cases*, 103 *Nw. U. L. Rev.* 463, 471 (2009).

want to be found liable because of a physician's negligence. In addition to preemption, initiating a medical malpractice suit against the physician instead of a tort claim against the manufacturer may be more appropriate in such cases. The physician, who reads the label, determines the medical device to use or the drug to prescribe. If the FDA has approved the drug or device, liability should then fall to the physician for his or her negligence and not to the manufacturer for complying with the FDA's approval process.

#### V. RECOMMENDATIONS FOR CONGRESSIONAL ACTION

The advantages of preemption are superior to the advantages of the state tort system in the context of medical devices and new drugs, and the FDA-approval process sufficiently examines drugs and devices.<sup>256</sup> The MDSA or future similar legislation should not be passed, and express preemption should continue for Class III medical devices that have received premarket approval. Currently, however, only PMA medical devices can receive the advantages of preemption, as no express or implied preemption applies for new drugs. To ensure that new drugs receive the same preemption advantages as PMA medical devices and to rectify the disparity caused by the *Riegel* and *Wyeth* decisions, the FDCA should be amended to include an express preemption provision for new drugs. This provision would amend the drug-approval section of the FDCA, § 505, and would introduce a provision similar to the PMA medical device express preemption provision. It would create a uniform standard of preemption for new drugs and PMA medical devices.

##### A. *Why an Express Preemption Provision Is Now Needed*

Thirty years ago, Congress only enacted an express preemption provision for PMA medical devices and not for new drugs.<sup>257</sup> At that time, an express preemption provision for new drugs was not necessary because the FDA subjected new drugs to a premarket-review process for safety and efficacy;<sup>258</sup> until *Wyeth*, there was still the possibility of implied preemption. As the Supreme Court stated in *Wyeth*, if Congress thought an express preemption provision was needed for drugs and that "state-law suits posed an obstacle to its objectives," it would have also created an express preemption provision for drugs.<sup>259</sup>

---

<sup>256</sup> See *supra* Part IV.

<sup>257</sup> 21 U.S.C. § 360k (2006); *Wyeth*, 129 S. Ct. at 1200.

<sup>258</sup> See *supra* Part II.A.

<sup>259</sup> *Wyeth*, 129 S. Ct. at 1200.

Unlike medical devices, no state rules “required premarket approval of the drugs . . . so no preemption clause was needed as a check against potentially conflicting state regulatory regimes.”<sup>260</sup>

Express preemption is now needed and justified for new drugs.<sup>261</sup> The proposed MDSA and the *Wyeth* decision indicate that an express preemption provision for new drugs is necessary because state tort suits pose an obstacle to the drug development process. Congress has already enacted express preemption provisions for almost all of the other products covered by the FDCA, including medical devices, cosmetics,<sup>262</sup> and nonprescription drugs.<sup>263</sup> Therefore, if Congress also enacted an express preemption provision for new drugs, it would not be unreasonable as new drugs undergo one of the most rigorous approval processes.

*B. Why New Drugs and Medical Devices Should Be Treated Uniformly as to Preemption*

The FDA is responsible for protecting the public health by ensuring the safety and efficacy of drugs and medical devices.<sup>264</sup> The FDA reviews the applications for new drugs and medical devices to ensure their safety and efficacy before these products can enter the market.<sup>265</sup> The review process for both is rigorous;<sup>266</sup> however, the two processes are distinct.<sup>267</sup>

The initial difference is found in the sections of the FDCA where the approval processes are located. New drugs are approved based on the procedures found in § 505 of the FDCA, and PMA devices are approved based on the procedures found in § 513 and § 515 of the FDCA.<sup>268</sup> New drugs and medical devices are subject to different standards for determining safety and efficacy.<sup>269</sup> The PMA process

<sup>260</sup> *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 342 (2008) (Ginsburg, J., dissenting).

<sup>261</sup> *See supra* Part IV.

<sup>262</sup> § 379s.

<sup>263</sup> *Id.* § 379r.

<sup>264</sup> *Id.* § 393(b)(2)(B)–(C).

<sup>265</sup> *See supra* Part II.B–C.

<sup>266</sup> *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475, 477 (1996) (explaining that the PMA process “is a rigorous one”); *see Riegel v. Medtronic, Inc.*, 552 U.S. 312, 343 (2008) (Ginsburg, J., dissenting) (“[T]he process for approving new drugs is at least as rigorous as the premarket approval process for medical devices.”).

<sup>267</sup> Peter Barton Hutt, Richard A. Merrill & Alan M. Kirschenbaum, *The Standard of Evidence Required for Premarket Approval Under the Medical Device Amendments of 1976*, 47 *FOOD & DRUG L.J.* 605, 606–07 (1992).

<sup>268</sup> § 355; *id.* § 360c; *id.* § 360e.

<sup>269</sup> Hutt, *supra* note 267, at 607 (comparing the approval processes).

requires that the medical device application provides a “reasonable assurance” that the device is safe and effective,<sup>270</sup> but § 505 does not contain the same requirement.<sup>271</sup> For new drugs, the effectiveness standard is “substantial evidence,” which requires that the application provide “substantial evidence that the drug will have the effect it purports . . . to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling.”<sup>272</sup> PMA devices require a more flexible standard for effectiveness; the PMA process does not include a “substantial evidence” requirement, and instead, effectiveness “may be established ‘on the basis of well-controlled investigations, including [one or more] clinical investigations.’”<sup>273</sup> Many, including the FDA, have indicated that the review and approval process for new drugs is more rigorous than PMA.<sup>274</sup> If PMA employs a lower standard that grants express preemption to manufacturers of PMA medical devices, new drug manufacturers who are subject to a more rigorous standard should be given the same, if not more, protections from liability. If PMA devices are subject to preemption, new drugs should be as well. Therefore, an express preemption provision for new drugs is both appropriate and in the public’s best interest.

*C. An Express Preemption Provision for New Drugs*

In drafting the language for the express preemption provision, § 360k of the MDA is the best model. The amendment would add § 355(w) to the FDCA, and in following the model of § 360k, it could be written as follows:

(w) General rule. No State or political subdivision of a State may establish or continue in effect with respect to a new drug any requirement (1) which is different from, or in addition to, any requirement applicable under this Act [21 U.S.C. §§ 301 et seq.] to

---

<sup>270</sup> § 360c(a)(1)(A)(i).

<sup>271</sup> Hutt, *supra* note 267, at 607 (distinguishing the approval processes).

<sup>272</sup> § 355(d).

<sup>273</sup> Hutt, *supra* note 267, at 608 (quoting 21 U.S.C. § 360c(a)(3)(B) (2006)).

<sup>274</sup> *See id.* at 608–09 (“Congress intended medical device manufacturers seeking [PMA] to be subject to a different, more flexible, standard of evidence of safety and effectiveness than new drug sponsors.”); *see also* Gostin, *supra* note 164, at 2313 (2008) (explaining that the standard for new drugs is higher than the standard for PMA); William M. Brown, *Déjà Vu All Over Again: The Exodus from Contraceptive Research and How to Reverse It*, 40 BRANDEIS L.J. 1, 9 (2001) (“FDA’s regulation of drugs is considered by many to be the most stringent in the world.”); Requirements I, 71 Fed.Reg. 3922, 3967 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, and 601). (“The FDA review process for an NDA is thorough and scientifically rigorous.”).

the drug, and (2) which relates to the safety or effectiveness of the new drug or to any other matter included in a requirement applicable to the new drug under this Act [21 U.S.C. §§ 301 et seq.].

This provision would preempt state drug requirements that are different from or in addition to any federal new drug requirement, with that being the § 505-approval process.<sup>275</sup> According to the Court in *Riegel*, the § 505-approval process would have to be found a requirement, and it would have to be a requirement specific to individual drugs.<sup>276</sup> Because the approval process for new drugs is more rigorous and requires a stricter standard for safety and effectiveness than the premarket-approval process for Class III medical devices, the Supreme Court may be even more likely to find it is a specific requirement relating to safety and effectiveness.<sup>277</sup> Assuming the § 505-approval process is found to be a requirement, any state requirement that conflicted with the FDA's approval process for new drugs would be preempted.

Application of the express preemption provision would only extend to new drugs for which a sponsor actually files a NDA under § 355(b). For example, drugs approved by filing an abbreviated new drug application ("ANDA") under § 355(j) would not fall within the express preemption provision because ANDA applications only require the application to demonstrate that the conditions of use have already been approved for another drug.<sup>278</sup> ANDA applications are filed for generic drugs and must only be proved a bioequivalent.<sup>279</sup>

---

<sup>275</sup> Because preemption alone will not replace the compensation mechanism of the state tort system, Congress should also consider creating a compensation program that would compensate individuals injured by new drugs. Currently, no compensation program exists for adverse reactions to drugs other than individual tort actions, and one of the main reasons that critics argue against preemption is that there is no opportunity for compensation for the harm suffered. See Gostin, *supra* note 164, at 2315; *Wyeth v. Levine*, 129 S. Ct. 1187, 1202 (2009) (describing the negatives of preemption). Therefore, a compensation scheme would also be advisable to make up for the fact that injured parties would be precluded from seeking compensation if there is express preemption. Such a scheme could be added as a subsection to the express preemption amendment.

<sup>276</sup> *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008) (explaining that "premarket approval is specific to individual devices").

<sup>277</sup> See *supra* note 274 and accompanying text; see also *Riegel*, 552 U.S. at 323.

<sup>278</sup> 21 U.S.C. § 355(j)(2)(A)(i) (2006). The ANDA process seems similar to the § 510(k) approval process of substantial equivalence and would most likely not meet the requirement of being a specific requirement as indicated in *Medtronic* and *Riegel*. See *supra* notes 75–77, 113, 123 and accompanying text.

<sup>279</sup> § 355(j). Bioequivalence is defined as "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug



## VI. CONCLUSION

The Supreme Court decisions of *Riegel* and *Wyeth* created a discrepancy in the way medical devices and new drugs are treated in the context of preemption. New drugs and medical devices are both subject to FDA approval and a finding of safety and efficacy; however, even though new drugs are subject to a more rigorous approval process, premarket-approved medical-device manufacturers are immune from state tort claims and new-drug manufacturers are not. The main basis for this discrepancy is the lack of an express preemption provision for new drugs.

Although this discrepancy has initiated proposed legislation to remove preemption for PMA devices and create a uniform standard of no preemption, the better solution would be to create a uniform standard of preemption. The advantages of preemption outweigh the advantages of the state tort system, and preemption can help remedy the problems of the state tort system. Preemption prevents the FDA, Congress's expert for drug and device approval, from being second guessed by a jury that does not have its experience or expertise. Preemption allows the FDA to have the final word on safety and efficacy, and it ensures that the public is protected. Preemption also allows for the development of new, innovative drugs and medical devices and prevents manufacturers from being liable for a physician's negligence. Preemption is needed for the development of drugs and medical devices and to ensure that both are safe and effective. Thus, the MDA's express preemption provision for PMA devices should remain intact, and the FDCA should be amended to include an express preemption provision for new drugs so that consumers can continue to have access to and protection from drugs and medical devices.