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# Meeting the Objectives of the MDA: Implied Preemption of State Tort Claims by the Medical Device Amendments

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**MEETING THE OBJECTIVES OF THE MDA: IMPLIED  
PREEMPTION OF STATE TORT CLAIMS BY THE  
MEDICAL DEVICE AMENDMENTS**

THERESA J. PULLEY RADWAN<sup>1</sup>

I.	INTRODUCTION . . . . .	344
II.	THE MEDICAL DEVICE AMENDMENTS . . . . .	344
	A. <i>Classification of Medical Devices</i> . . . . .	345
	B. <i>Good Manufacturing Practice Requirements (GMP)</i> . . . . .	346
	C. <i>Labeling Requirements</i> . . . . .	346
	D. <i>The Pre-Market Approval Process</i> . . . . .	346
	E. <i>Exceptions to the Pre-Market Approval Process</i> . . . . .	347
	F. <i>Post-Market Regulation</i> . . . . .	348
	G. <i>Purposes of the Act</i> . . . . .	349
	H. <i>The Express Preemption Clause of the Medical Device Amendments</i> . . . . .	350
III.	THE GENERAL LAW OF PREEMPTION . . . . .	352
	A. <i>Express Preemption</i> . . . . .	352
	B. <i>Implied Preemption</i> . . . . .	352
	C. <i>Traditional State Functions</i> . . . . .	354
	D. <i>Remedies</i> . . . . .	355
IV.	PREEMPTION OF STATE TORT CLAIMS UNDER THE MEDICAL DEVICE AMENDMENTS . . . . .	355
	A. <i>The Caselaw on Preemption</i> . . . . .	355
	B. <i>State Torts: Elements</i> . . . . .	357
	1. <i>Design Defects</i> . . . . .	358
	2. <i>Manufacturing Defect Claims</i> . . . . .	358
	3. <i>Inadequate Warning</i> . . . . .	359
	4. <i>Strict Liability</i> . . . . .	360
	5. <i>Warranties</i> . . . . .	361
	C. <i>The Case for Implied Preemption</i> . . . . .	361
V.	CONCLUSION . . . . .	363

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## I. INTRODUCTION

During its 1995 term, the United States Supreme Court granted certiorari to the Eleventh Circuit Court of Appeals to hear the case of *Lohr v. Medtronic, Inc.*<sup>2</sup> In doing so, the Court agreed to resolve a debate that began two decades earlier—determining if Congress, in passing the Medical Device Amendments<sup>3</sup> (MDA) to the Federal Food, Drug and Cosmetic Act of 1938,<sup>4</sup> intended to prevent potential plaintiffs from using state tort law to recover against manufacturers who place an allegedly defective device on the market. In a complicated web of lower court decisions, some state tort claims have been preempted and some have been permitted pursuant to the federal law of preemption.

This article attempts to reconcile the competing purposes of the MDA, and to offer one alternative to effectuate Congress' purposes without preempting some claims and permitting others. First, this article will describe the arrangement of the MDA, including the classification provisions for medical devices and the preemption provision of the MDA. Next, this article will interpret the caselaw regarding preemption in general, and specifically preemption of state tort claims by the MDA. Finally, this article seeks to reconcile two competing purposes of Congress in enacting the MDA through implied preemption of state tort claims, with exceptions for devices which have never been subjected to the Food and Drug Administration's (FDA) pre-market approval process, or for which such approval was gained fraudulently.

## II. THE MEDICAL DEVICE AMENDMENTS

Prior to the enactment of the MDA in 1976,<sup>5</sup> medical devices were regulated primarily by the state through actions in tort and contract.<sup>6</sup> The FDA's power

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<sup>2</sup>116 S. Ct. 806, *aff'd in part, rev'd in part*, 116 S. Ct. 2240 (1996). Oral argument in *Lohr* was heard on April 23, 1996. At oral argument the Supreme Court justices appeared to be skeptical of preempting all state tort claims. As Chief Justice William H. Rehnquist noted, preemption of all state tort claims was "an extraordinary sweep." Associated Press, *Justices Skeptical in Medical Device Case*, BOSTON GLOBE, Apr. 24, 1996.

<sup>3</sup>Medical Device Amendment, Pub. L. No. 94-295 (1976).

<sup>4</sup>The Food, Drug and Cosmetic Act gave the FDA some authority to regulate devices after they had been introduced onto the market, but the Act was not widely used, except on "quack" devices. Angela Woodley Kronenberg, *King v. Collagen Corporation: FDA Approval Insulates Medical Device Manufacturers from State Common Law Liability*, 11 J. CONTEMP. HEALTH L. & POL'Y 563 (Spring 1995).

<sup>5</sup>The MDA were passed in the aftermath of numerous deaths and injuries resulting from the largely unregulated Inter-Uterine Device industry. Laura K. Jortberg, *Who Should Bear the Burden of Experimental Medical Device Testing: The Preemptive Scope of the Medical Device Amendments under Slater v. Optical Radiation Corp.*, 43 DEPAUL L. REV. 963, 975 (1994).

<sup>6</sup>*Lohr v. Medtronic, Inc.*, 116 S. Ct. at 2240 (see lower court, 56 F.3d 1335, 1339 (11th Cir. 1995)).

to regulate was limited to devices labeled as "drugs."<sup>7</sup> The MDA provided the FDA the power to regulate all medical devices.

#### A. Classification of Medical Devices

The MDA classify all medical devices into one of three categories. These categories dictate the extent of required FDA regulation over the device. Class I devices include those that are of little or no threat to public health,<sup>8</sup> such as tongue depressors or rubber gloves. Class I devices are subject only to the generally applicable provisions included in the MDA, such as labeling requirements and good manufacturing practice requirements.<sup>9</sup>

Devices which pose a threat to public health, but are not generally life-threatening, fall into the category of Class II devices.<sup>10</sup> Devices such as tampons are included in this category. Like Class I devices, Class II devices are subject to the MDA's general provisions. In addition, device-specific controls may be enacted by the FDA to ensure the safety of these devices, including "the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines . . . , recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance."<sup>11</sup> In 1990, under the Safe Medical Devices Act, Congress altered this requirement, so that the FDA no longer needs to pass such device-specific regulations.<sup>12</sup>

The most regulated devices under the MDA are Class III devices, which have the potential for an "unreasonable" risk of injury, or are designed to support or sustain life.<sup>13</sup> Heart pacemakers and catheters fall within this category. Less than five percent of all medical devices are included within this highly-regulated category.<sup>14</sup> Beyond compliance with the general provisions

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<sup>7</sup>See *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1319 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995).

<sup>8</sup>21 U.S.C. § 360c(a)(1)(A) (1976).

<sup>9</sup>For further discussion on these generally applicable requirements, see *supra* §§ (I)(B) and (I)(C).

<sup>10</sup>21 U.S.C. § 360c(a)(1)(B) (1976).

<sup>11</sup>*Id.*

<sup>12</sup>Other changes pursuant to the 1990 Amendments included increased power of the FDA to stop distribution and inform hospitals of potentially dangerous devices, 21 U.S.C. § 360h(e)(1)(B) (1976); power of the FDA to subpoena evidence in evaluating PMA applications, 21 U.S.C. § 333(f)(2)(A) (1976); and creation of civil penalties, up to \$15,000 for each violation and \$1 million in any individual proceeding, for violations of the FDA provisions, 21 U.S.C. § 333(f)(1)(A) (1976).

<sup>13</sup>*Id.* at § 360c(a)(1)(C) (1976).

<sup>14</sup>*Hearings Before the House Government Reform and Oversight Comm. Subcomm. on National Economic Growth, Natural Resource and Regulatory Affairs* (1995) (prepared testimony of Grant A. Wright, President of Inventive Products, Inc.).

of the MDA, Class III devices must undergo a rigorous pre-market approval (PMA) process before being introduced into the marketplace.<sup>15</sup>

### *B. Good Manufacturing Practice Requirements (GMP)<sup>16</sup>*

The MDA permit the FDA to enact regulations governing the "manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation . . ." <sup>17</sup> of medical devices to ensure good manufacturing practices and safety of these devices. This provision applies to all devices, regardless of classification under the MDA.

### *C. Labeling Requirements<sup>18</sup>*

Although the MDA provide little guidance regarding requirements for labeling of medical devices, regulations enacted by the FDA pursuant to its authority under the MDA create labeling requirements for manufacturer compliance.<sup>19</sup> These provisions require that the manufacturer provide a label for any device, excepting surgical devices, indicating whether a device is for use only upon prescription or by a physician.<sup>20</sup> The labeling provisions also require a manufacturer to dictate the proper use of the device and any side effects or hazards of the device, unless commonly known to licensed practitioners.<sup>21</sup> Manufacturers must also include the date of issuance or the date of the latest revision of the current label.<sup>22</sup>

### *D. The Pre-Market Approval Process*

The PMA process begins with an application to the FDA, providing to the FDA all information which the applicant knows or reasonably should know about the design, manufacture, use, or labeling of the device for which it seeks approval.<sup>23</sup> This disclosure should include an explanation of any potential problems regarding the device which developed or occurred during testing or usage of the device.

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<sup>15</sup>21 U.S.C. § 360e(c)(1) (1976).

<sup>16</sup>21 U.S.C. §§ 360j(f) (1976).

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

<sup>18</sup>21 C.F.R. § 801.109 (1995).

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

<sup>20</sup>21 C.F.R. § 801.19(b)(1) (1995).

<sup>21</sup>21 C.F.R. § 801.109(c) (1995).

<sup>22</sup>21 C.F.R. § 801.109(e) (1995).

<sup>23</sup>21 U.S.C. § 360c(e) (1976); *Understanding the FDA's Medical Device Pre-Market Approval (PMA) Process*, BIOMEDICAL MARKET NEWSL., Apr. 1, 1994.

Once the application is complete and sent to the FDA, the FDA submits the application to an outside panel of experts for review.<sup>24</sup> The experts generally come from the fields of medicine, science, and manufacturing.<sup>25</sup> The panel then reviews the application, and submits its recommendation to the FDA. Although the FDA generally accepts the recommendation of the panel, it is not obliged to do so.<sup>26</sup>

The PMA process is fraught with criticism. One of the most frequent criticisms of the process is its alarming lack of speed.<sup>27</sup> Approval of a medical device through the PMA process can take months or even several years.<sup>28</sup> One example of the painfully slow PMA process is the situation of an artificial heart developed by Novacor in 1984. The heart has been used successfully since 1984 throughout Europe, but could not be sold in the United States a decade later because it had not yet received FDA approval.<sup>29</sup> As a result of instances like this, many medical professionals complain that "U.S. patients are being deprived of the newer, more advanced generations of devices to which European patients have access. Americans are finding that they must go abroad to take advantage of these technologies. And U.S. device firms are themselves moving production and research facilities to other countries."<sup>30</sup> For example, in fiscal-year 1993, the FDA received approximately 100 new applications for approval of Class III medical devices for market. The FDA approved only twenty-four devices for market.<sup>31</sup>

#### *E. Exceptions to the Pre-Market Approval Process*

When the MDA were introduced in 1976, a number of medical devices were already on the market. Indeed, it was the defects in these devices which fueled the legislative fire to pass the MDA. However, in passing the MDA, Congress realized that some exceptions would need to be made to prevent the complete disappearance of medical devices, particularly effective devices, from the

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<sup>24</sup>21 U.S.C. §§ 360e(c)(1), § 360e(c)(2) (1976).

<sup>25</sup>21 U.S.C. § 360c (1976).

<sup>26</sup>*Understanding the FDA's Medical Device Pre-Market Approval Process*, *supra* note 23.

<sup>27</sup>*Id.*

<sup>28</sup>*Id.*

<sup>29</sup>Tom Davey, *Medical Device Firms in FDA Stranglehold*, S.F. BUS. TIMES, May 20, 1994.

<sup>30</sup>HIMA's 40 New Recommendations on Reforming the FDA, BIOMEDICAL MARKET NEWSL., Feb. 1, 1995 (quoting report); *see also* Davey, *supra* note 29 (time period for approval of minor modifications was an average of 195 days in 1993).

<sup>31</sup>*Understanding the FDA's Medical Device Pre-Market Approval (PMA) Process*, *supra* note 23.

market in 1976.<sup>32</sup> As a result, three exceptions were created to the PMA requirement.<sup>33</sup>

Any device which was introduced before the effective date of the MDA, May 28, 1976, is exempt from the PMA requirement.<sup>34</sup> This provision is known as the "grandfather clause." Additionally, any device which is currently being tested thoroughly by the manufacturer for safety and effectiveness, in order to stimulate development of the device, does not need to undergo the PMA process.<sup>35</sup> Finally, a device which is "substantially equivalent" to a device already on the market need not receive approval before marketing.<sup>36</sup> Pre-market notification of the substantially equivalent device is required in lieu of the PMA process.<sup>37</sup> To be "substantially equivalent" to a device already on the market, a device should have the same intended use and technological characteristics or same safety and effectiveness as the device already on the market.<sup>38</sup>

#### F. Post-Market Regulation

A manufacturer's duty to report to the FDA concerning medical devices does not end with approval under the PMA process.

Every person who is a manufacturer, importer, or distributor of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness.<sup>39</sup>

This duty to report to the FDA regarding the device includes an obligation to report to the FDA any instance in which the manufacturer has information

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<sup>32</sup>Dale B. Hinson, *High Noon for Device Preemption—A Second Opinion*, 5 MEALEY'S LITIG. REP.: DRUGS & MED. DEVICES 18 (March 4, 1996).

<sup>33</sup>According to one source, ninety-nine percent of all medical devices currently enter the market without regulation by the PMA process through one of these exceptions. Brief Amici Curiae of American Association of Retired Persons, Consumers Union, Consumer Federation of America, National Women's Health Network, Command Trust Network and Valv in Support of Respondents/Cross-Petitioners Lora Lohr and Michael Lohr, *Lohr v. Medtronic, Inc.*, 116 S. Ct. at 2240 (Nos. 95-754 and 95-886) (citing H.R. Rep. 808, 101st Cong., 2nd Sess. 14, reprinted in 1990 U.S.C.C.A.N. 6307). Presumably, this extraordinary number will decrease as new technology develops.

<sup>34</sup>21 U.S.C. § 360e(b)(1)(A) (1976).

<sup>35</sup>*Id.* at § 360j(g).

<sup>36</sup>*Id.* at § 360e(b)(1)(B).

<sup>37</sup>*Id.* at § 360(k).

<sup>38</sup>21 U.S.C. § 360c(i)(1)(A).

<sup>39</sup>*Id.* at § 360i(a).

which reasonably indicates that the device may have played a factor in a death or serious injury,<sup>40</sup> or malfunctioned such that it would have been likely to cause death or serious injury.<sup>41</sup> Similar obligations to report potentially defective devices rest upon users of the devices, including doctors, hospitals, ambulances, nursing homes, and outpatient treatment facilities.<sup>42</sup>

Under the 1990 Amendments to the MDA, post-market surveillance is required for devices first introduced into the market after January 1, 1991, if the device may cause serious injury or death, is intended to be used in lengthening life, or if the device presents a serious health risk.<sup>43</sup> This amendment does not apply to devices approved under the original MDA.

### G. Purposes of the Act

The MDA were passed to effectuate two strong, but sometimes conflicting, interests. The first of these interests is to promote the safety and effectiveness of medical devices in order to protect public health.<sup>44</sup> The second is to encourage the development and marketing of medical devices by creating a uniform regulatory scheme, and to prevent overregulation of the devices so that manufacturers can develop these new products without a prohibitive cost.<sup>45</sup> The House of Representatives enumerated these competing interests when passing the MDA:

Those involved in the development, promotion, and application of medical devices generally agree that the public deserves more protection against unsafe, unproven, ineffective, and experimental medical devices. But this belief is counterbalanced by an equally strong conviction that excessive or ill-conceived Federal device regulation would stifle progress in this field.<sup>46</sup>

The Senate concurred in these interests, stating that "[s]imply put, the [MDA] sought to avoid overregulation, thus eliminating unnecessary resource costs to industry and the government, foster incentives to encourage innovation in a

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<sup>40</sup>*Id.* at § 360i(a)(1)(A).

<sup>41</sup>*Id.* at § 360i(a)(1)(B).

<sup>42</sup>21 U.S.C. § 360i(b).

<sup>43</sup>*Id.* at § 360l.

<sup>44</sup>*Id.* at §§ 360c(a)(1)(A)(i), 360c(a)(1)(B), 360e(d)(2).

<sup>45</sup>*Id.* at §§ 360j(g)(1), 360k(a). *See also*, Richard Thornburgh, *Don't Let Litigation Kill Medical Miracles*, WASH. TIMES, Apr. 23, 1996 at A15 (quoting Sen. Ted Kennedy as stating that the FDA was "structured to guard against excessive governmental restrictions which might inhibit innovation in the development and advancement of biomedical products".)

<sup>46</sup>H.R. Rep. No. 853, 94th Cong., 2d Sess. 10 (1976); *see also*, S. Rep. No. 33, 94th Cong., 1st Sess. 5, 12 (1976).



relatively youthful industry and, most importantly, provide the public reasonable assurances of safe and effective devices."<sup>47</sup>

The struggle between these two objectives, promoting a means for ensuring safe and effective products for consumers while preventing overregulation for manufacturers, creates a conflict in the courts. In an ideal world, these two objectives would work together to quickly and efficiently put a safe and effective device on the market. The world is far from ideal, however, and when a product is introduced into the market which is not safe, the courts are left to balance these two competing interests.

On the one hand, to promote safe products to the greatest extent possible would mandate that plaintiffs be permitted to maintain an action in tort or contract against the manufacturer for the production of an unsafe product. In prohibiting costly overregulation of manufacturers, however, the courts would seek to prevent such state-law claims. It is the inherent conflict between these two goals which has led to battle in the courts.

#### *H. The Express Preemption Clause of the Medical Device Amendments*

In enacting the MDA, Congress considered the possibility that state law would potentially conflict with the new federal law. A preemption clause within the MDA states that:

Except as provided in subsection (b) of this section, 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.<sup>48</sup>

This provision expressly preempts state law claims which are different from or create additional requirements to the provisions of the MDA.

Until 1996, nearly every court which had considered this language had held that state tort law is a state "requirement" under this provision because state tort law has the ability to require a manufacturer to endure additional testing or modification to prevent liability.<sup>49</sup> The plurality in the Supreme Court's recent decision in the *Medtronic* case disagreed, holding that a state law is only

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<sup>47</sup>S. Rep. No. 513, 101st Cong., 2d Sess. 13 (1990) (discussing 1990 Amendment).

<sup>48</sup>21 U.S.C. § 360k(a) (1976).

<sup>49</sup>*Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992); *Michael*, 46 F.3d at 1323; *Reeves v. Acromed Corp.*, 44 F.3d 300, 304 (5th Cir.), *cert. denied*, 115 S. Ct. 2251 (1995); *Anguiano v. E.I. DuPont De Nemours & Co., Inc.*, 44 F.3d 806, 809 (9th Cir. 1995); *Medtronic*, 56 F.3d at 1342; *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 16 (1st Cir. 1994); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1168 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995). *But see*, *Kennedy v. Collagen*, 67 F.3d 1453 (9th Cir. 1995), *cert. denied*, 116 S. Ct. 2579 (1996).

a "requirement" if it is "specific." Section 360(k) "refers to 'requirement' many times throughout its text. In each instance, the word is linked with language suggesting that its focus is device-specific enactments of positive law by legislative or administrative bodies, not the application of general rules of common law by judges and juries."<sup>50</sup> Whether a state law is sufficiently "specific" to be a "requirement" is an inherently factual determination for which the higher court provided little guidance. Furthermore, the concurring opinion of Justice O'Connor states that a requirement need not be specific to be preempted, so long as it is different from or additional to a federal requirement.<sup>51</sup> The Court far from settled the issue of how specific or detailed a law must be to trigger preemption by the MDA, or even whether the law must be codified to be preempted.

The PMA process is also a "requirement applicable under this chapter."<sup>52</sup> Thus, "specific" state tort law may be preempted by the MDA to the extent that it creates a different or additional demand upon a manufacturer.<sup>53</sup>

At first glance, this provision seems to indicate that many state law causes of action could be preempted by the MDA. However, one provision included in the MDA, the "Savings Clause" indicates otherwise. The Savings Clause states that "[c]ompliance with an order [under the MDA] shall not relieve any person from liability under Federal or State law."<sup>54</sup> Clearly, this provision indicates that the MDA was not intended by Congress to preempt all state and federal liability for manufacturers.<sup>55</sup> However, the Savings Clause also fails to state that *all* state tort law liability is preserved in light of the MDA.<sup>56</sup> Furthermore, the Supreme Court has held that a "general 'remedies' savings clause cannot be allowed to supersede the specific substantive pre-emption provision . . . ."<sup>57</sup> Thus, if congressional intent to preempt is clear, even a Savings Clause cannot save state remedies.

Under the preemption provision of the MDA, a state may receive an exemption from the preemption provisions if required by "compelling local conditions" and "compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter".<sup>58</sup>

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<sup>50</sup>*Medtronic*, 518 U.S. \_\_\_, 64 U.S.L.W. 4625, 4631 (1996).

<sup>51</sup>*Id.* at 4636.

<sup>52</sup>*Martello*, 42 F.3d at 1169.

<sup>53</sup>For further discussion, see *infra* Section IV and notes 105-107.

<sup>54</sup>21 U.S.C. § 360(h) (1976).

<sup>55</sup>*Medtronic*, 56 F.3d at 1342.

<sup>56</sup>*Id.*

<sup>57</sup>*Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 385 (1992).

<sup>58</sup>12 U.S.C. § 360k(b) (1976).

## III. THE GENERAL LAW OF PREEMPTION

Article VI of the United States Constitution states that:

This Constitution, and the laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.<sup>59</sup>

Pursuant to the Supremacy Clause, numerous cases have held that the Constitution, and federal law passed thereunder, is the supreme law of the land.<sup>60</sup> "[C]onsideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law."<sup>61</sup>

*A. Express Preemption*

Preemption of state law by federal law is ultimately a question of congressional intent.<sup>62</sup> Federal law preempts state law only if Congress has indicated a clear intent to preempt by passing the federal law.<sup>63</sup> If the federal statute contains an express preemption provision, the courts must first look to this provision<sup>64</sup> because the express preemption provision "necessarily contains the best evidence of Congress' pre-emptive intent."<sup>65</sup> In a close case, the presumption is against preemption.<sup>66</sup>

*B. Implied Preemption*

When congressional intent is not clearly stated in an express preemption provision, congressional intent must be inferred. One method of inferring congressional intent is to use the reasonable interpretation of an agency, if

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<sup>59</sup>U.S. CONST. art. VI, § 2.

<sup>60</sup>*CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 663-64 (1993) (preempting state tort claims regarding permitted speed of train as in conflict with Federal Railroad Safety Act, but permitting claim for negligence); *Hillsborough County v. Automated Med. Lab.*, 471 U.S. 707, 712 (1985) (citing *Gibbons v. Ogden*, 9 U.S. (1 Wheat.) 1, 211 (1824)).

<sup>61</sup>*Maryland v. Louisiana*, 451 U.S. 725, 746 (1981).

<sup>62</sup>*Hawaiian Airlines, Inc. v. Norris*, 114 S. Ct. 2239, 2243 (1994); *Forbus v. Sears Roebuck & Co.*, 30 F.3d 1402, 1405 (11th Cir. 1994).

<sup>63</sup>*Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

<sup>64</sup>*Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 95 (1983); *Nationsbank of N.C., N.A. v. Variable Annuity Life Ins. Co.*, 115 S. Ct. 810, 813-14 (1995).

<sup>65</sup>*CSX Transp., Inc.*, 507 U.S. at 664.

<sup>66</sup>*Cipollone*, 505 U.S. at 518; *Morales*, 504 U.S. at 383-85.

Congress has delegated its rulemaking authority to an agency.<sup>67</sup> Conveniently, the FDA has published its interpretation of the preemption provisions of the MDA, stating that, "[s]tate or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act . . . ."<sup>68</sup> The courts which have considered the FDA's interpretation in analyzing preemption under the MDA have unanimously held that the FDA's interpretation is a reasonable one.<sup>69</sup> The problem with the FDA's interpretation is that it fails to indicate what requirements are sufficiently "specific" to invoke preemption.

Congressional intent to preempt may also be inferred when an implied conflict exists.<sup>70</sup> An implied conflict arises whenever a person cannot comply with both federal and state laws simultaneously<sup>71</sup> or if the state law stands as an obstacle to accomplishing Congress' purpose in enacting the federal law.<sup>72</sup>

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<sup>67</sup>*Chevron, U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837, 843-44, *reh'g denied*, 468 U.S. 1227 (1984). *But see, Anguiano*, 44 F.3d at 809; *Ginochio v. Surgikos, Inc.*, 864 F. Supp. 948, 953 (N.D. Cal. 1994); *Oja v. Howmedica, Inc.*, 848 F. Supp. 905, 906-07 (D. Colo. 1994); *Larsen v. Pacesetter Sys., Inc.*, 837 P.2d 1273, 1282 (Haw. 1992).

<sup>68</sup>21 C.F.R. § 808.1 (1976).

<sup>69</sup>*Medtronic*, 56 F.3d at 1345; *Michael*, 46 F.3d at 1324; *Reeves*, 44 F.3d at 304-05 (metal bone implant causes back injury); *Martello*, 42 F.3d at 1169; *Mendes*, 18 F.3d at 17-19. Note, however, that the Supreme Court has only considered the FDA interpretation in reference to the MDA's express preemption provision on one occasion. *Hillsborough County*, 471 U.S. at 714-15. Since rendering that decision, however, the Supreme Court issued its decision in *Cipollone*, a decision which many courts have held to mean that if a federal statute has an express preemption provision, the Court may not consider any other evidence of congressional intent in analyzing the extent of preemption. *See, e.g., Mendes*, 18 F.3d at 16; *Greenwood Trust Co. v. Commonwealth of Mass.*, 971 F.2d 818, 823 (1st Cir. 1992), *cert. denied*, 506 U.S. 1052 (1993) (When "Congress includes an express preemption clause in a statute, judges ought to limit themselves to the preemptive reach of that provision without essaying any further analysis under the various theories of implied preemption."). *But see, Freightliner Corp. v. Myrick*, 115 S. Ct. 1483, 1487 (1995) (holding that *Cipollone* does not stand for the proposition that if Congress has included an express preemption provision, implied preemption is not possible, rather it refuses to preempt design defect claims for truck brake systems in light of the National Safety Act).

<sup>70</sup>Some courts have indicated that implied preemption may not be used when, as in this situation, an express preemption provision exists. *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1420 (5th Cir), *cert. denied*, 510 U.S. 824 (1993).

<sup>71</sup>A variation of this type of implied preemption occurs when state standards are more stringent than federal standards, such that compliance with federal standards may not be sufficient to prevent liability. For example, in *Jones v. Rath Packing Co.*, a California statute regulating the labeling of weight on packages of meat was preempted by the Federal Meat Inspection Act because the state statute failed to account for the possibility of moisture loss, and thus, was more strict than the federal standard. 430 U.S. 519, 531 (1977).

<sup>72</sup>*Freightliner Corp.*, 115 S. Ct. at 1487, (citing *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

A state statute which is inconsistent with the objectives of a federal statute must yield to the federal statute.<sup>73</sup> In *Morales v. Trans World Airlines*,<sup>74</sup> for example, the court held that the Airline Deregulation Act of 1978, which prohibited state laws "relating to" airline rates, preempted guidelines governing the content and format of airline advertising written by the National Association of Attorneys General, because a significant relationship existed between the cost of advertising and rates charged to customers.<sup>75</sup> *Morales* indicates that a conflict may be found by looking beneath the language of the statute to the actual effect of the laws.

When there is no conflict between state and federal law, preemption is not implied.<sup>76</sup> For example, in *Department of Revenue of Oregon v. ACF Industries, Inc.*,<sup>77</sup> the Court held that a railroad could be permitted to pay state property tax despite a provision of the federal act prohibiting taxes that discriminate against railroads. Because the property tax was generally applicable to all property, rather than simply railroads, the tax did not violate Congress' intent to prohibit discriminatory taxes.<sup>78</sup> Thus, even if Congress did not expressly state that a state law is preempted, the Supremacy Clause dictates that state law succumb to federal law in the event of a conflict; to preempt, however, requires a true conflict between purposes or the language of the law.

### C. Traditional State Functions

The courts use caution in preempting state laws concerning powers which are traditionally given to the states.<sup>79</sup> For example, public health and safety are matters traditionally governed by the states.<sup>80</sup> "When determining the breadth of a federal statute that impinges upon or pre-empts the States' traditional powers, [courts] are hesitant to extend the statute beyond its evident scope."<sup>81</sup>

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<sup>73</sup>*Air Line Pilots Ass'n Int'l v. UAL Corp., Int'l Ass'n*, 874 F.2d 439, 445 (7th Cir. 1989), *aff'd*, 897 F.2d 1394 (7th Cir. 1990) (holding that provision in collective bargaining agreement violated Railway Labor Act, and thus, could not be enforced under state law).

<sup>74</sup>504 U.S. at 374.

<sup>75</sup>*Id.* at 388-89.

<sup>76</sup>*Bravman v. Baxter Healthcare Corp.*, 842 F. Supp. 747, 753 (S.D.N.Y. 1994) (holding that MDA preempts state actions regarding duty to warn).

<sup>77</sup>114 S. Ct. 843 (1994).

<sup>78</sup>*Id.* at 848.

<sup>79</sup>*King v. Collagen Corp.*, 983 F.2d 1130, 1137 (1st Cir.), *cert. denied*, 510 U.S. 824 (1993) (citing *Hillsborough County*, 471 U.S. at 715).

<sup>80</sup>*CSX Transp., Inc.*, 507 U.S. at 664; *Talbott v. C.R. Bard, Inc.*, 865 F. Supp. 37, 43 (D. Mass. 1994), *aff'd*, 63 F.3d 25 (1st Cir. 1995); *Kemp v. Pfizer, Inc.*, 835 F. Supp. 1015, 1019 (E.D. Mich. 1993).

<sup>81</sup>*Department of Revenue of Oregon v. ACF Indus.*, 114 S. Ct. 843, 850 (1994) (citing *Cipollone*, 112 S. Ct. at 2614). *See also*, *Hillsborough County*, 471 U.S. at 715 (public health

Because these powers are traditionally reserved for the states, the courts may assume that Congress did not intend to preempt them absent a clear statement of intent from Congress to the contrary.

#### D. Remedies

Courts also use caution in the preemption of state law claims if preemption renders a plaintiff without remedy.<sup>82</sup> In *Silkwood v. Kerr-McGee*,<sup>83</sup> the Court considered preemption of state tort laws by the federal Atomic Energy Act.<sup>84</sup> In *Silkwood*, federal regulations governed defendant's nuclear power plant, which was contaminated with plutonium. Despite an apparent attempt by Congress to preempt state claims, the Court held that Congress could not have intended to leave a plaintiff who was exposed to plutonium without a remedy against a corporation simply because the plant was regulated by federal law.<sup>85</sup> Again, the courts may assume that Congress did not intend to leave injured plaintiffs without a judicial remedy, absent a clear indication of congressional intent to do so.

### IV. PREEMPTION OF STATE TORT CLAIMS UNDER THE MEDICAL DEVICE AMENDMENTS

#### A. The Caselaw on Preemption

The Supreme Court heard arguments in the case of *Lohr v. Medtronic, Inc.*<sup>86</sup> on April 23, 1996. *Medtronic* is the only case which the U.S. Supreme Court has heard on preemption of state tort law by the MDA since its enactment in 1976.<sup>87</sup> *Medtronic* arose from the claims of a patient who was implanted in 1987 with a Medtronic pacemaker which failed three years later due to a defective wire carrying electronic impulses to the heart. The Eleventh Circuit Court of Appeals

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act governing collection procedures did not preempt local ordinance governing other aspects of blood donation).

<sup>82</sup>*Silkwood v. Kerr-McGee*, 464 U.S. 238, 251-52 (1984) ("It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.") However, the cases at hand do not involve illegal conduct as long as FDA guidelines are complied with, and thus the *Silkwood* quote does not apply. Indeed, these cases are just the opposite in that corporations are trying to preempt claims because they complied with federal law.

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

<sup>84</sup>42 U.S.C. § 2021(a)(1) (1959).

<sup>85</sup>*Silkwood*, 464 U.S. at 257.

<sup>86</sup>*Medtronic*, 116 S. Ct. at 2240.

<sup>87</sup>The Court has refused similar cases. See e.g., *Michael*, 46 F.3d 1316 (3d Cir.), cert. denied, 116 S. Ct. 67 (1995); *Reeves*, 44 F.3d 300 (5th Cir.), cert. denied, 115 S. Ct. 2251 (1995); *Martello*, 42 F.3d 1167 (8th Cir. 1994), cert. denied, 115 S. Ct. 2614 (1995).

held that most of plaintiff's state law tort claims were preempted by the MDA's provisions governing manufacturing and labeling of medical devices.<sup>88</sup>

On June 26, 1996, the Supreme Court rendered a decision in *Medtronic*, written by Justice Stevens, in which Justices Kennedy, Souter, and Ginsburg concurred.<sup>89</sup> Justices Rehnquist, O'Connor, Scalia, Thomas, and Breyer concurred in part, and dissented in part. The Court reversed, in part, the decision of the Eleventh Circuit, holding that none of the plaintiffs' state law tort claims were preempted by the Medical Device Amendments. In the process of making this decision, six other cases to which the Supreme Court had granted certiorari were remanded in light of the *Medtronic* decision.<sup>90</sup>

The unusual part of this decision was that the Medtronic pacemaker at issue in the case never went through the PMA process. It entered the market as the "substantial equivalent" of a device which entered the market prior to the effective date of the MDA. Thus, neither the Medtronic pacemaker nor its predecessor were required to undergo the extensive FDA procedures required to ensure safety and effectiveness. For this reason, the Court refused to preempt state law tort claims regarding the design of the pacemaker. The MDA did not regulate the design of the pacemaker, and to preempt claims regarding products which never went through the PMA process would allow a product to enter the market without any of the safety protections envisioned by Congress.

Unfortunately, the *Medtronic* decision, in combination with other decisions, creates a complicated web of guidelines in determining what claims are preempted by the MDA. Even the Supreme Court indicated that preemption is case-specific and relies heavily upon a factual determination.<sup>91</sup> A general principle which can be extracted from each decision is the rule that unless the FDA has passed a regulation or instituted testing governing the problem which the state tort seeks to address, claims under state law are not preempted.

Prior to the *Medtronic* decision, most caselaw concerning preemption of state tort claims by the MDA have held that most, or all, state tort claims relating to a Class III device brought before them are preempted by the MDA.<sup>92</sup> In

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<sup>88</sup>*Medtronic*, 116 S. Ct. at 2249.

<sup>89</sup>*Medtronic, Inc. v. Lohr*, 518 U.S. \_\_\_, 64 U.S.L.W. 4625 (1996).

<sup>90</sup>*Duvall v. Bristol-Myers Squibb*, 518 U.S. \_\_\_, 65 U.S.L.W. 1 d136 (1996); *English v. Mentor Corp.*, 518 U.S. \_\_\_, 65 U.S.L.W. 1 d136 (1996); *Martin v. Teletronics Pacing Sys.*, 518 U.S. \_\_\_, 65 U.S.L.W. 1 d136 (1996); *Mentor Corp. v. Bingham*, 518 U.S. \_\_\_, 65 U.S.L.W. 1 d136 (1996); *Mentor Corp. v. Feldt*, 518 U.S. \_\_\_, 65 U.S.L.W. 1 d136 (1996); *Mitchell v. Collagen Corp.*, 518 U.S. \_\_\_, 65 U.S.L.W. 1 d136 (1996).

<sup>91</sup>*Medtronic*, 518 U.S. \_\_\_, 64 U.S.L.W. 4625.

<sup>92</sup>This conclusion remains the same whether FDA approval was gained properly or as a result of fraud upon the FDA. *Michael*, 46 F.3d at 1328-29; *Reeves*, 44 F.3d at 307; *National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988, 992 n.2 (8th Cir. 1994); *Stamps*, 984 F.2d at 1421; *Talbot*, 865 F. Supp. at 49. See also, *Papas v. Upjohn Co.*, 985 F.2d 516, 518-19 (11th Cir.), cert. denied, *Papas v. Zoecon Corp.*, 510 U.S. 913 (1993)

*Duncan v. Iolab Corp.*,<sup>93</sup> the court preempted all of plaintiff's negligence, strict liability, and breach of warranty claims. In *Mendes v. Medtronic, Inc.*,<sup>94</sup> the court preempted plaintiff's claims for implied warranty, negligent failure to warn, negligent manufacturing, and implied warranty because the FDA's labeling requirements and good manufacturing provisions specifically regulated the areas of manufacturing and warning.

On the other hand, claims relating to a Class I or Class II device are often not preempted. Class II devices are only subject to the general regulations of the MDA governing labeling and manufacturing which affect Class I devices, unless the FDA issues device specific regulations.<sup>95</sup> Thus, the FDA generally has no control over the design of a device, and state tort law is the only remedy available to a plaintiff for defectively designed Class I and Class II devices.<sup>96</sup> For example, in *Smith v. Pingree*,<sup>97</sup> the court held that a Florida statute regulating the fitting of hearing aids was not preempted because it did not govern the same area as the MDA, namely safety of hearing aids. In *Anguiano v. E.I. DuPont de Nemours & Co., Inc.*,<sup>98</sup> a case involving a lawsuit against DuPont for a Teflon-based temporomandibular joint, a Class II medical device, the court held that preemption of state law tort claims is limited to areas with specific FDA requirements applicable to the device. In that case, the FDA had not issued any regulations governing joint implants, and as a Class II device, the joint was not subject to PMA of its design. Thus, design defect claims were not preempted.

### B. State Torts: Elements

In order to determine which state tort claims are preempted under the MDA, the courts have utilized a three-step analysis. First, the courts determine what state "requirements" are.<sup>99</sup> State tort law generally holds a manufacturer liable in tort for defects in design, manufacture or warning regarding a product, or for strict liability. A manufacturer may also be liable in quasi-contract for a breach of implied or express warranty. Second, the courts determine the federal

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(compliance with FIFRA regulations is an agency determination, not a court determination).

<sup>93</sup>12 F.3d 194 (11th Cir. 1994).

<sup>94</sup>18 F.3d 13 (1st Cir. 1994).

<sup>95</sup>Claims for inadequate warning are preempted, however, due to the labeling requirements of the MDA. *Kimberly-Clark*, 38 F.3d at 990 (holding, however, that manufacturing claims are not preempted despite the good manufacturing provisions).

<sup>96</sup>*Stamps*, 984 F.2d at 1419.

<sup>97</sup>651 F.2d 1021, 1024 (5th Cir. 1981).

<sup>98</sup>44 F.3d at 810.

<sup>99</sup>In *Medtronic*, the Supreme Court plurality rejected the idea that a state common law tort can be labeled a "requirement" on the manufacturer. However, the concurring justices disagreed.



requirements on the manufacturer under the MDA.<sup>100</sup> Finally, the court must compare the two requirements to determine if the state law adds anything to the federal requirement.<sup>101</sup>

### 1. Design Defects

Of all of the tort claims which may be leveled against a manufacturer, defective design is the least likely to be preempted by the MDA. In fact, each member of the Supreme Court reached this conclusion with regard to the pacemaker in *Medtronic*.<sup>102</sup> In particular, when a product has not undergone the PMA process, whether under the grandfather clause, the substantially equivalent clause, or Class I or II device requirements, design defect claims are often not preempted.<sup>103</sup> On the other hand, a product which has undergone the rigorous PMA process may be exempt from state tort claims for the defect in its design, because design is heavily regulated by the FDA under its PMA process.<sup>104</sup> Although the *Medtronic* Court refused preemption of the design defect claim, *Medtronic* involved a product which did not undergo the PMA process. Thus, no conflict occurred between a decision of the FDA regarding the device's effectiveness and state tort law.

### 2. Manufacturing Defect Claims

The federal requirements of the MDA include the "Good Manufacturing Process" statute (GMP).<sup>105</sup> Under the GMP statute, the FDA has the authority to monitor the methods, facilities, controls, packaging, storage, installation, and all other aspects of manufacturing of any medical device (in any class) to ensure safe manufacturing processes. Most courts have held that the GMP preempts state tort law claims of defective manufacture of a product because the statute specifically regulates manufacture of medical devices. If a product meets the federal requirements, a manufacturer should not then be held liable

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<sup>100</sup>See *supra* § (I)(H), concluding that PMA constitutes a federal requirement.

<sup>101</sup>The express preemption provision of the MDA states that the state may not establish any requirement "which is different from, or in addition to, any requirement applicable under this chapter to the device . . ." 21 U.S.C. § 360k(a) (1976).

<sup>102</sup>518 U.S. \_\_\_, 64 U.S.L.W. 4625, 4637.

<sup>103</sup>*Larsen*, 837 P.2d at 1282.

<sup>104</sup>As the Supreme Court noted in *Medtronic*, the PMA process is rigorous. Often as many as 1200 hours are spent evaluating a device under the PMA process. *Medtronic*, 518 U.S. at \_\_\_, 64 U.S.L.W. at 4627 (citing *Hearings before the Subcomm. on Health and the Environment of the House Comm. on Energy & Commerce*, 100th Cong., 1st Sess. at 384 (1987)). In contrast, devices which do not need to undergo the PMA process may receive as little as twenty hours of attention to determine their equivalence to products already on the market. *Id.* at 4627-4628, citing *Hearings before the Subcomm. on Health and the Environment of the House Comm. on Energy & Commerce*, 100th Cong., 1st Sess. at 384 (1987)).

<sup>105</sup>21 U.S.C. §§ 360j(f), 360j(f)(a)(A) (1976).

under state law because to hold the manufacturer liable essentially creates a higher standard of liability for the manufacturer than existed under federal law. Note, however, that the plurality in *Medtronic* disagreed. To the extent that a state statute enforces the same or narrower standards upon a manufacturer as federal law, the statute is not preempted. Section 360(k) merely prevents states from imposing *more* stringent requirements upon a manufacturer than federal law.<sup>106</sup> This simply acts as an incentive to comply with federal law and, according to the Court, furthers Congress' purposes in enacting the MDA.

In her opinion, however, Justice O'Connor disagreed, stating that the:

FDA's Good Manufacturing Purpose (GMP) regulations impose comprehensive requirements relating to every aspect of the device-manufacturing process, including a manufacturer's organization and personnel, buildings, equipment, component controls, production and process controls, packaging and labeling controls, holding distribution, installation, device evaluations, and record keeping . . . . The Lohrs' common-law claims regarding manufacture would, if successful, impose state requirements 'different from, or in addition to' the GMP requirements, and are therefore pre-empted. In similar fashion, the Lohrs' failure-to-warn claim is pre-empted by the extensive labeling requirements imposed by the FDA.<sup>107</sup>

Again, the Court's decision is split, with the plurality holding that state common law is not preempted, even by the GMP. The result is not so clear, however, for "specific" state requirements, in light of the concurring opinion of the Court, which may differ from federal law.

### 3. Inadequate Warning

Like claims for defective manufacturing of a medical device, claims for inadequate warning regarding a medical device were, prior to *Medtronic*, generally preempted due to comprehensive MDA provisions regarding this area.<sup>108</sup> Specifically, the MDA's labeling provisions<sup>109</sup> govern the manufacturer's duty to warn consumers of the proper usage of the device, the hazards and side-effects thereto, and the prescriptive nature of the device. The FDA even provides regulations for use of a device not in accordance with the

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<sup>106</sup>As the Court noted, a narrower state statute is "different from" the federal requirements. However, the Court refused such a literal reading of section 360(k), stating that "such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule." *Medtronic*, 518 U.S. at \_\_\_, 64 U.S.L.W. at 4632.

<sup>107</sup>*Medtronic*, 518 U.S. at \_\_\_, 64 U.S.L.W. at 4638.

<sup>108</sup>*King*, 983 F.2d at 1139; *Bravman*, 842 F. Supp. at 760-61.

<sup>109</sup>21 C.F.R. § 801.109 (1976).

label.<sup>110</sup> Any state law which adds additional requirements could be to these federal requirements could be preempted.

However, with the onset of the recent *Medtronic* decision, the Court has refused to preempt all state law claims regarding inadequate warning merely due to the existence of specific provisions within the MDA. Like defective manufacturing claims, claims regarding the labeling of medical devices are only preempted if they are more stringent than federal requirements.<sup>111</sup> In Florida, where the *Medtronic* case arose, the "general state common-law requirements . . . were not specifically developed 'with respect to' medical devices. Accordingly, they are not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements."<sup>112</sup> Because of the lack of specificity in Florida's law, the law did not create an additional burden on Medtronic, and was not preempted.

#### 4. Strict Liability

Strict liability claims were almost universally preempted by the MDA prior to *Medtronic*. The state law of strict liability imposes liability on the manufacturer of a device regardless of any level of fault. The MDA, to the contrary, imposes liability (by not approving the device for market) on products which are unsafe in their manufacture, design, or labeling.<sup>113</sup> Thus, the state law adds a level of liability not found under the federal law and was expressly preempted under § 360(k). Again, *Medtronic* involved a device that was never tested for safety by the FDA, so such a claim would not bypass a decision of the FDA.

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<sup>110</sup>21 U.S.C. § 360(k) (1976); *Reeves*, 44 F.3d at 304-05.

<sup>111</sup>Though the Supreme Court cited the preemption provision's statement that state requirements are to be preempted if they are "different from or in addition to," *Medtronic*, 518 U.S. at \_\_, 64 U.S.L.W. at 4630 (emphasis added), the Court seemingly abandoned the express language of the statute in favor of an interpretation that only preempted state law claims that were different from and in addition to the federal law.

<sup>112</sup>*Medtronic*, 518 U.S. at \_\_, 64 U.S.L.W. at 4634. The Court also stated that the federal requirements "reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements." *Id.* Read together, these provisions indicate that even if a state law specifically regulates labeling and manufacturing requirements, it would not be preempted because federal law is not sufficiently specific or comprehensive to indicate a congressional intent to preempt. However, the court focused on the generality of state law requirements, and thus a door may have been left open to preempt state law requirements which are more stringent and specific than those in Florida.

<sup>113</sup>*Medtronic*, 56 F.3d at 1350-51.

## 5. Warranties

Express warranty claims are a breed of quasi-contract claims.<sup>114</sup> Numerous courts have held that contract claims do not constitute a "state requirement."<sup>115</sup> Thus, even if a claim for breach of express warranty adds to the federal requirements under the MDA,<sup>116</sup> the express preemption provision of the MDA only preempts *state* law actions. A contract is entered into between the parties, not the state, and thus does not constitute a state-imposed requirement on the manufacturer.<sup>117</sup> The preemption provision of the MDA does not apply.

Implied warranty claims may be distinguished from express warranty claims because it is state law that creates a cause of action for implied warranty.<sup>118</sup> Where the parties have not expressly contracted as to the safety of the goods, the requirement is state imposed as opposed to self-imposed.<sup>119</sup> Because an implied warranty adds requirements for the manufacturer to abide by, it may be preempted. Again, however, *Medtronic* refused to preempt implied warranty claims under common law, at least for products which did not undergo safety testing by the FDA.

### C. The Case for Implied Preemption

Preemption of a state statute may be implied when the state law is inconsistent with enforcement of the purposes of the federal law. In preemption analysis, the court should "consider the relationship between state and federal laws as they are interpreted and applied, not merely as they are written."<sup>120</sup>

As a practical matter, in the case of Class III devices and the MDA, neither of Congress' express purposes is being fully served. The purposes of the MDA conflict in some cases; both purposes cannot be served at once. However, in an effort to serve both purposes, the courts have encountered a situation in which neither purpose is truly effectuated.

Congress' first goal in enacting the MDA, to ensure safety of devices entering the marketplace, is not met by preemption of claims. To best ensure safety of devices, all tort claims would need to be permitted. However, to allow all state tort liability claims would render the MDA meaningless in that it would create simply a minimum safety standard, yet subject the manufacturers to the same liability that existed before enactment of the MDA.

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<sup>114</sup>*Michael*, 46 F.3d at 1325-27.

<sup>115</sup>*Id.*; *Ministry of Health, Province of Ontario, Canada v. Shiley, Inc.*, 858 F. Supp. 1426, 1439-40 (C.D. Cal. 1994).

<sup>116</sup>The labeling provisions of the MDA constitute a federal regulation governing the express warranties of the manufacturer.

<sup>117</sup>*Michael*, 46 F.3d at 1325-27.

<sup>118</sup>*Talbott*, 865 F. Supp. at 51.

<sup>119</sup>*Michael*, 46 F.3d at 1325.

<sup>120</sup>*Jones*, 430 U.S. at 527.

Likewise, Congress' second objective, to further the progress of medicine by minimizing the cost of placing safe and effective devices on the marketplace, is also not served by the current state of the law. The law as it stands creates a complicated web of claims, in which some are preempted and others are not. It is perfectly permissible to preempt some causes of action and not others.<sup>121</sup> However, to minimize production costs, all causes of action which interfere with Congress' objectives should be preempted. Beyond the legal fees and court costs which will be incurred by manufacturers in untangling this web of cases, the judgments which will be rendered on the claims not preempted are precisely what Congress intended to avoid by passing the MDA.

The most consistent means for solving this dilemma is through implied preemption of all state tort causes of action relating to Class III devices which were approved through the PMA process, or which are substantially similar to products approved through the PMA process.<sup>122</sup> The congressional purpose of

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<sup>121</sup>American Airlines, Inc. v. Wolens, 115 S. Ct. 817, 826 (1995) (Airline Deregulation Act).

<sup>122</sup>There will be some minor inconsistency in treatment of Class III devices because some such devices have not, either themselves or through their predecessors, undergone the PMA process, and thus would lack preemptive power under this construction. However, with time, the technology of 1976 should become outdated, so that all products on the marketplace will be replaced with technology which has either used the PMA process or is substantially equivalent to technology which has undergone the PMA process. Preemption of products which have undergone the PMA process from state tort claims would also serve as an incentive to manufacturers to follow the PMA process. For this reason, it is advisable not to preempt claims against manufacturers who gain PMA approval fraudulently. At this time, fraud does not create a private cause of action. *But see Shiley, Inc.*, 858 F. Supp. at 1439 (the MDA does not preempt a claim that the manufacturer negligently failed to comply with MDA regulations because the state law is not imposing a requirement different from or in addition to the federal law); *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173 (5th Cir. 1988). Even the Supreme Court has indicated that illegal actions may create an exemption from the law of preemption. In *Silkwood*, the Court considered a case in which a young woman died from plutonium poisoning. 464 U.S. at 238. The Court held that all tort remedies could not be preempted, because to do so would leave the plaintiff defenseless against a manufacturer who had committed a violation of the law. *Id.* at 251. "It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by *illegal* conduct." *Id.*

One example of the deadly possibilities when fraud is used to gain FDA approval of a Class III medical device was shown in *Talbott*, 865 F. Supp. at 87. Bard had gained approval of its "Mini-Profile" Catheter, used in balloon angioplasty procedures. The balloon on the catheter was designed to inflate within the patient's artery, unlogging the artery, and then deflate to resume the flow of blood in the patient's body. However, the Bard catheter had numerous reported instances of failure to deflate, thus blocking the flow of blood, and leading to injury or death. Bard personnel realized the problem, but failed to tell the FDA of the situation. It thus fraudulently obtained FDA approval. The *Talbott* court held that the state tort claims were preempted by the MDA. *Id.* at 43-45. However, this decision left the decedent's family remediless against a manufacturer who had illegally gained FDA approval of its product, in violation of the *Silkwood* provisions. An alternative would be to permit state tort claims in the event of fraud. The state tort law would not add an additional requirement to the federal law because it

safety should theoretically still be served by preemption, because the FDA is permitted, and indeed required, to regulate the manufacture, design, and labeling of Class III products to ensure safety.<sup>123</sup> Limiting preemption to products which have undergone the PMA process (excepting, of course, products which gain FDA approval fraudulently) would provide a measure of protection from these devices.

Furthermore, implied preemption would promote the federal goal of uniform liability of manufacturers. Without the possibility of state regulation of manufacturers through tort law, liability will be consistent among the states. Otherwise, a manufacturer would essentially be forced to make the product comply with the strictest liability laws in the country to avoid liability therein, a costly and time-consuming endeavor. If this should occur, fewer products would be available on the market, a result which actually works against public health and safety. In addition, the cost of developing new products would remain economically feasible for manufacturers who would pay for the PMA process, but not state claims. Finally, implied preemption would eliminate the confusion and inconsistencies in the courts regarding preemption.<sup>124</sup>

#### V. CONCLUSION

In an ideal world, the MDA would provide to the FDA adequate authority and resources to ensure that only safe and effective devices enter the marketplace. No state tort actions would be necessary because devices were designed and manufactured in a safe way. Obviously, such an ideal could never be reached. As a result, the two objectives of Congress in passing the MDA are

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merely requires the manufacturer to comply with the MDA. Most courts have been hesitant to accept this argument. See *Silkwood*, 464 U.S. at 238.

<sup>123</sup>Arguably, the objective of safety would be better served if FDA approval through the PMA process could be gained at a faster pace, so that new products could enter the marketplace at a faster speed. At least one report has recommended that Congress provide a "mission statement" to the FDA to streamline the PMA process. *HIMA's 40 New Recommendations on Reforming the FDA*, *supra* note 30.

There is no doubt that the FDA, as it currently stands, cannot prevent all dangerous medical devices from entering the marketplace. See Brief Amici Curiae of American Association of Retired Persons, et al., *supra* note 33. Arguably, Congress does not adequately fund the FDA for the purposes it has provided. However, such decisions of funding and establishing the power of agencies are congressional functions. The determination of how to best protect the public is a congressional determination; the courts are bound by the law of preemption and Congress' statutes as enacted.

Arguably, today's Congress is more willing to accept that state tort remedies are needed to ensure the safety and effectiveness of devices on the marketplace. See 141 Cong. Rec. H2941-H2948 (Mar. 9, 1995); 141 Cong. Rec. H3027 (Mar. 10, 1995) (allowing for compensatory damages for medical devices under tort reform bill). Again, however, any changes must be enacted by Congress, not the courts.

<sup>124</sup>Because the *Madtronic* decision dealt with a device which did not undergo the PMA process, and whose predecessors did not undergo the PMA process, implied preemption would not conflict with the Court's decision if it is limited to cases in which products were tested extensively by the FDA.

at odds with each other. To ensure that the most safe and effective devices are on the marketplace, regulation should include pre-market regulation by the FDA and post-market regulation through state tort actions. However, to ensure cost-effectiveness in development of new devices requires a minimum of regulation.<sup>125</sup>

Regardless of what solution is ideal for balancing these competing objectives, the courts are bound by the law of preemption.<sup>126</sup> The courts are in the unenviable position of attempting to discern the intent of Congress in passing the MDA. As most courts have noted, the express preemption provision of the MDA combined with current preemption law indicates that at least some state tort claims were intended to be preempted by the MDA.

Unfortunately, the current court decisions have created confusing precedent, in which some causes of action are preempted and others are permitted. This current maze of decisions fails to serve either congressional purpose in passing the MDA. It is possible, however, to fully serve one of Congress' purposes by preempting all state tort claims for devices which have undergone the PMA process and received FDA approval. Statutory regulation serves to regulate potentially dangerous devices *before* they enter the marketplace—before they have the opportunity to cause injury or death. Tort actions can only seek to

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<sup>125</sup>As one source states,

[t]he law has worked sufficiently well during the last 20 years to allow the most dramatic era of medical innovation and advancement in history. Overturning the pre-emption would be enough to bring this dramatic growth in the medical device industry to a grinding halt.

The court, in one fell swoop, would open the door to the establishment of 50 new state laws. Essentially, juries would be making decisions about medical technology, not doctors, researchers or trained experts at the FDA.

Some 64 percent of device manufacturers in this country have fewer than 20 employees. It is these small companies that would be hit the hardest. The threat of crushing litigation and skyrocketing insurance rates would force them to either pull products from the market or not conduct any business at all.

Wayne Barlow, *Medical Devices go to Supreme Court*, SAN ANTONIO EXPRESS-NEWS, May 1, 1996.

<sup>126</sup>Arguably, prohibiting state tort claims may cause manufacturers to rely on the FDA to test its products.

The practical effect of these holdings is that FDA approval, which previously was only permission to market a product, now represents a virtual 'safe harbor' under the proper conditions. The wisdom of these decisions is debatable. They may lead manufacturers to assume a more relaxed attitude toward testing and may encourage them to rely on the FDA to do the bulk of product testing.

Eric B. Bruce, *Avoiding Product Liability Claims: How Much Testing is Enough?*, 62 DEF. COUNS. J. 391, 396 (1995). However, given the cost and time involved in gaining FDA approval, it is to the manufacturer's benefit to ensure that its device is in a condition to enable it to pass inspection. Furthermore, it is Congress' responsibility, not the courts, to determine the best way to further its objectives regarding safety of medical devices.

compensate victims after the harm has already occurred, and tort remedies are arbitrary.<sup>127</sup> Assuming that the FDA properly regulates devices before they enter the marketplace, regulation is kept to a minimum, enabling manufacturers to develop new devices.<sup>128</sup> Safety is still a factor. No one would disagree that it is better to prevent a dangerous device from entering the marketplace than to suffer the consequences of such a device on the market. Implied preemption, then, would create a predictable outcome and permit manufacturers to feasibly create medical devices to ensure public health and safety.

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<sup>127</sup>See *id.* at 397 (arguing that "short of FDA approval of certain products, there is nothing a manufacturer can do that will guarantee freedom from all future products liabilities," and providing a checklist of ways to limit the likelihood of product liability suits).

<sup>128</sup>The FDA has proposed more stringent regulations for medical device designs, following a study by the FDA indicating that design defects lead to more than half of defective product recalls. Paul H. Sunshine, *The Preemptive Scope of the Medical Device Amendments of 1976*, 50 *FOOD & DRUG L.J.* 191, 191 (1995).



