

## Preemption Under the MDA: Can *Bates* Mend the Wound?

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#### INTRODUCTION

The human body is a limited resource that depletes over time. In our increasingly technological age, the wonders of modern medicine have come to include reliance on medical devices that assist and sustain the human body. These devices extend the amount of resources we have to rely on when the human form fails. However, with our increased reliance on medical devices, new problems have arisen regarding the extent to which these devices should be regulated and monitored. Current government regulation by the Federal Drug Administration (“FDA”) serves as a rubber stamp endorsing the medical device as a safe product. This policy has created a conflict within the legal system where a “safe” medical device causes injury to a consumer in need. Traditionally, where medical error by the human hand or judgment causes harm, those injured are provided recourse in the law through common law tort claims and medical malpractice statutes. However, the advent of medical devices supplementing the human hand where it can no longer aid coupled with the broad regulatory scheme surrounding such devices leaves the question of whether persons injured by medical devices will have the same recourse under the law.

The legal system has not provided a solution to the problem of whether or not a person can sue under state common law tort principles for injuries caused by a medical device. The issue occurs due to the Federal Drug Administration’s regulation of the safety and effectiveness of medical devices. The FDA is responsible for regulating and supervising medical devices used for medical care. The statute detailing the extent of the FDA’s regulation of medical devices includes an express preemption clause, which has caused great controversy in its interpretation. The circuit courts as well as the Supreme Court have reviewed the FDA preemption clause and the tension it creates with state common law tort claims. This comment focuses specifically on the most important and certainly the most dangerous class of medical devices, Class III. In addition, this comment discusses the circuit court decisions that have split over the issue of whether persons have a right of action against device manufacturers in light of an express preemption clause forbidding state law claims that impose different requirements than the FDA.

Traditionally, state common law tort claims provide recourse from injury caused by negligence and defective products resulting from a defective design, a manufacturing defect, or a failure to warn. In the context of medical devices, such claims might conflict with the FDA's determination that the device was safe for human use. For example, a prevailing judgment against a pacemaker manufacturer for negligent design appears contradictory to the FDA's approval of the pacemaker as safe for human use. The argument for federal preemption of state law claims follows from the conflict between FDA requirements and common law tort judgments against the manufacturer that conflict with the FDA's requirements for the device. The argument against preemption counters that adverse judgments in common law tort claims would not conflict with the FDA requirements, because they impose parallel requirements. If the medical device is defective, persons who are harmed should have recourse in the law. Both arguments hinge on the definition of different "requirements" with respect to FDA regulation.

This comment provides a summary of the FDA's regulation of medical devices and the circuit split over the scope of the express preemption clause prohibiting states from imposing any requirement that is either different from or in addition to a specific federal regulation.<sup>1</sup> The Supreme Court's decision in *Medtronic, Inc. v. Lohr* has left the circuit courts without a clear test to apply with respect to the FDA's regulation of Class III medical devices.<sup>2</sup> The extent to which FDA regulation preempts state common law claims has been a source of frustration for both the circuit courts and the plaintiffs who wish to litigate such claims. This comment will advocate a more coherent approach to the issue. By applying the recent Supreme Court decision in *Bates v. Dow Agrosciences*, this comment clarifies the scope of preemption that should apply when the FDA approves a device through the premarket approval process.<sup>3</sup> This comment provides a new test through which circuit courts should reevaluate their stance on preemption. Furthermore, this comment will discuss the impact of the *Bates* decision and present a new framework to guide future circuit court decisions. This new approach will allow state common law claims that parallel federal safety and effectiveness requirements.

Part I provides a basic overview of the Medical Device Amendments and the FDA, particularly the express preemption clause that has been the source of the circuit split. This section provides a brief overview of the purpose of the FDA's regulation in the area of medical

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<sup>1</sup> 21 U.S.C. § 360k(a) (2006).

<sup>2</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

<sup>3</sup> *Bates v. Dow Agrosciences, L.L.C.*, 125 S. Ct. 1788 (2005).

devices and details the different categories and classes of medical devices. Part I also describes the premarket approval process and discusses the express preemption clause contained within the Medical Device Amendments. This section provides an overview of the principle statutes and medical device classifications that are essential for an informed reading of later sections.

Part II provides a summary of the controlling circuit court decisions that have established the scope of the MDA's preemptive effect over state tort claims. This section is the most comprehensive part of the comment. It serves as a general survey, which provides the basic facts, reasoning, and outcome of each relevant circuit court decision. This section divides the circuit court decisions into three categories according to the courts' common analyses of the issue. The contrast among the three categories of circuit court decisions illustrates the expansive nature of the circuit split as well as the need for a uniform test.

Part III summarizes the recent Supreme Court decision in *Bates v. Dow Agrosciences* and recommends a solution to the circuit split. This comment provides a new test which applies the *Bates* decision to the FDA premarket approval process, despite the failure of the Supreme Court to directly address the issue.<sup>4</sup> The new framework suggests a "parallel requirements" test that circuit courts should apply to determine the scope of preemption with respect to the common law tort claim. Part III urges courts to look to the intent of the Medical Device Amendments and Congress in enacting the express preemption clause and apply the "parallel requirements" test. This section further discusses some of the concerns related to allowing tort claims of negligence to be brought against device manufacturers. The comment concludes by advocating the imposition of the new "parallel requirements" test as suggested by the *Bates* decision.

#### I. THE MEDICAL DEVICE AMENDMENT AND THE EXPRESS PREEMPTION PROVISION

The Federal Drug Administration is entrusted with a great amount of responsibility as the governmental regulator of the current health care system in the United States. The role of the FDA has continued to grow to the point where its role as a regulator affects every single person living in the United States; however, the FDA's duties extend far beyond the scope of this comment. The FDA is both respected and criticized by the public and corporations alike. It continues to be a gatekeeper for products entering the medical market. However, in its role as a gatekeeper,

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

conflicts have arisen regarding the protection of the products and the companies that have passed through its gates.

The FDA acts as the ultimate gatekeeper with respect to medical devices, forbidding use of devices that have failed to meet its approval. Such devices are regulated according to a comprehensive statutory scheme that was enacted over thirty years ago. In response to concern in the 1970's relating to medical devices that were unregulated, Congress passed the Medical Device Amendment of 1976 ("MDA") and created a broad regulatory scheme providing for medical device review and classification.<sup>5</sup> A basic understanding of the definition of medical devices and their classifications is necessary in order to understand the extent of the legal analysis of this comment.

#### *A. Classification of Medical Devices*

Medical devices exclude drugs, but include the devices that diagnose human illness and devices used to cure or improve illnesses and disabilities.<sup>6</sup> Some medical devices are more extensive in composition than others; some devices are made from one singular part and others require many moving parts working together. The difference between a plastic bandage and an implanted pacemaker requires the FDA to separately regulate the different devices into classes according to their complexity and their risk to humans. The FDA divides medical devices into three classes under the MDA.<sup>7</sup>

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<sup>5</sup> For a well-summarized background of the history of FDA regulation and congressional action see Sasha B. Rieders, Note, *State Law Tort Claims and the FDA: Proposing a Consumer-oriented Prescription in Medical Device Cases*, 25 *CARDOZO L. REV.* 1159 (2004).

<sup>6</sup> 21 U.S.C. § 321(h) (2006). The statute explains that [t]he term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is – (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

*Id.*

<sup>7</sup> See Gregory J. Scandaglia & Therese L. Tully, *Express Preemption and Premarket Approval under the Medical Device Amendments*, 59 *FOOD & DRUG. L.J.* 245 (2004) ("Class I Devices-devices that 'present minimal potential for harm to the user.' For example, elastic bandages are classified as Class I devices. Class II Devices-devices that

Class I devices are those subject to general controls that “are sufficient to provide reasonable assurance of the safety and effectiveness of the device.”<sup>8</sup> Only general controls are necessary with respect to Class I devices because these devices have a relatively low risk factor for human use. Additionally, a Class I device is one that the FDA deems relatively safe although the FDA cannot determine how much control the device should receive.<sup>9</sup> A device will be categorized in Class I, even if the effects of its use are unknown, so long as the intended use of the device does not greatly impact human health and its foreseeable use would not be dangerous to human health.<sup>10</sup>

Class I medical devices are usually simple in design and execution.<sup>11</sup> These devices are not subject to strict controls because their use presents the least amount of risk to the consumer.<sup>12</sup> Device manufacturers of Class I devices are subject to general administrative controls including registration of the device and record keeping.<sup>13</sup> However, if the device is ever found to be dangerous or cause harm, the manufacturer is required to notify the FDA.<sup>14</sup> The manufacturer of a Class I device must also comply with requirements that the device be sanitary and include accurate product labeling, which does not mislead the consumer.<sup>15</sup> Common examples of Class I devices include plastic

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pose a greater risk of harm than those in Class I, but less risk than those in Class III. Class II devices include items such as some home pregnancy tests. Class III Devices—devices that sustain or support life, are implanted, or present a potential unreasonable risk of illness or injury. Class III devices also include some lower-risk products that lack predicates. Class III devices represent approximately ten percent of the medical devices on the market. Examples of Class III devices include pacemakers and breast implants.” (citations omitted)).

<sup>8</sup> 21 U.S.C. § 360c(a)(1)(A)(i)(2006).

<sup>9</sup> *Id.* § 360c(a)(1)(A)(ii). The statute states that

[a] device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but because it—(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and (II) does not present a potential unreasonable risk of illness or injury, is to be regulated by the controls referred to in clause(i).

*Id.*

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

<sup>11</sup> U.S. Food and Drug Administration, Center for Devices and Radiological Health, Device Advice, Device Classes, <http://www.fda.gov/cdrh/devadvice/3132.html> (last visited Nov. 20, 2006).

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

<sup>13</sup> 21 U.S.C. § 360(f)-(j).

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

<sup>15</sup> 21 U.S.C. §§ 351-52 (2006).

bandages, examination gloves, and certain types of hand-held surgical instruments.<sup>16</sup>

Class II devices include devices where the general controls are insufficient to maintain safe use of the product and additional restrictions and control are imposed on certain devices by the FDA.<sup>17</sup> Class II devices include electronic wheelchairs, infusion pumps, and surgical drapes.<sup>18</sup> Specific Class II medical devices may be exempt from additional controls where the FDA feels “these exemptions will relieve manufacturers from the need to submit premarket notification submissions for these devices and will enable the FDA to redirect the resources that would be spent on reviewing such submissions to more significant public health issues.”<sup>19</sup> Class II devices separate generally harmless devices, listed in Class I, and Class III devices, which represent a risk of significant harm. These “more significant public health issues” are reflected in the FDA’s concern over the classification of Class III medical devices.<sup>20</sup>

A Class III medical device is a device that requires more stringent controls imposed by the FDA due to the risk associated with the device and its use in maintaining human life. The statute defines a Class III medical device as one that plays such an important role in “supporting or sustaining human life” or is unreasonably dangerous that it requires substantially more control than required by Class I and II devices.<sup>21</sup> Common examples of Class III medical devices include laser eye surgery equipment, pacemakers, replacement heart valves and breast implants.<sup>22</sup> Consumers who seek the aid of Class III medical devices generally have a substantial need for the product to maintain their quality of life. Often times, people rely on these devices to support their existence in this world. The FDA provides an electronic database through which consumers and companies alike can search for Class III medical

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<sup>16</sup> U.S. Food and Drug Administration, Center for Devices and Radiological Health, Device Advice, Device Classes, <http://www.fda.gov/cdrh/devadvice/3132.html> (last visited Nov. 20, 2006).

<sup>17</sup> 21 U.S.C. § 360c(a)(1)(B) (2006).

<sup>18</sup> U.S. Food and Drug Administration, Center for Devices and Radiological Health, Device Advice, Device Classes, <http://www.fda.gov/cdrh/devadvice/3132.html> (last visited Oct. 29, 2006).

<sup>19</sup> U.S. Food and Drug Administration, Center for Devices and Radiological Health, Device Advice, Medical Device 510(k) and Good Manufacturing Practice Exemptions list, FDA website, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/315.cfm> (last visited Nov. 20, 2006).

<sup>20</sup> *Id.*

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

<sup>22</sup> See Scandaglia & Tully, *supra* note 7.

devices.<sup>23</sup> Class III medical devices are marketable only after passing either the “premarket notification” (“PMN”) or “premarket approval process” (“PMA”).<sup>24</sup> The PMN and the PMA represent more stringent controls that correspond to the high stakes intrinsic to use of Class III medical devices.

The PMA process has been described as “rigorous,” requiring extensive submissions, time, and expense on behalf of device manufacturers in order to market a Class III device to the public.<sup>25</sup> The goal behind this process requires the manufacturer of the device to “provide the FDA with a ‘reasonable assurance’ that the device is both safe and effective.”<sup>26</sup> The PMA application submitted by the manufacturer requires that the manufacturer of the device have undertaken numerous scientific studies, including non-clinical laboratory studies and clinical investigations.<sup>27</sup> Where a Class III device was approved by the FDA through the PMA process, this comment answers the lingering question of whether injured consumers may bring common law tort claims against the device’s manufacturer.

The success of PMA process, in assuring the safety of medical devices, has been subject to great debate and Congress has acted with

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<sup>23</sup> Device product classifications can be found by searching the Product Classification Database, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>. The database search provides the name of the device, classification, and a link to the Code of Federal Regulations (CFR), if any. The CFR provides the device type name, identification of the device, and classification information.” U.S. Food and Drug Administration, Center for Devices and Radiological Health, Device Advice, Overview-When a PMA is Required, <http://www.fda.gov/cdrh/devadvice/pma/> (last visited Oct. 29, 2006).

<sup>24</sup> 21 U.S.C. §§ 360c(a)(1)(C), 360e(b). The PMN process is also known as the “§ 510(k) process” and provides for approval of a device, without undergoing the more extensive PMA. *Id.* The FDA must determine that the device is “substantially equivalent” to a device that was in existence before the MDA. *Id.* The PMN process acts similar to a rubber stamp on a medical device that has a substantial equivalent already functioning in the market. *Id.* The PMN process is far less extensive than the PMA approval process. *Id.* The court in *Medtronic* held that a device that undergoes the PMN process and subsequently causes injury to a consumer will not enjoy preemptive protection from state common law tort claims. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996). The scope of this holding has created a division in the courts of appeals. Although the majority of the circuit courts apply *Medtronic* to hold devices approved under the PMA process to a higher standard and find preemption, the Supreme Court failed to comment on the issue, hence the nature of this note. *See id.*

<sup>25</sup> *Medtronic*, 518 U.S. at 477.

<sup>26</sup> *Id.* (citing 21 U.S.C. § 360e(d)(2)). “PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).” U.S. Food and Drug Administration, Center for Devices and Radiological Health, Device Advice, Overview-Introduction, <http://www.fda.gov/cdrh/devadvice/pma/> (last visited Oct. 29, 2006).

<sup>27</sup> *See* 21 C.F.R. § 814.20 (2006).



respect to the process's efficiency. Congress enacted the Safe Medical Devices Act of 1990 due to concern over the way medical devices were being approved under the PMA process.<sup>28</sup> Additionally, Congress passed the FDA Modernization Act of 1997 in order "to ensure the timely availability of safe and effective new products that will benefit the public and to ensure that our Nation continues to lead the world in new product innovation and development."<sup>29</sup> The FDA issued a statement of guidance regarding the FDA Modernization Act urging a more streamlined and "least burdensome approach" for future regulation. The ideal goal of the least burdensome approach when applied to premarket approval would be a reduction in regulatory burden and industry resources, all the while maintaining the safety of the public.<sup>30</sup> Still, it is unlikely that the FDA can maintain an effective PMA approval process by applying the least burdensome approach given the increased demands on the FDA and consumer reliance on medical devices. In fact, the FDA's PMA process can easily be described as burdened itself.

The overview of the PMA approval process for Class III medical devices should provide an idea of the difficult and tedious effort required to offer medical devices to the public. Given the great responsibility and duty of the FDA in governing the medical devices on the market, the legislature has afforded the FDA protection in the form of an express preemption clause.<sup>31</sup> The exact scope of the express preemption clause as applied to the FDA's use of the PMA process has been the subject of great debate, with courts finding on both ends of the spectrum. Thus, a brief summary of the meaning of preemption and its application is necessary in order to set the context by which courts have argued to limit state common law tort claims.

### *B. Express Preemption and the Circuit Splits*

Preemption of state law is derived from the Supremacy Clause, which states that the "[l]aws of the United States . . . shall be the supreme

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<sup>28</sup> The Safe Medical Devices Act of 1990, Pub. L. No. 101-629, § 4(a), 104 Stat. 4511, 4515 (1990) (codified as amended at 21 U.S.C. § 360c (2006)).

<sup>29</sup> S. REP. NO. 105-43 (1997), <http://thomas.loc.gov/cgi-bin/cpquery/T?report=sr043&dbname=105&> (last visited Oct. 29, 2006).

<sup>30</sup> The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry, <http://www.fda.gov/cdrh/ode/guidance/1332.html> (last visited Oct. 29, 2006). *But see* Goodlin v. Medtronic, 167 F.3d 1367, 1372 (11th Cir. 1999) ("[T]he entire purpose of the PMA process is for the FDA to obtain a 'reasonable assurance' that the device is safe and effective.")

<sup>31</sup> 21 U.S.C. § 360k(a) (2006).

Law of the Land.”<sup>32</sup> Therefore, “state law that conflicts with federal law is ‘without effect.’”<sup>33</sup> As the Supreme Court held in *Medtronic v. Lohr*:

In all pre-emption cases, and particularly in those in which Congress has “legislated . . . in a field which the States have traditionally occupied,” we “start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”<sup>34</sup>

Where a statute such as the MDA contains an express preemption clause the “task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress’ pre-emptive intent.”<sup>35</sup>

The MDA includes an express preemption clause, codified at 21 U.S.C. § 360k, which outlines the situations where federal law surpasses state law with respect to FDA medical device regulation.<sup>36</sup> The FDA’s interpretation of § 360k further elaborates that preemption only applies if the FDA has specifically issued equivalent regulations or device specific regulations that conflict with state requirements and that those state requirements are “different from, or in addition to, the specific [FDA] requirements.”<sup>37</sup> The express preemption clause is meant to avoid the conflict that would exist if states enforced requirements with respect to medical devices that clashed with the federal requirements set forth by the FDA. The preemption clause was also meant to address the tension created between the states’ interest in maintaining the health and welfare of its citizens and the FDA’s role as the gatekeeper for the medical

<sup>32</sup> U.S. CONST. art. VI, cl. 2.

<sup>33</sup> *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992)(quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)).

<sup>34</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (citations omitted).

<sup>35</sup> *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993).

<sup>36</sup> The express preemption provision of the MDA provides 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 chapter.

21 U.S.C. § 360k(a) (2006).

<sup>37</sup> 21 C.F.R. § 808.1(d) (2005).

State or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements.

*Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1372 (11th Cir. 1999).

device market. However, the boundaries of the express preemption clause remain to be tested, as the scope of the clause as applied to state common law tort claims is the subject of debate.

A majority of circuit courts have found that state common law tort claims are preempted by the express preemption provision; however, the courts' reasoning is splintered.<sup>38</sup> A minority of circuits have held that state common law tort claims are not preempted. Those courts have allowed such suits to proceed where a Class III medical device has caused injury. In the following section, this comment will detail each circuit court's stance on the scope of the MDA's express preemption provision. The Supreme Court's decision, in *Medtronic v. Lohr*, and the Court's recent decision, in *Bates v. Dow Agrosiences*, will be used to advocate the application of a new "parallel requirements" test to determine the scope of preemption in the context of the PMA approval process. It is important to employ a uniform approach to the scope of preemption and the ability of injured consumers to seek recourse in the legal system. The MDA does not provide a private right of action. Thus, consumers are left to seek legal action through state common law tort claims.<sup>39</sup> The circuit split over whether state common law claims can survive against device manufacturers effectively leaves some consumers with a remedy in the legal system and most without.

### C. *The Supreme Court's Decision in Medtronic v. Lohr*

The Supreme Court's precedent on federal preemption with respect to FDA regulation has been inconsistent at best and leaves a lack of guidance for future circuit court decisions on the matter. In *Medtronic v. Lohr*, the Supreme Court held that state common law tort claims were *not* preempted by the FDA's approval of a medical device through the § 510(k) process.<sup>40</sup> The plaintiff in the case brought various state common law tort claims sounding in negligence and product liability as a result of injuries suffered from a pacemaker that was implanted in her chest.<sup>41</sup> The pacemaker was considered a Class III medical device, which entered the market through the § 510(k) process.<sup>42</sup> The § 510(k) process differs from the PMA approval process, because it is a determination that the product being approved, in this case the pacemaker, is substantially equivalent to a similar device on the market and therefore it is unnecessary to go

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<sup>38</sup> 21 U.S.C. § 360k(a).

<sup>39</sup> *Medtronic*, 518 U.S. at 487.

<sup>40</sup> *Id.* at 470.

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

<sup>42</sup> *Id.* at 480.

through the more rigorous PMA process.<sup>43</sup> Despite the difference in approval processes, the express preemption provision applied to the pacemaker and the Supreme Court analyzed the scope of its language with respect to the plaintiff's state common law tort claim.<sup>44</sup>

The Court first looked to the intent of Congress in enacting the MDA and noted that Congress did not intend to preclude all state common law claims.<sup>45</sup> The Court stated, "when Congress enacted § 360k, it was primarily concerned with the problem of specific, conflicting state statutes and regulations rather than the general duties enforced by common-law actions."<sup>46</sup> Congress did not intend to prevent persons injured by medical devices from seeking recourse in state courts.<sup>47</sup> Where a state requirement parallels the federal requirement the Court held that there would be no preemption, as parallel requirements would not be considered "different from or in addition to."<sup>48</sup> The Court, in a plurality opinion, rejected the medical device manufacturer's argument that the express preemption provision barred every state common law claim from being brought against them.<sup>49</sup> The Court stressed that it was unlikely Congress meant to preempt state common law tort claims where the language of the preemption provision points to more specific "requirements," such as state statutes or regulations.<sup>50</sup> However, the Court neglected to find that state common law claims would "never" constitute specific state requirements, leaving the debate open with respect to the limits of the preemption clause.<sup>51</sup>

Justice Breyer issued a concurring opinion, which set forth the position that "requirements" in the express preemption provision of the MDA could very well include state common law tort claims.<sup>52</sup> Justice Breyer focused on the effect of an adverse state court judgment and expressed how the state common law tort claim would be no different from a state regulation.<sup>53</sup> The concurring opinion noted the difficulty in interpreting the express preemption provision in the MDA where the

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<sup>43</sup> *Id.* at 478.

<sup>44</sup> *Id.*

<sup>45</sup> *Id.* at 487.

<sup>46</sup> *Id.* at 491. "The legislative history also confirms our understanding that 360(k) [sic] simply was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions." *Id.*

<sup>47</sup> *Id.* at 487.

<sup>48</sup> *Id.* at 470.

<sup>49</sup> *Id.* at 486.

<sup>50</sup> *Id.* at 490-91.

<sup>51</sup> *Id.* at 503.

<sup>52</sup> *Id.* at 504 (Breyer, J., concurring).

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

language is “highly ambiguous.”<sup>54</sup> Despite Justice Breyer’s skeptical review of the preemption provision with respect to state common law tort claims, he ultimately found that plaintiff’s claims were not preempted due to the lack of specificity imposed on the device through the § 510(k) process.<sup>55</sup>

Justice O’Connor issued an opinion concurring in part and dissenting in part. Justice O’Connor agreed with Justice Breyer that state common law claims resulting in damages would have the same effect as a device specific state regulation. However, Justice O’Connor voiced her disagreement with the interpretation that the MDA provision only preempts *specific* federal requirements and stressed that the focus should be whether the requirements are “different from, or in addition to” the federal requirements.<sup>56</sup> Despite her argument for preempting state common law claims that compete with federal requirements, Justice O’Connor concurred in the judgment where the state common law tort claims were not effectively different from the minimal federal requirements imposed under the § 510(k) process.<sup>57</sup>

The Court’s plurality decision in *Medtronic* has left the circuits without substantial guidance. The majority of circuit courts interpret *Medtronic* to find no preemption where a device has been approved under the § 510(k) process.<sup>58</sup> However, the decision failed to address the preemption analysis where the medical device at issue has undergone the more extensive examination under the PMA process. The decision also failed to institute a clear test, which future courts could apply to the preemption issue. The decision in *Medtronic* led to disjointed opinions from the circuit courts. Since the decision in *Medtronic*, circuit courts have attempted to piece together various tests that would follow the language used by the Supreme Court. Without a clear path to follow, the circuit courts have split three different ways and the need for a uniform test becomes more apparent as time goes by.

## II. THE CIRCUIT SPLITS—THREE CATEGORIES OF REASONING

The decisions of the circuit courts of appeal can be divided into three categories, with a majority finding that the express preemption clause in the MDA defeats state common law tort claims. The first category encompasses those circuits that conclude that the requirements of state common law claims differ from those imposed by the PMA

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<sup>54</sup> *Id.* at 505.

<sup>55</sup> *Id.* at 506-08.

<sup>56</sup> *Id.* at 512 (O’Connor, J., concurring in part and dissenting in part).

<sup>57</sup> *Id.* at 513.

<sup>58</sup> *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1373 (11th Cir. 1999).

process and, therefore, must be preempted according to the statute. These courts have looked to how a state law judgment would create a different requirement for manufacturers of medical devices than the one set forth by the PMA process. The second category consists of those circuits which have found state common law tort claims preempted by the PMA process because the process itself constitutes a specific federal requirement. These courts reason that the holding in *Medtronic* does not extend to devices approved under the PMA process due to the extensive nature of testing and scrutiny required, which conflicts with state common law claims. The third category of court decisions hold that the PMA approval process *does not* preempt state common law tort claims; these courts support claims brought against device manufacturers sounding in negligence and product liability. With slight variation, these courts reason that the PMA process is not a device specific control, lacking any requirement directed at the particular device. To further develop these categories, this comment will now summarize the different circuit court decisions per each category and provide the factual basis on which each case was decided. This summary will show the reader the variety of potential claims and the scope of preemption.

#### *A. Category I—Preemption Based on Different State Requirements*

##### 1. The First Circuit

The First Circuit's pre-*Medtronic* decisions in *King v. Collagen Corp.*<sup>59</sup> and *Talbott v. C.R. Bard, Inc.*<sup>60</sup> held that federal law preempted state common law tort claims including negligence and breach of warranties against medical device manufacturers. In *King*, the plaintiff brought claims arising from an injury caused by Zyderm, an injection approved to treat skin imperfections and wrinkles as a Class III medical device.<sup>61</sup> The plaintiff suffered a severe injury to her face due to the Zyderm injection.<sup>62</sup> She then brought several state common law claims against the device manufacturer.<sup>63</sup> The court held that all state common law claims were preempted because the cause of action against the manufacturer imposed a specific *state* requirement that is prohibited by 21 U.S.C. § 360k.<sup>64</sup> Although this case was decided prior to *Medtronic*, subsequent First Circuit cases have affirmed its holding finding that state

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<sup>59</sup> 983 F.2d 1130 (1st Cir. 1993).

<sup>60</sup> 63 F.3d 25, 27 (1st Cir. 1995).

<sup>61</sup> *King*, 983 F.2d at 1131.

<sup>62</sup> *Id.* at 1132.

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

<sup>64</sup> *Id.* at 1135-36.

common law tort claims are preempted because they impose different and additional requirements than the federal requirement promulgated under the MDA.<sup>65</sup>

Post-*Medtronic*, the district courts have questioned the First Circuit's current position concerning preemption.<sup>66</sup> In *Haidak v. Collagen Corp.*, a plaintiff, with injuries and claims paralleling the plaintiff in *King*, brought a claim against the manufacturer of Zyderm.<sup>67</sup> The one difference between *Haidak* and *King* was that the injuries in *King* were an "unintended result of which both she and the FDA were unaware."<sup>68</sup> In analyzing the application of *King* to the issue of PMA approval preemption of state common law tort claims, the district court held that "[p]ost-*Medtronic*, this court cannot conclude beyond peradventure of doubt that the First Circuit's decision in *King* would necessarily be the same."<sup>69</sup> The court held that the manufacturer could not succeed at the summary judgment phase by arguing that the PMA process preempts any state law claims as a matter of law.<sup>70</sup> While not deciding the issue of preemption, given the facts of the case, the court suggested that preemption would apply only where the FDA had enacted device specific requirements.<sup>71</sup> The PMA process in itself did not preempt common law claims.<sup>72</sup> Therefore, future state common law

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<sup>65</sup> *Id.* at 1131.

<sup>66</sup> See *Haidak v. Collagen Corp.*, 67 F. Supp. 2d 21 (D. Mass. 1999).

<sup>67</sup> *Id.* at 25.

<sup>68</sup> *Id.* at 34. The court explained:

While *King* implies a broad preemptive sweep, it is apparent to the court that *King* is factually distinct from the instant matter. There, the plaintiff's negligence claim, indeed all her claims, arose out of an unwanted autoimmune reaction to Zyderm. As the First Circuit made clear, the FDA was especially involved in the labeling process regarding the inclusion of contraindications regarding autoimmune reactions. The *King* plaintiff's allegations derived from the fact that Defendant failed to reveal known dangerous propensities of Zyderm despite explicit FDA directives to do so. In the instant matter, the gravamen of [the p]laintiff's claim is very different. Although [the p]laintiff advances a very generalized complaint—that Defendant was "careless and negligent in the design, manufacture, distribution, sale and/or conveyance of the product"—the core of her claim is that the Zyderm migrated from the injection site, an unintended result of which both she and the FDA were unaware.

*Id.* (internal citations omitted).

<sup>69</sup> *Id.* at 29.

<sup>70</sup> *Id.*

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

<sup>72</sup> *Id.* at 29-33. The claim at issue in this case arose from use of a Collagen injection approved under the PMA process that was applied to the plaintiff's eyes and nose. *Id.* The Collagen caused injury by migrating throughout her body to form a mass in her lymph node. *Id.* The migration of the Collagen to another part of the body was a result that was not addressed or known by the FDA. *Id.* The court explained:

claims against Class III device manufacturers could be brought against device manufacturers in the First Circuit where the FDA has failed to enact device specific requirements.

## 2. The Second Circuit

In *Becker v. Optical Radiation Corp.*, the Second Circuit found that state common law tort claims were requirements that would interfere with requirements that the PMA process imposed on device manufacturers.<sup>73</sup> The court held that such state claims were preempted. This case concerned a “prosthetic device implanted in cataract patients to replace the natural lens of the eye.”<sup>74</sup> The court analyzed the PMA process reviews and compared them to the claims brought by the plaintiff.<sup>75</sup> The Second Circuit determined that, if the plaintiff were allowed to prevail on these claims, the judgment against the device manufacturer would constitute additional requirements different from those posed by the PMA process.<sup>76</sup> Thus, the FDA’s determination that the device was safe for human use preempted those claims that directly conflicted with that determination.<sup>77</sup>

The Class III medical device at issue in *Becker* was not approved by the PMA process at the time it was implanted in the plaintiff’s eye.<sup>78</sup> The device had an investigator device exemption from the PMA process and the plaintiff was part of a study to determine its safety and effectiveness.<sup>79</sup> However, the court’s decision was not affected by the experimental nature of the device as “the [c]ourt stated that the state law claims were pre-empted whether or not the device was subject to the specific regulations, or the general regulations relating to an IDE.”<sup>80</sup> The court concluded that its interpretation of the MDA’s express preemption

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Although the court is loathe to address [the p]laintiff’s claim of migration in any detail, it appears that the claim, as so framed, might be able to avoid the broad preemptive bar of the MDA. Nothing in the record to date suggests that the FDA enacted specific requirements regarding the standard of care necessary to obviate product migration.

*Id.* at 34.

<sup>73</sup> *Becker v. Optical Radiation Corp.*, 66 F.3d 18 (2d Cir. 1995).

<sup>74</sup> *Id.* at 19.

<sup>75</sup> *Id.* at 20.

<sup>76</sup> *Id.* Although the decision was made pre-*Medtronic*, the Second Circuit has not changed its ruling and the district courts have not provided any criticism. The state of such claims in light of *Medtronic* is subject to argument.

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

<sup>78</sup> *Id.* at 19.

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

<sup>80</sup> *Berish v. Richards Med. Co.*, 937 F. Supp. 181, 183 (N.D.N.Y. 1996) (holding that the *Medtronic* decision does not conflict with the holding in *Becker*).



provision applied to state statutory law as well as common law.<sup>81</sup> The Second Circuit aligns with the other circuits that consider state common law tort claims as different requirements, which conflict with the FDA and trigger preemption by federal law.

### 3. The Fourth Circuit

The Fourth Circuit in *Duvall v. Bristol Myers-Squibb* interpreted the Supreme Court's decision in *Medtronic* and stated that "§ 360k(a) of the MDA preempts state-law causes of action to the extent that, if successful, they would impose requirements different from or additional to requirements specifically applicable to the particular device under the MDA."<sup>82</sup> The plaintiff in *Duvall* brought claims against a Class III device manufacturer for breach of warranty, defective design and failure to warn, among other state law claims.<sup>83</sup> The plaintiff had been implanted with an inflatable penis prosthesis that was approved by the FDA through the § 510(k) process.<sup>84</sup> The court found that the plaintiff's state common law claims would have been preempted if the FDA had issued device specific requirements to the device at issue.<sup>85</sup> In its holding, the court noted that the § 510(k) process did not constitute a federal device specific requirement because the device was only subject to general controls for approval.<sup>86</sup> This case did not decide the issue of whether or not the PMA process would preempt state common law tort claims, but it showed that the Fourth Circuit would most likely have found the claims preempted because they were additional requirements with respect to the PMA process.

In *Woods v. Gliatech*, the District Court for the Western District of Virginia decided that state common law tort claims were not preempted where the FDA issued a conditional PMA to a Class III medical device.<sup>87</sup> The plaintiff had suffered injuries as a result a Class III medical device applied as a gel to lessen scarring and pain after surgery.<sup>88</sup> The plaintiff's claims against the manufacturer included state common law tort claims for negligence, breach of warranty and fraud on the public.<sup>89</sup> Aligning itself with the Eleventh Circuit, this court found that "the FDA's review

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<sup>81</sup> *Becker*, 66 F.3d at 19.

<sup>82</sup> *Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324, 332 (4th Cir. 1996).

<sup>83</sup> *Id.* at 326.

<sup>84</sup> *Id.* at 328. Note that approval through the § 510(k) process means that a substantially similar device was preexistent in the marketplace at the time of application.

<sup>85</sup> *Id.* at 332.

<sup>86</sup> *Id.*

<sup>87</sup> *Woods v. Gliatech, Inc.*, 218 F. Supp. 2d 802 (W.D. Va. 2002).

<sup>88</sup> *Id.* at 804.

<sup>89</sup> *Id.* at 805.

and approval of the PMA, by itself, imposes no ascertainable federal requirements.”<sup>90</sup> Therefore, the court did not allow the defendant manufacturer of the medical device to use the *conditional* PMA approval as protection from the lawsuit.<sup>91</sup> It is unclear how this broad holding will be applied, and, specifically, whether the Fourth Circuit will apply the same analysis to the completion of the PMA process, as opposed to only a condition approval.<sup>92</sup>

#### 4. The Fifth Circuit

In *Martin v. Medtronic*, the Fifth Circuit held that § 360k(a) preempts state products liability claims when the Class III medical device manufacturer complies with the FDA’s PMA process.<sup>93</sup> The plaintiffs’ claims against the Class III medical device manufacturer included product liability claims for negligence and breach of warranty.<sup>94</sup> The plaintiffs were implanted with pacemakers and suffered injuries allegedly from a defective lead wire in the device.<sup>95</sup> The court held that *Medtronic* did not overrule its decision in *Stamps v. Collagen Corp.*, because the holding in *Stamps* correctly found state tort claims preempted under the MDA.<sup>96</sup> The court stated, “we can conclude only that general duties of care can generate specific requirements that

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<sup>90</sup> *Id.* at 808. The court further rejected the circuit court decisions finding that “the PMA approval process itself constitutes a specific federal requirement” rejecting views held by the Fifth, Sixth, Seventh, and Ninth Circuits. *Id.* at 807.

<sup>91</sup> *Id.* at 808-10 n.4. While holding that the conditional PMA approval was not a specific federal requirement preempting state law, the court gave further ammunition for its holding. *Id.* The device manufacturer Gliatech had engaged in deceptive practices with respect to the reporting and submission of medical data about the use of its device to the FDA. *Id.*

The FDA’s approval letter specifically stated: “Failure to comply with the conditions of approval invalidates this approval order. Gliatech subsequently pled guilty to submission of materially false and misleading data with respect to the U.S. study. Thus, even assuming the conditional PMA constitutes a preemptive requirement, the court finds that Gliatech’s failure to comply with the PMA conditions invalidated the FDA’s approval of ADCON-L.”

*Id.* at 808 n.4 (internal citations omitted).

<sup>92</sup> See *Murphy v. Playtex Family Prods. Corp.*, 69 F. App’x. 140 (4th Cir. 2003) (holding that state law claims, relating to failure to warn and the labeling of tampons, were preempted by the FDA’s specific approval of labeling requirements and the FDA’s consideration of risks involved with the product).

<sup>93</sup> *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001).

<sup>94</sup> *Id.* at 575.

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

<sup>96</sup> *Id.* at 580.

conflict with specific FDA requirements” and supported a finding that the PMA process itself constituted a specific federal requirement.<sup>97</sup>

Despite finding the plaintiffs’ claims preempted, the Fifth Circuit provided a possible avenue for relief for litigants attempting to sue a medical device manufacturer. The court, with reference to the *Medtronic* decision, stated that “common law duties that incorporate the PMA process, such as the general duty to take due care to comply with the PMA process in labeling or manufacturing, will never contain specific requirements that are additional to or different from federal requirements.”<sup>98</sup> The court implied that it would allow a claim that encompassed aspects similar to those imposed by the PMA process. The scope of the general duty stated by the Fifth Circuit and the extent to which a court would entertain such claims seems unclear. Therefore, the Fifth Circuit provides for a possible private right of action against medical device manufacturers that do not comply with the PMA process.<sup>99</sup>

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<sup>97</sup> *Id.* at 582. The court noted that [t]his reasoning is consistent with the majority opinion; while the general duty, standing on its own, is not a threat to federal requirements and is not developed specifically “with respect to” medical devices, the elements needed to prove a violation of that general duty may be very specifically tailored to the device, and the state court action may therefore threaten specific federal requirements.

*Id.* <sup>98</sup> *Id.* at 583 n.8. Recognizing binding precedent in the Fifth Circuit, the court in *Betterton v. Evans* found that the plaintiff’s state law claims against a pacemaker manufacturer were preempted despite a slightly illogical holding. 351 F. Supp. 2d 529, 536 (N.D. Miss. 2004). In its conclusion, the court expressed its discomfort with its holding:

The court notes its disdain for this mandatory conclusion given that “Congress enacted the Medical Device Amendments of 1976, in the words of the statute’s preamble, ‘to provide for the safety and effectiveness of medical devices intended for human use.’” The evidence presented in this case to date indicates that the subject pacemaker simply did not work. A pacemaker can hardly be said to be safe and effective when it not only does not work, but also requires subjecting a patient to the agony of opening and reopening his chest[,] because the pacemaker is malfunctioning and neither the pacemaker–company representative nor the surgeon implanting it can figure out how to make it work. In other words, the court must abide by the law which unfortunately disallows patients or their heirs a remedy when a FDA–approved Class III medical device malfunctions and ceases to be safe and effective.

*Id.* (internal citations omitted).

<sup>99</sup> *Martin*, 254 F.3d at 583 (“In the context of the PMA process, we agree that state tort suits that allege, as the basis of their claim, that the approved FDA requirements have not been met are not preempted.”); see *Haddock v. Mentor Tex.*, No. 3:03-CV-2311-B, 2005 U.S. Dist. LEXIS 4975 (N.D. Tex. Mar. 25, 2005) (suggesting that plaintiffs, who

### 5. The Eighth Circuit

The Eighth Circuit in *Brooks v. Howmedica, Inc.* followed the majority rule when it held that the PMA process imposed specific federal requirements on the medical device where the FDA had required additional warnings, and that a state common law tort claim would impose “specific state requirement[s] ‘different from, or in addition to’ specific federal requirements.”<sup>100</sup> Bone cement is a Class III medical device.<sup>101</sup> The plaintiff in this case brought products liability claims for injuries resulting from her occupational use of bone cement.<sup>102</sup> As a nurse, the plaintiff was responsible for mixing the bone cement used in orthopedic surgeries.<sup>103</sup> She claimed that the manufacturer’s inadequate labeling failed to warn her of the dangerous vapors, which result from mixing the cement.<sup>104</sup> The court developed a three-step test to determine whether the PMA preempts the state common law claims.<sup>105</sup> The court must first determine what federal requirement was imposed on the medical device manufacturer in getting the device on the market.<sup>106</sup> Second, the court must discern the state requirement that would be imposed on that manufacturer.<sup>107</sup> In the third and final step, the court must “compare the two to determine whether they present conflicting obligations” on the device manufacturer.<sup>108</sup> If so, the court will find the state claims preempted under § 360k.<sup>109</sup> This approach looks at the specificity of both the federal requirement and the state requirement.

Importantly, this decision did not imply that the PMA approval process would *always* constitute a specific federal requirement or that state common law tort claims would always be specific state requirements. The court’s three-step test provides a case-by-case evaluation of the device allegedly causing injury and the claims brought against the manufacturer. Additionally, the court distinguished its holding from those circuits that have not found preemption:

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show evidence that the manufacturer of the Class III device, failed to follow the PMA standards could avoid federal preemption).

<sup>100</sup> *Brooks v. Howmedica, Inc.* 273 F.3d 785, 799 (8th Cir. 2001) (quoting 21 U.S.C. § 360k (2006)).

<sup>101</sup> *Id.* at 789.

<sup>102</sup> *Id.* at 787.

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

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

<sup>105</sup> *Id.* at 799 (Bye, J., dissenting in part).

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

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

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

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

Those circuit court decisions since [*Medtronic*] which have not found preemption in failure to warn cases were faced with circumstances different from those in this case. . . . In *Goodlin v. Medtronic, Inc.*, a case in which the FDA had issued no statement or order of requirements beyond review and approval of the initial PMA, the Eleventh Circuit ruled that simple approval of the PMA application imposes no federal “requirements.” The *Goodlin* court implied, however, that it would find preemption in a case involving an “ascertainable requirement in an express FDA” order or regulation. That is what we have here, where the FDA has issued a series of specific mandates regarding the label for Simplex [bone cement]. Simplex has been subject to continuing and specific FDA regulation, beyond its initial approval through the PMA process.<sup>110</sup>

Therefore, the Eighth Circuit’s position with respect to devices approved by the PMA process, without further regulation by the FDA, remains an open question. Given the language used by the Eighth Circuit, the court would be unlikely to find such claims preempted where the FDA gave the device only PMA approval. The Eighth Circuit would most likely draw the line where the FDA has subjected the device to additional modification or requirements after the PMA approval process.

#### *B. Category II—Preemption Based on the PMA Process*

##### 1. The Third Circuit

The Third Circuit recently shifted its reasoning to hold that state common law tort claims were preempted by the MDA. In *Horn v. Thoratec Corp.*, the plaintiff brought product liability claims against the device manufacturer of a “HeartMate” pump, a device that surgeons implant into patients to allow blood flow to certain areas of the heart.<sup>111</sup> The lower court applied a two-prong test to find that the PMA approval process constitutes a specific requirement of the FDA and preempts state common law claims.<sup>112</sup> The court found that such state claims would be preempted if “1) the FDA has established specific federal requirements that are applicable to that particular device, and 2) the state claim is different from, or in addition to, the specific federal requirements.”<sup>113</sup> Applying this test, the court held that any judgment by a state court as to a specific product’s safety directly conflicts with the FDA’s

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<sup>110</sup> *Id.* at 795-96 (majority opinion) (internal citations omitted).

<sup>111</sup> *Horn v. Thoratec Corp.*, 376 F.3d 163, 164-65 (3d Cir. 2004).

<sup>112</sup> *Id.* at 165.

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

determination, through the PMA process, that the product was safe.<sup>114</sup> The lower court began and ended its analysis by finding the PMA approval process was a “specific federal requirement.”<sup>115</sup>

However, the Third Circuit did not define what constitutes a “requirement” for preemption. The court engaged in a general discussion of the rigors of the PMA and the back and forth communication between the FDA and the manufacturer during the process.<sup>116</sup> The court found that the PMA process was a federal requirement and held “the requirements imposed by the FDA upon the HeartMate when it was granted PMA approval are precisely ‘the sort of concerns regarding a specific device’ which the Supreme Court intimated would give rise to preemption under § 360k(a).”<sup>117</sup> The court concluded that the PMA process “imposed *mandatory conditions*” on the medical device and equated it to a federal requirement.<sup>118</sup> Additionally, the Third Circuit considered an amicus curiae brief, filed on behalf of the FDA, providing the agency’s opinion that the “PMA approval in this particular case requires preemption,” in which the Court found support for its holding.<sup>119</sup>

In his dissent, Judge Fuentes expressed strong opposition to the majority’s reasoning in *Horn*.<sup>120</sup> Judge Fuentes agreed that the PMA process was a specific federal requirement but he disagreed that all state common law tort claims were “specific requirements.”<sup>121</sup> Judge Fuentes also rejected the majority’s reliance on the amicus curiae brief submitted by the FDA that urged a finding of preemption in this case.<sup>122</sup> The dissent refers to Congressional purpose in enacting the MDA as protecting consumers from harmful medical devices and rejects the majority’s

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

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

<sup>116</sup> *Id.* at 169-70.

<sup>117</sup> *Id.* at 169.

<sup>118</sup> *Id.* at 170. The analysis of what constitutes a federal requirement for purposes of preemption has varied greatly from circuit to circuit, giving rise to the different categories provided by this note. See *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1375-76 (11th Cir. 1999). “The approval represents only a finding that the manufacturer’s proposal to market a device has reasonably assured the FDA of the device’s safety and effectiveness. . . . [T]he approval [does not, however] provide any indication of what (if any) specific substantive requirements the FDA may have applied to reach that result.” *Id.* at 1375. Additionally, FDA authorization “is clearly specific to the device under review, but because the approval itself neither reveals nor imposes any ascertainable substantive prerequisite for approval that we could compare to a purportedly conflicting state requirement, the approval itself does not fit within section 360k(a)(1)’s demand for a specific federal requirement.” *Id.* at 1376.

<sup>119</sup> *Horn*, 376 F.3d at 177.

<sup>120</sup> *Id.* at 180 (Fuentes, J., dissenting).

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

<sup>122</sup> *Id.* at 182 n.29.

conclusion that Congressional purpose was to balance the manufacturer's need for innovation versus the consumer's need for safety.<sup>123</sup> With Judge Fuentes as the lone dissenter, the majority rule will stand strong in the Third Circuit, which finds preemption for most state common law tort claims.<sup>124</sup>

## 2. The Sixth Circuit

In *Kemp v. Medtronic*, the Sixth Circuit found that state common law product liability claims, fraud on the FDA, and state failure to warn claims were all preempted by the PMA process.<sup>125</sup> The plaintiff brought common law negligence and product liability claims against a Class III device manufacturer for injuries sustained due to an allegedly defective wire in her pacemaker.<sup>126</sup> The FDA approved the pacemaker at issue through the PMA process and thereafter subjected the device to a PMA supplement due to a modification of the materials used in its lead wire.<sup>127</sup> Two years before surgeons implanted the plaintiff with the device, the FDA recognized a "significant risk of failure" for the lead surrounding the wire and the device manufacturer issued a "Health Safety Alert" about the specific model pacemaker.<sup>128</sup> Additionally, the court noted that "the FDA has never promulgated federal regulations regarding the manufacture of pacemaker leads."<sup>129</sup>

In rejecting the Eleventh Circuit's reasoning in *Goodlin v. Medtronic*, the court recognized the difficulty the respective courts of appeal have encountered while interpreting the Supreme Court's decision in *Medtronic*.<sup>130</sup> The court first found that the PMA process was a specific federal requirement and agreed with the device manufacturer

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<sup>123</sup> *Id.* at 185 ("As the [*Medtronic*] court observed, the purpose of the MDA was to protect consumers by ensuring the safety and effectiveness of medical devices. Contrary to . . . assertions, protection of the medical device industry from excessive regulation was a minimal concern." (citations omitted)).

<sup>124</sup> The Third Circuit's scope of the FDA's preemption clause appears to be the broadest of all of the circuit court decisions in that it finds that the PMA process is a specific federal requirement, regardless of the device. *Id.* at 169 (majority opinion). The Third Circuit also holds that state tort claims relating to the device are additional requirements, regardless of the claim. *Id.* Therefore, regardless of the device regulated or the claim proposed against it, the Third Circuit would most likely find all claims preempted by the FDA's PMA approval.

<sup>125</sup> *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 237 (6th Cir. 2000).

<sup>126</sup> *Id.* at 219.

<sup>127</sup> *Id.*

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

<sup>129</sup> *Id.* at 226.

<sup>130</sup> *Id.* at 224 ("The various courts of appeals that have confronted issues of preemption arising under the MDA have struggled mightily with [*Medtronic's*] language in the effort to discern its holding.").

that “it is the totality of the design, manufacturing processes, and labeling—when coupled with the prohibition against modifying them—that represents the specific federal requirement.”<sup>131</sup> The Sixth Circuit concluded that a verdict against the device manufacturer would constitute a “requirement different from and in addition to those established by the FDA”; therefore, the plaintiff’s state law tort claims were specific state requirements.<sup>132</sup> The finding that the PMA process constitutes a device specific requirement that conflicts with state law claims has been upheld in later Sixth Circuit decisions.<sup>133</sup>

### 3. The Seventh Circuit

The Seventh Circuit most recently joined the majority precedent. In *McMullen v. Medtronic*, the Seventh Circuit found that the specific federal requirements imposed by the FDA preempted state law tort claims.<sup>134</sup> The plaintiff brought state common law claims for failure to warn against a Class III device manufacturer because of injuries he suffered from the implantation of a tremor control device in his brain.<sup>135</sup> The FDA approved the Class III device, as well as the additional specific warnings displayed on the device, through the PMA process.<sup>136</sup> The plaintiff premised a failure to warn claim on the information the manufacturer issued regarding new risks of injury or death through the use of the device.<sup>137</sup> The plaintiff claimed that, although the device manufacturer had issued a warning regarding a new risk of injury, the warning came too late to avoid his injury.<sup>138</sup>

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<sup>131</sup> *Id.* at 228.

<sup>132</sup> *Id.* at 230. The concurring opinion notes the possibility of a claim for failure to comply with the federal requirements. *Id.* Judge Moore, citing to the majority opinion, agreed that

“a claim premised on the violation of FDA requirements established for a Class III device through the PMA process is not automatically preempted.” Thus as the majority recognizes, a claim for negligence per se premised on the absence of a platinum sputter barrier as required by the FDA approval would not be preempted because the state claim would not impose requirements different from or additional to the federal requirements.

*Id.* at 237 (Moore, J., concurring) (internal citations omitted).

<sup>133</sup> See *Cupek v. Medtronic*, 405 F.3d 421 (6th Cir. 2005) (holding to its previous stance on preemption despite an attempt by the plaintiffs from *Kemp v. Medtronic* to bring suit again for modified claims against the medical device manufacturer); see also *Moore v. Sulzer Orthopedics, Inc.*, 337 F. Supp. 2d 1002 (N. D. Ohio 2004).

<sup>134</sup> *McMullen v. Medtronic, Inc.*, 421 F.3d 482 (7th Cir. 2005).

<sup>135</sup> *Id.* at 484.

<sup>136</sup> *Id.* at 485.

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

<sup>138</sup> *Id.*



Relying on its previous decision in *Mitchell v. Collagen Corp.*, the court found that the PMA process is a specific federal requirement, which preempted the plaintiff's claims.<sup>139</sup> The court held that the warnings provided with a device were approved by the FDA and that a state law failure to warn claim directly conflicts with the specific federal requirement.<sup>140</sup> Although the *Mitchell* Court acknowledged its significant difficulty interpreting the Supreme Court's *Medtronic* decision and the scope of the FDA requirements,<sup>141</sup> the Seventh Circuit considered the PMA process to be a specific federal requirement preempting state common law claims. The Seventh Circuit's difficulty analyzing the preemption issue shows the problem presented to all circuit courts.

### *C. Category III—Common Law Claims Are Not Preempted*

#### 1. The Ninth Circuit

The Ninth Circuit, in *Kennedy v. Collagen Corp.*, held that the PMA approval process, by itself, is not a "requirement" with respect to a specific device.<sup>142</sup> The plaintiff brought common law claims of negligence and product liability against a device manufacturer for injuries sustained from an injection of collagen.<sup>143</sup> The court reversed the summary judgment order and held that the common law claims were not

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<sup>139</sup> *Id.* at 490.

<sup>140</sup> *Id.* at 488 ("If *Medtronic* believed that a warning different from the one approved by the FDA was appropriate in light of an adverse event, it was required to seek FDA approval of any proposed changes. These are relevant federal requirements limiting [the manufacturer's] conduct as to the warnings it issued to [the device] recipients." (citing 21 C.F.R. § 814.39(a)).

<sup>141</sup> The court stated:

The implementing regulation for the FDA is likewise imprecise and fails to address squarely the issue of preemption by common law causes of action. Lastly, although we have an obligation to be absolutely faithful to the holdings of the Supreme Court of the United States, the holding in *Medtronic* contains several ambiguities that impair our ability to perceive with absolute clarity the path that the court has chosen for us to follow. . . .

The ambiguity central to our task is the tension between the holding of the Court embodied in the text immediately above and Justice Breyer's belief, essential to the formation of a majority, that at least some state-based causes of action would be preempted by the MDA. Like the majority of courts that already have had to deal with this quandary, we believe that the *Medtronic* disposition must be read as acknowledging that at least some state-based common law causes of action must be considered 'requirements' as that term is employed in the MDA.

*Mitchell v. Collagen Corp.*, 126 F.3d 902, 910 (7th Cir. 1997).

<sup>142</sup> *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995), *overruled in part by* *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

<sup>143</sup> *Id.* at 1454.

preempted by the PMA process where the FDA had not issued a device specific requirement.<sup>144</sup> The court explained:

*All Class III devices are required to obtain pre-market approval before being sold in interstate commerce. The fact that the pre-market approval process involves specific requirements, must not be confused with the pre-market approval requirement itself acting as a specific requirement. The result of holding that the pre-market approval process is a “specific requirement applicable to a particular device” is the preemption of claims which, if barred, leave injured plaintiffs without any remedy in state or federal court.*<sup>145</sup>

The court further expressed its disbelief that this preemption clause would effectively bar all state common law tort claims, stating “[i]t is difficult to believe that Congress would, without comment, remove all means of recourse for those injured by illegal conduct.”<sup>146</sup>

However, the court in *Papike v. Tambrands, Inc.* limited the holding in *Kennedy*: “[t]o the extent [the court] concluded in *Kennedy* that the MDA cannot preempt any state common-law causes of action, the conclusion cannot survive in light of the concurring and dissenting opinions in *Medtronic*.”<sup>147</sup> The plaintiff, in *Papike*, brought common law claims against a device manufacturer arising from injuries caused by her use of tampons.<sup>148</sup> Tampons are Class II medical devices and manufacturers of tampons must comply with specific labeling requirements.<sup>149</sup> The FDA requires specific content in warning labels due to the risk of Toxic Shock Syndrome to women who use Tampons; such requirements are codified in 21 C.F.R. § 801.430 (2006).<sup>150</sup> In *Papike v. Tambrands, Inc.*, the court held that the FDA regulations specific to the device at issue preempted state law failure to warn claims.<sup>151</sup>

It is unclear to what extent, if at all, the Ninth Circuit would find preemption where a Class III medical device is subject only to the PMA process. *Papike* is an easily distinguishable case, where the product at issue was subject to very specific content based warnings and where the plaintiff’s claims were based on inadequate warnings.<sup>152</sup> However, the district court in *Clement v. Kaiser Foundation* read the court’s decision

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<sup>144</sup> *Id.*

<sup>145</sup> *Id.* at 1459 (internal citations omitted).

<sup>146</sup> *Id.* at 1456 (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)).

<sup>147</sup> *Papike v. Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir. 1997).

<sup>148</sup> *Id.* at 738.

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

<sup>150</sup> *Id.* at 743.

<sup>151</sup> *Id.* at 738.

<sup>152</sup> *See id.*

in *Papike* to hold that the PMA process in itself will constitute a specific requirement.<sup>153</sup> The court stated that the “Ninth Circuit’s decision in *Papike* supports the conclusion that the MDA would preempt some tort claims against the particular devices at issue in this case.”<sup>154</sup>

## 2. The Tenth Circuit

The Tenth Circuit in *Oja v. Howmedica* held that the FDA approval of a device is not, standing alone, a specific federal requirement.<sup>155</sup> In this case, the plaintiff brought a negligent failure to warn and products liability action against *Howmedica* for injuries related to an artificial hip implant, a Class II medical device that was marketed under the § 510(k) process.<sup>156</sup> The hip implant was also approved under an IDE exception for a specific type of use and ultimately received a conditional PMA approval for such use.<sup>157</sup> Although the issue did not involve preemption of a Class III device specifically approved under the PMA process, the Tenth Circuit provided instructive language as to how it would rule in a Class III case.<sup>158</sup>

From the Supreme Court’s *Medtronic* decision, the Tenth Circuit discerned a two prong test for MDA preemption issues.<sup>159</sup> The court found that *Medtronic* required both a federal requirement and a state requirement aimed at regulating a specific device.<sup>160</sup> The first prong requires a determination that the FDA imposed a specific federal requirement applicable to the medical device.<sup>161</sup> The second prong asks whether there are any general state common law requirements specifically developed ‘with respect to’ medical devices imposed by a claim.<sup>162</sup> Applying this test to the facts of the case, the court determined that the FDA made labeling demands of the hip implant’s manufacturer.<sup>163</sup> The FDA specifically prohibited the manufacturer from

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<sup>153</sup> *Clement v. Kaiser Found. Health Plan, Inc.*, No. CV04-704 WJR (MCx), 2004 U.S. Dist. LEXIS 26414 (C.D. Cal. Dec. 17, 2004).

<sup>154</sup> *Id.* at \*16.

<sup>155</sup> *Oja v. Howmedica*, 111 F.3d 782, 789 (10th Cir. 1997).

<sup>156</sup> *Id.* at 784-87. The FDA’s final rule determined that the device was class II and stated that the “classification as a class III device was ‘not necessary to provide reasonable assurance of the safety and effectiveness of the device.’” *Id.* at 787 (citing 21 C.F.R. § 860.93 (2005)).

<sup>157</sup> *Id.* at 787. The hip implant was ultimately approved under the § 510(k) process for use without cement. *Id.*

<sup>158</sup> *Id.* at 788.

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

<sup>160</sup> *Id.* (internal citations omitted).

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

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

<sup>163</sup> *Id.* at 789.

labeling its product for non-cement use.<sup>164</sup> The court held that the labeling mandate constituted a federal requirement in satisfaction of the first prong.<sup>165</sup>

However, the court determined that the state law claim for failure to warn was “not specifically developed ‘with respect to’ medical devices”; therefore, it failed the second prong.<sup>166</sup> The court explained that a claim for failure to warn cannot be specific to a device where it is universally applied to all device manufacturers for all devices.<sup>167</sup> The manufacturer’s duty to warn is not device specific so as to conflict with the federal requirements of safety.<sup>168</sup> Thus, the court concluded that the MDA did not preempt the state common law claim of negligent failure to warn.<sup>169</sup>

Although the court in *Howmedica* did not decide or discuss whether the PMA process would constitute a federal requirement, it appears that they would not follow the majority rule. In the Tenth Circuit’s analysis, the court examined whether the FDA had imposed specific requirements or restrictions on the device, as opposed to whether the process under either the § 510(k) or the IDE exception were requirements standing alone.<sup>170</sup> In *Howmedica*, the FDA had imposed a specific requirement, which prohibited the manufacturer from labeling or promoting a specific use of the device.<sup>171</sup> The Seventh Circuit, in evaluating the *Howmedica* decision, stated that unlike the majority of the circuits, “[i]t appears that the Tenth Circuit would hold . . . that generic common law causes of action do not meet this test because, when stated without application to a particular product, they cannot be said to have been developed ‘in relation to’ the medical device in question.”<sup>172</sup>

### 3. The Eleventh Circuit

The Eleventh Circuit, in *Goodlin v. Medtronic*, found that the PMA approval process is not a specific federal requirement and state common law tort claims are not preempted.<sup>173</sup> In *Goodlin*, the Class III medical device at issue was a pacemaker approved by the FDA through the PMA

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<sup>164</sup> *Id.*

<sup>165</sup> *Id.*

<sup>166</sup> *Id.*

<sup>167</sup> *Id.* (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501 (1996)).

<sup>168</sup> *Id.*

<sup>169</sup> *Id.*

<sup>170</sup> *Id.*

<sup>171</sup> *Id.* at 789.

<sup>172</sup> *Mitchell v. Collagen Corp.*, 126 F.3d 902, 913 n.4 (7th Cir. 1997).

<sup>173</sup> *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1382 (11th Cir. 1999).

approval process.<sup>174</sup> The plaintiff brought claims against the device manufacturer for negligent design and product liability for injuries resulting from implantation and removal of a pacemaker.<sup>175</sup> The court “d[id] not believe that requirements applicable to all devices that receive the FDA’s approval via the PMA process satisfy the [Supreme] Court’s demand for a specific requirement that applies to a particular device.”<sup>176</sup>

The court began its analysis by reviewing the extensive measures undertaken by the device manufacturer in order to complete the PMA approval process, which spanned over a period of seven years.<sup>177</sup> The court distinguished the Supreme Court’s holding in *Medtronic* due to the different approval processes and did not find the *Medtronic* decision controlling.<sup>178</sup> The *Goodlin* Court did, however, apply the Supreme Court’s test for determining preemption.<sup>179</sup> The *Goodlin* Court stated that preemption of a state common law claim requires the “(1) the imposition of a specific federal requirement that (2) applied to a particular device and (3) focused on the safety and effectiveness of the device.”<sup>180</sup> According to the Eleventh Circuit, the relevant inquiry boils down to whether the PMA process is a specific federal requirement regarding the safety of a specific device.<sup>181</sup>

The Eleventh Circuit looked to the dictionary definition of “requirement” as well as the Congressional intent behind the MDA to decide whether the PMA process was a federal requirement. The court found that the PMA process did not “require” anything specific of the

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<sup>174</sup> *Id.* at 1368. The pacemaker at issue in this case was slightly different than the pacemaker at issue in *Medtronic*, and it was approved by the PMA process and not the § 510(k) process. Additionally, the facts at issue in this case were nearly identical to the facts presented in *Kemp v. Medtronic*, 231 F.3d 216 (6th Cir. 2000).

<sup>175</sup> *Id.* at 1369.

<sup>176</sup> *Id.* at 1377 (citing *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1458-59 (9th Cir. 1995), *overruled in part* by *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996)).

<sup>177</sup> *Id.* at 1370.

<sup>178</sup> Specifically, the court held:

Despite the striking superficial similarity of the cases, the Supreme Court’s disposition of [*Medtronic*] provides little more than a rudimentary analytical framework to guide our resolution of *Medtronic*’s preemption claims in this case because [*Medtronic*] involved the 510k [sic] process rather than the PMA process, and because the Court fractured in an all but irreconcilable manner over the extent to which section 360k(a) would ever preempt a general state common law tort claim.

*Id.* at 1371 (citing *Mitchell v. Collagen Corp.*, 126 F.3d 902, 910 (7th Cir. 1997)).

<sup>179</sup> *Id.* at 1372.

<sup>180</sup> *Id.* (citing *Medtronic v. Lohr*, 518 U.S. 470, 492-94 (1996)).

<sup>181</sup> *Id.* This test is the opposite of the inquiry by the first category of circuits who look to whether the state common law tort claim constitutes a different requirement, not whether the PMA approval process is a requirement.

manufacturer in relation to its device.<sup>182</sup> The PMA process applied to all devices and the court stated that the process was not a “specific requirement that applies to a particular device.”<sup>183</sup> The court also found that Congress’s intent behind the MDA would be thwarted by allowing state law claims to be preempted.<sup>184</sup> The court noted that as Congress enacted the MDA to protect consumers from unregulated medical devices, it does not follow that Congress would, at the same time, preclude recourse for injured consumers.<sup>185</sup> Therefore, the Eleventh Circuit refused to find that the PMA process preempted state common law claims.<sup>186</sup> In conclusion, the court stated, “the FDA’s approval of a medical device pursuant to the PMA process, standing alone, imposes no specific federal requirement applicable to a particular device and, therefore, has no preemptive effect under section 360k(a) of the MDA.”<sup>187</sup>

Concluding with the Eleventh Circuit’s decision in *Goodlin*, the disparity that plagues the circuit courts regarding the application of the express preemption clause of 360k(a) is obvious. Since the Supreme Court in *Medtronic* failed to provide a clear path to follow, the courts have applied disjointed tests to varying facts. The three categories of reasoning are gross categories at best, with some circuits deviating from the lines placed by this comment. However, the disorganized reasoning and the split among the circuits is critical; the decisions affect the rights of injured consumers throughout the nation. The scope of preemption in this context remains to be answered by the Supreme Court. However, the recent decision in *Bates v. Dow Agrosciences* provides insight into the proper test to be applied to the preemption issue.<sup>188</sup>

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<sup>182</sup> *Id.* at 1375-76; *see supra* note 118.

<sup>183</sup> *Id.* at 1377 (citing *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1458-59 (9th Cir. 1995), *overruled in part by* *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996)).

<sup>184</sup> *Id.* at 1378.

<sup>185</sup> *Id.* at 1377-78.

The PMA process permits the FDA to regulate the introduction and sale of medical devices to assure their minimal safety for public consumption—it does not appear to address the appropriate standards of liability once the product enters the marketplace. Our inability to discern a specific requirement that fits the demands of section 360k(a) in the FDA’s approval process, therefore, finds broader support in the language and structure of the MDA and is consistent with the factual backdrop that prompted Congress to enact the MDA.

*Id.*

<sup>186</sup> *Id.* at 1382.

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

<sup>188</sup> *Bates v. Dow Agrosciences, L.L.C.*, 544 U.S. 431 (2005).

III. THE *BATES* DECISION AND THE “PARALLEL REQUIREMENTS” TEST

The Supreme Court recently decided an issue of federal preemption in *Bates v. Dow Agrosciences*.<sup>189</sup> The decision instructs on the issue left undecided by *Medtronic*: whether the FDA’s premarket approval process preempts state common law tort claims. The issue of preemption in *Bates* was whether the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”) preempted state common law tort claims. The express preemption provision in the FIFRA statute states that “[s]uch State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.”<sup>190</sup> This language mirrors the MDA’s express preemption clause.<sup>191</sup> Since both clauses preempt state “requirements,” the Supreme Court’s discussion should guide future interpretations of the MDA’s express preemption clause.

Texas peanut farmers suffered the harm at issue in *Bates* after using the pesticide “Strongarm” on their crops.<sup>192</sup> The peanut farmers alleged the pesticide caused extensive crop damage.<sup>193</sup> Dow, the company that made and sold the pesticide, had a conditional registration from the EPA, which enabled it to market and sell the pesticide to the peanut farmers shortly before the planting season.<sup>194</sup> The farmers alleged that Dow failed to include a warning on Strongarm regarding the damage to peanuts grown in soil with a pH higher than 7.0.<sup>195</sup> Although Dow knew that Strongarm caused such crop damage when used at certain pH levels, the label made no such claim.<sup>196</sup> In fact, the label stated, “Use of Strongarm is recommended in all areas where peanuts are grown”; farmers who used Strongarm in accordance with the recommendation experienced extensive damage to their peanut crops because the pH levels were 7.2 and higher.<sup>197</sup> The farmers sued Dow claiming negligence, strict liability,

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

<sup>190</sup> 7 U.S.C. § 136v(b) (2006).

<sup>191</sup> The MDA provides:

[N]o 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.

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

<sup>192</sup> *Bates*, 544 U.S. at 434.

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

<sup>194</sup> *Id.*

<sup>195</sup> *Id.* at 435.

<sup>196</sup> *Id.*

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

“fraud, breach of warranty and violation of the Texas Deceptive Trade Practices-Consumer Protection Act.”<sup>198</sup> Dow defended by claiming that the farmers’ suit was preempted by the express preemption provision of the FIFRA.<sup>199</sup>

The Court of Appeals for the Fifth Circuit affirmed the district court’s determination that the express preemption clause in the FIFRA preempted the farmers’ state law claims.<sup>200</sup> The Fifth Circuit analyzed the express preemption clause in the FIFRA in a manner similar to the analyses applied by circuit courts in Category I, which consider state actions to be requirements contrary to the MDA express preemption provision.<sup>201</sup> The Fifth Circuit concluded that “[f]or a state to create a labeling requirement by authorizing a claim linked to the specifications of a label, even where the EPA has elected not to impose such labeling requirements, would clearly be to impose a requirement ‘in addition to or different from those’ required under FIFRA.”<sup>202</sup> The Fifth Circuit came to this conclusion despite its acknowledgement that the EPA does not impose product *specific* labeling requirements regarding the effectiveness of the product registered under FIFRA.<sup>203</sup>

The Supreme Court granted writ of certiorari and reversed the Fifth Circuit.<sup>204</sup> The Supreme Court found that preemption did not apply to the farmers’ state common law claims.<sup>205</sup> Although the Fifth Circuit followed the majority of its sister circuits, the Supreme Court noted that the reasoning was incorrect.<sup>206</sup> The Court began its analysis of the express preemption clause with a history of the FIFRA and the intent behind the statute,<sup>207</sup> which was similar to the analysis the Court applied to the MDA in *Medtronic Inc. v. Lohr*.<sup>208</sup>

The Supreme Court first noted that the preemption clause in the FIFRA only applied to state “requirements.”<sup>209</sup> The Court explicitly stated that “[a]n occurrence that merely motivates an optional decision does not qualify as a requirement.”<sup>210</sup> In defining requirement in terms of what it is not, the court stated that the “[c]ourt of [a]ppeals was therefore

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<sup>198</sup> *Id.*

<sup>199</sup> *Id.* at 436.

<sup>200</sup> *Dow Agrosciences, L.L.C. v. Bates*, 332 F.3d 323, 331 (5th Cir. 2003).

<sup>201</sup> *See supra* Part II.A.

<sup>202</sup> *Dow Agrosciences*, 332 F.3d at 331.

<sup>203</sup> *Id.* at 330.

<sup>204</sup> *Bates*, 544 U.S. at 454; *Bates v. Dow Agrosciences L.L.C.*, 542 U.S. 936 (2004).

<sup>205</sup> *Bates*, 544 U.S. at 445.

<sup>206</sup> *Id.* at 436.

<sup>207</sup> *Id.* at 437-42.

<sup>208</sup> 518 U.S. 470, 475-80 (1996).

<sup>209</sup> *Bates*, 544 U.S. at 443.

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



quite wrong when it assumed that any event, such as a jury verdict, that might ‘induce’ a pesticide manufacturer to change its label should be viewed as a requirement.”<sup>211</sup> Therefore, the Court stuck down the “effects-based” definition of requirement and explained that “[a] requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.”<sup>212</sup> The Court determined that, while a requirement is not a jury verdict alone, the definition could still “reach[] beyond positive enactments, such as statutes and regulations, to embrace common-law duties.”<sup>213</sup>

Also important to the analysis, the court found that the statute only preempts state law claims that are “*in addition to or different from*” the requirements under the FIFRA.<sup>214</sup> The Court concluded, “a state-law labeling requirement is not pre-empted by [the statute] if it is equivalent to, and fully consistent with, FIFRA’s misbranding provisions.”<sup>215</sup> The Court then went on to find support in its definition of requirement and the scope of preemption from its previous decision in *Medtronic*, which it clearly interpreted as creating a “parallel requirements” approach to preemption.<sup>216</sup> The Court referred to Justice O’Connor’s concurrence in *Medtronic*, which stated “[s]ection 360k does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*.”<sup>217</sup> According to the Court, this provided support for the principle that state law remedies could be provided to injured consumers where the federal law does not allow for such remedy.<sup>218</sup>

The Supreme Court also used *Medtronic* to justify its holding that FIFRA does not preempt state law tort claims where they parallel to federal requirements. The Court explained:

“Even if it may be necessary as a matter of Florida law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be ‘different from’ the federal rules in a literal sense, such a

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<sup>211</sup> *Id.*

<sup>212</sup> *Id.* at 445.

<sup>213</sup> *Id.* at 443.

<sup>214</sup> *Id.* at 447.

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

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

<sup>217</sup> *Id.* at 448 (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 513 (1996) (O’Connor, J., concurring in part and dissenting in part)).

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

difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule.”<sup>219</sup>

The Court further emphasized “that a state-law labeling requirement must in fact be equivalent to a requirement under FIFRA in order to survive pre-emption.”<sup>220</sup> The parallel requirements holding in *Bates* should be applied to preemption under the MDA; the relevant inquiry should become whether state common law tort claims equate to the federal requirements of safety imposed by the PMA process.

#### *A. Applying Bates to the Express Preemption Clause*

Although the two statutes are substantively different, the Supreme Court’s interpretation of the FIFRA’s express preemption clause is instructive as to the future interpretation of preemption under the PMA process. The language utilized by the two statutes is nearly identical and the Supreme Court looked to its own decision in *Medtronic* for the definition of “requirement.” The Supreme Court’s decision in *Bates* could allow state common law tort claims against device manufacturers where the claims parallel federal requirements. The PMA process itself is not a specific federal requirement under this analysis, because it is the guarantee of safety that the state law claims should be compared with.

The PMA process is meant to ensure the safety and effectiveness of medical devices and most state common law tort claims parallel the requirement of safety. Claims that parallel the interests promoted by PMA approval should be allowed to go forward in state courts. Preemption should only apply where state common law claims ask for something different than was required in the PMA process. The circuit courts in Category I and Category II should reevaluate their positions on preemption.<sup>221</sup> The Court’s language in *Bates* is very clear; it advocated an interpretation of the term “requirement” that allows for state common law tort claims where the federal requirements are also in the interest of safety.<sup>222</sup> The Court explained that “we would nevertheless have a duty to accept the reading that disfavors pre-emption. ‘[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly preempt state-law causes of action.’”<sup>223</sup>

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<sup>219</sup> *Id.* at 448, n.23 (quoting *Medtronic*, 518 U.S. at 495).

<sup>220</sup> *Id.* at 453.

<sup>221</sup> *See supra* Part II.A-B.

<sup>222</sup> *Bates*, 544 U.S. at 449.

<sup>223</sup> *Id.* (quoting *Medtronic*, 518 U.S. at 485).

*Bates* also provided examples of what Congress most likely intended when it drafted the preemption clause to prohibit additional or different state requirements. The court explained:

The legislative history of the 1972 amendments suggests that Congress had conflicting state labeling regulations in mind when crafting § 136v(b) [the FIFRA preemption clause]. As one industry representative testified: “Some States might want the word ‘flammable,’ some ‘inflammable.’ . . . Some States might want red lettering; others orange, another yellow, and so forth. We ask this committee, therefore, to recognize, as the Congress has in a number of similar regulatory statutes, the industry’s need for uniformity by providing for this in the act.” . . . By contrast, the lengthy legislative history is barren of any indication that Congress meant to abrogate most of the common-law duties long owed by pesticide manufacturers.<sup>224</sup>

This language indicates that Congress intended to preempt state specific requirements that would effectively result in conflicting interstate conditions and increased burdens on manufacturers. In the medical device context, the courts should apply the same analysis to allow claims that effect parallel requirements. It is likely that when Congress chose the term “requirement” it meant a requirement to be something specific about a device that differed from state to state, so as to ensure uniform device performance as well as to avoid overburdening device manufacturers. It does not follow that Congress intended to suspend state law claims sounding in negligence and product liability where medical devices malfunction and cause harm to consumers. The requirements imposed by state common law tort claims would be in concurrence with the intent of the MDA and the purview of the FDA’s regulation of the devices so long as the common law tort claims relate to safety. Applying the “parallel requirements” test to MDA preemption issues would effectively allow most state common law tort claims and provide consumers the necessary recourse in the law that Congress intended.

Although the *Bates* Court did not address the PMA process, the decision provides ammunition for opponents of preemption under the MDA. Opponents of preemption can cite to *Bates* and show how the holding allows state common law tort claims, which are similar to the general requirements imposed by the PMA process. Applying this analysis, opponents of preemption could show that state common law

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<sup>224</sup> *Id.* at 452 n.26 (citation omitted).

claims are merely different remedies, which are not precluded as requirements under section 360k.<sup>225</sup>

*B. The Appropriate Legal Standard*

With *Bates* as ammunition and the split amongs the circuits, the stage is set for change. Some persons injured by defective Class III medical devices can seek recourse in the law, while most cannot. The Supreme Court must step in, because, unfortunately, it appears that the circuits will remain divided. The meaning of the term “requirement” has been debated throughout numerous court opinions. Even the courts that align themselves in outcome are not uniform in the test they apply. The appropriate legal standard should be the “parallel requirements” test. The *Bates* decision should provide clarity to the preemption analysis and courts should find that state common law claims are not preempted where the FDA has failed to issue device specific requirements.

This debate has become one of judicial legislation. The circuit courts have tried to determine the scope of a statute’s express preemption clause armed with an ambiguous Supreme Court decision that has provided little guidance. Where the legislature has been unclear as to the scope of a statute’s coverage regarding preemption, judicial legislation should be avoided. The Supreme Court recognized an obligation to avoid judicial legislation where it is properly “left to Congress the task of drafting a narrower statute.”<sup>226</sup> Additionally, the Supreme Court stated, in *Burns v. United States*, that “[a]lthough ‘we construe statutes, where possible, so as to avoid rendering superfluous any parts thereof,’ it is not our practice to supplement their provisions simply because we think that some statutory provision might usefully do further duty than Congress has assigned to it.”<sup>227</sup> Unlike judicial legislation, which supplements a statute’s original intent, the Legislature has the power to change the wording of a statute to best represent its intent.

Concerns regarding the separation of powers are abundant where circuit courts make inconsistent decisions affecting private litigants’ rights. If Congress feels that state common law tort claims cause manufacturers harm, then it is within Congress’s power to amend the statute to specifically exclude such actions. The Ninth Circuit in *Kennedy v. Collagen* stated that “[t]he federal law requiring the pre-market approval of Class III devices was not enacted in order to free

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<sup>225</sup> *Id.* at 448 (citing *Medtronic*, 518 U.S. at 485 (O’Connor, J., concurring in part and dissenting in part)).

<sup>226</sup> *United States v. Nat’l Treasury Employees Union*, 513 U.S. 454, 479 (1995).

<sup>227</sup> *Burns v. United States*, 501 U.S. 129, 145 (1991) (citing *Astoria Fed. Sav. & Loan Ass’n v. Solimino*, 499 U.S. 946 (1991)).

manufacturers from the everyday burdens of the marketplace after they are permitted to enter it.”<sup>228</sup> Therefore, finding manufacturers immune from state common law tort claims is in direct contravention to the intent of Congress in enacting the MDA.

Forum shopping, due to the advantageous positions held by patients injured within a jurisdiction that allows state common law tort claims against Class III medical device manufacturers even where they are approved under a PMA process, is also a concern. Unfortunately, most persons injured by medical devices are not circuit court judges, lawyers, device manufacturers or members of the FDA. Rather, they are injured consumers who would not know to check whether the medical device they are using was approved under the § 510(k) process or the PMA process. Consumers expect that, if they are injured by a device through no fault of their own, they have recourse for their suffering through the legal system. If the goal behind enacting the MDA was protecting persons injured by medical devices, taking away the right to sue for these injuries is unfair.

Allowing state common law tort claims would relieve some of the burden placed on the FDA as the ultimate arbitrator of what is safe and good.<sup>229</sup> The FDA is the ultimate gatekeeper of what medical devices enter the market. In addition, the FDA takes the pressure off the manufacturer by making sure the product is safe. The public relies on the FDA for its critical determination that a medical device is safe for use. Recently, the FDA has come under major fire with regards to its handling of medical devices and the safety it promises.<sup>230</sup> Failing to give the injured a right to compensation in the legal system is manifestly unjust. The FDA’s approval of a device is a necessary and important step in achieving the goal of safety for consumers, but the legal system should step in where the FDA fails to provide recourse for the injured.

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<sup>228</sup> *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1460 (9th Cir. 1995), *overruled in part by Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (“Premarket approval is supposed to benefit consumers, not create a rose garden, free from liability, for manufacturers. Courts which have held to the contrary have done so in contravention of the FDA’s regulations and statement concerning the preemptive scope of the MDA.”).

<sup>229</sup> For an interesting discussion on a different problem related to the FDA’s regulation of medical devices stemming from its role as the primary gatekeeper of market access, see Noel D. Campbell, *Replace FDA Regulation of Medical Devices with Third-Party Certification*, No. 288, CATO POLICY ANALYSIS, Nov. 12, 1997, <http://www.cato.org/pubs/pas/pa-288.pdf>.

<sup>230</sup> See Barry Meier, *U.S. Regulators Criticized on Oversight of Heart Devices*, N.Y. TIMES, September 16, 2004.

## CONCLUSION

Finding state common law tort claims preempted by the FDA's premarket approval of a Class III medical device would render injured consumers without the appropriate recourse in the law. "[T]he MDA provides no federal means by which injured plaintiffs can pursue legal remedies against the manufacturers of defective medical devices."<sup>231</sup> By allowing such claims to proceed against device manufacturers, in certain cases, the states would be allowing "remedies" rather than imposing "requirements." The "parallel requirements" test provides the appropriate analysis by which courts can uniformly approach a growing problem. Additionally, tort law claims generally relate to the safety of the device and parallel the federal safety standards. The Supreme Court decision in *Bates* should be combined with the holding in *Medtronic* to create a more permissive scheme for allowing common law claims where the medical device is approved by the PMA process and not subject to any specific requirements.

Furthermore, allowing state common law claims into court would not be the end-all for device manufacturers. The success of such common law tort claims would be questionable because the FDA's approval should naturally create a *presumption* of safety that the plaintiff would have to overcome. The issue is getting such claims into court and allowing injured consumers a right of action. By allowing state law claims, the states would not be an additional gate through which the device manufacturer must pass; the FDA will retain its primary role as a gatekeeper. However, once allowed through that gate by the FDA, the medical device manufacturers should not be able to roam free by gaining substantial immunity from suit because their devices have been approved by the PMA process. In light of the split among the circuit courts and the Supreme Court's decisions in *Medtronic* and *Bates*, state common law claims should not be preempted where they parallel federal requirements. Injured consumers should be allowed to bring claims against medical device manufacturers. The ultimate goal of the FDA's role in medical device regulation *should* be safety of the patient. Allowing state common law claims would support that goal.

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<sup>231</sup> *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1379 (11th Cir. 1999) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 487 (1996)) ("Reading the PMA process to impose specific federal requirements that enjoy preemptive effect under section 360k, therefore, would deprive all persons suffering injury as a result of a defective device--the very class of persons that Congress intended to protect by enacting the MDA--of 'most, if not all relief.'").