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# CONSUMER NEWS

## Supreme Court Restricts State Tort Claims Against Federally-Approved Medical Devices

By Thomas A. McCann\*

In a case with huge implications for the health care industry and patients injured by faulty medical devices, the U.S. Supreme Court in February closed the door to many state personal injury lawsuits for certain federally-approved medical products.<sup>1</sup>

The Court ruled in *Riegel v. Medtronic Inc.* that federal law preempts any state common law claims against a medical device that has passed the federal approval process and conforms to its mandates.<sup>2</sup> The Court reasoned that a state jury should not be allowed to second guess the U.S. Food and Drug Administration after it extensively reviews each product and assesses its individual benefits and risks before allowing it to be sold.<sup>3</sup> The decision has prompted a flood of court filings across the country from device manufacturers seeking dismissals of state personal injury suits against their products.<sup>4</sup> The ruling also has spurred threats from Congress to

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<sup>1</sup> David Stout, *Justices Make It Tougher to Sue Medical Device Manufacturers*, N.Y. TIMES, February 20, 2008, available at <http://www.nytimes.com/2008/02/20/washington/20cnd-device.html?ex=1204174800&en=1e8c689cd5b390ac&ei=5018&partner=BRITANNICA>.

<sup>2</sup> *Riegel v. Medtronic Inc.*, 128 S. Ct. 999, 1008 (2008).

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

<sup>4</sup> Barnaby J. Feder, *Medical Device Ruling Redraws Lines On Lawsuits*, N.Y. TIMES, February 22, 2008, at C2.

introduce legislation to overturn *Riegel* and allow such state lawsuits to go forward.<sup>5</sup>

The case before the Court concerned the Evergreen Balloon Catheter, a medical device produced by Minneapolis, Minn.-based Medtronic, Inc.<sup>6</sup> In 1996, an Evergreen catheter burst inside Charles Riegel as he underwent an angioplasty at a New York hospital.<sup>7</sup> Riegel entered the hospital because he had suffered a myocardial infarction, and his right coronary artery was both heavily calcified and “diffusely diseased.”<sup>8</sup> According to the opinion, Riegel’s doctor inserted the catheter in an attempt to expand the clogged artery; however, the catheter’s labeling stated that the product would be risky for patients with diffused or calcified blood vessels.<sup>9</sup> The label also warned that the catheter should not be inflated beyond a pressure of eight atmospheres.<sup>10</sup> The doctor inflated the Medtronic catheter five times over the course of the procedure, eventually to a pressure of 10 atmospheres, at which point the catheter ruptured. Riegel developed a heart blockage, went on life support, and had to undergo emergency coronary bypass surgery to save his life.<sup>11</sup>

Charles and Donna Riegel sued in the United States District Court for the Northern District of New York, alleging that Medtronic’s catheter was designed, labeled, and manufactured defectively in violation of New York common law and that the defects caused Riegel to suffer severe and permanent injuries.<sup>12</sup> Among the Riegels’ state claims were breach of implied warranty; strict liability; negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the product; and loss of consortium between the couple.<sup>13</sup>

However, the district court dismissed all of the Riegels’ claims, reasoning that the Medtronic catheter was a federally-

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

<sup>6</sup> *Riegel*, 128 S. Ct. at 1005.

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

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

<sup>9</sup> *Id.*

<sup>10</sup> *Riegel*, 128 S. Ct. at 1005.

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

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

<sup>13</sup> *Id.* at 1005-06.

approved medical device, strictly regulated by the U.S. Food and Drug Administration, and that federal law preempts any liability under state law.<sup>14</sup> The United States Court of Appeals for the Second Circuit affirmed the dismissals, and the U.S. Supreme Court granted certiorari.<sup>15</sup>

At the heart of the case are the Medical Device Amendments of 1976 (“MDA”), a federal statute designed to replace traditional state-by-state regulation of potentially dangerous medical devices with a highly-detailed federal oversight system.<sup>16</sup> To place such oversight securely in the federal domain, the MDA expressly preempts all state requirements “different from, or in addition to, any requirement applicable to the device” under federal law and which “relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device.”<sup>17</sup> The Medtronic Evergreen Balloon Catheter is categorized as a Class III medical device, which has the most stringent approval process under the federal system. Class III devices include such items as replacement heart valves, implanted cerebella stimulators and pacemaker pulse generators.<sup>18</sup>

The maker of a Class III device must submit to a “rigorous” premarket approval process, in which the company must produce a multivolume application with reports of all studies and investigations of the device’s safety and effectiveness that have been published or should reasonably be known to the company; full statements of all the device’s components and principles of operation; a specimen of the proposed labeling; and a full description of the methods and controls used for making and processing the device.<sup>19</sup> Before making a decision, the FDA can refer the product to a panel of outside experts or request additional data.<sup>20</sup>

The FDA spends an average of 1,200 hours reviewing each application and grants premarket approval only if there is “reasonable

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<sup>14</sup> *Riegel*, 128 S. Ct. at 1005-06.

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

<sup>16</sup> *Id.* at 1003, 28 U.S.C. § 301 *et seq.*

<sup>17</sup> 28 U.S.C. § 360k(a)

<sup>18</sup> *Riegel*, 128 S. Ct. at 1003.

<sup>19</sup> *Id.* at 1004, 28 U.S.C. § 301e(c)(1).

<sup>20</sup> *Riegel*, 128 S. Ct. at 1004.

assurance” of the product’s “safety and effectiveness.”<sup>21</sup> The FDA also reviews the product’s labeling to ensure that the product is safe and effective under the conditions of use set forth in the label, and to make sure the label is neither false nor misleading.<sup>22</sup> Once the FDA approves the device, federal law forbids the company from making any changes to the product’s design, labeling or manufacture without filing another application for “supplemental premarket approval.”<sup>23</sup> Even after the product receives approval, it is subject to regular reporting requirements, including reports of any malfunctions; any incidents in which the device may have contributed to a patient’s death or serious injury; or any new clinical studies or investigations about which the applicant reasonably should know.<sup>24</sup> In that event, the FDA can withdraw its approval.

The balloon catheter used on Riegel received premarket approval from the FDA in 1994, and changes to its labeling received supplementary approvals in 1995 and 1996.<sup>25</sup> In order for these federal regulations to preempt a state common law claim, the court had to decide whether state tort law imposed additional or different “requirements” than those under the federal law.<sup>26</sup> The Court held that state common law duties do qualify as “requirements” under the MDA because tort liability means a defendant has violated a state obligation, and tort claims are designed to be “a potent method of governing conduct and controlling policy.”<sup>27</sup> Moreover, the Court said that a state’s tort law that requires a catheter to be safer but less effective than the model the FDA approved disrupts the federal regulatory scheme in just the same way a contrary state regulation would.<sup>28</sup>

Further, the Court reasoned that it was illogical to think Congress would have preempted state regulations but allowed state lawsuits and that it was “implausible that the MDA was meant to

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<sup>21</sup> *Id.*, 28 U.S.C. § 360e(d).

<sup>22</sup> 28 U.S.C. §§ 360c(a)(2)(B), 360e(d)(1)(A).

<sup>23</sup> 28 U.S.C. §§ 360e(d)(6)(A)(i), 360e(d)(6); 21 C.F.R. § 814.39(c) (2008).

<sup>24</sup> *Riegel*, 128 S. Ct. at 1005.

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

<sup>26</sup> *Id.* at 1007.

<sup>27</sup> *Id.* at 1008 (citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992)).

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

grant greater power. . .to a single state jury than to state officials acting through state administrative or legislative. . .processes.”<sup>29</sup> Justice Scalia, who authored the majority opinion, noted that a key purpose behind the MDA was to promote a policy of thorough cost/benefit analysis with respect to cutting-edge new medical products.<sup>30</sup> The Court emphasized that the FDA purposefully approves certain devices that present great risks if they nonetheless offer great benefits in light of reasonable alternatives in the marketplace.<sup>31</sup> For instance, the agency has approved certain heart devices for seriously ill children even though the survival rate of those who use the device is less than 50 percent.<sup>32</sup>

In the Court’s opinion, at least state regulations “could. . .be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA.”<sup>33</sup> A jury, on the other hand, “sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.”<sup>34</sup> Hence, the Court said, state tort law is even less deserving of protection.<sup>35</sup> Finally, the Court looked at the text of the statute, finding that the wording “suggests that the solicitude for those injured by FDA-approved devices. . .was overcome in Congress’ estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 states to all innovations.”<sup>36</sup>

The Riegels additionally argued that common law claims like negligence and strict liability should not be preempted because they are general duties that do not apply specifically to medical devices.<sup>37</sup> However, the Court rejected that argument, stating that nothing in the

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<sup>29</sup> *Riegel*, 128 S. Ct. at 1008 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 504 (1996)).

<sup>30</sup> *Riegel*, 128 S. Ct. at 1004.

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

<sup>32</sup> *Id.*

<sup>33</sup> *Id.* at 1008.

<sup>34</sup> *Id.*

<sup>35</sup> *Riegel*, 128 S. Ct. at 1008.

<sup>36</sup> *Id.* at 1009.

<sup>37</sup> *Id.* at 1009-10.

statutory text supports such a reading.<sup>38</sup> The Court found that all such general tort claims question the regulatory decisions of the FDA and must be dismissed.<sup>39</sup> The Court, however, did not say all claims related to the device need be thrown out. A plaintiff may still sue for damages in state court if she alleges that the medical device at issue violated the FDA regulations.<sup>40</sup> Such a claim would be “parallel” to the federal rules, and wouldn’t impose “additional requirements.”<sup>41</sup>

The Court ruled eight to one that the MDA preempted the Riegels’ state tort claim. However, Justice Ginsburg wrote a strong dissent, stressing that the decision marks an unwise “constriction on state authority” in an area where state law historically dominates.<sup>42</sup> Ginsburg reasoned that the MDA should be analyzed in the proper context. Congress passed the law in 1976 in the wake of huge publicity surrounding the Dalkon Shield intrauterine device, which was used by about 2.2 million women and caused dozens of injuries and deaths.<sup>43</sup> In none of the media reports did Congress stress the need to limit state liability claims.<sup>44</sup> The real purpose of the preemption provision, Ginsburg said, was to prevent state agencies from enforcing their own regulations on medical devices when the FDA was trying to provide that role, something that California was actively doing before the federal government stepped in.<sup>45</sup>

Ginsburg said that the FDA has stated in the past that “FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection.”<sup>46</sup> She further stated the Court’s decision in *Riegel* “has the ‘perverse effect’ of granting broad immunity ‘to an

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<sup>38</sup> *Id.* at 1010.

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

<sup>40</sup> *Riegel*, 128 S. Ct. at 1011.

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

<sup>42</sup> *Id.* at 1013.

<sup>43</sup> *Id.* at 1014-15.

<sup>44</sup> *Id.* at 1015.

<sup>45</sup> *Riegel*, 128 S. Ct. at 1013.

<sup>46</sup> *Id.* at 1015; Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 11 (1997).

entire industry that, in the judgment of Congress, needed more stringent regulation,' not exemption from liability in tort litigation."<sup>47</sup>

Ginsburg noted that the MDA created no federal compensatory remedy for consumers who are injured by a product that went through the FDA approval process, suggesting that Congress did not intend to preempt state tort claims.<sup>48</sup> She stated it was "difficult to believe that Congress would, without comment, remove all means of judicial recourse' for large numbers of consumers injured by defective medical devices."<sup>49</sup> Importantly, Ginsburg stressed that the *Riegel* decision does not speak to federal preemption of state tort claims where evidence of the medical device's defect came to light only after the device received premarket approval.<sup>50</sup>

Within hours of the ruling, its effects rippled throughout the country's law offices. That same day, the lawyers in a group of Florida state court cases concerning Johnson & Johnson Co.'s drug-coated Cypher heart stent received an email from the judge asking for briefs on whether the lawsuits should be allowed to continue.<sup>51</sup> The ruling also could have a major effect on mass tort cases against medical device makers Boston Scientific Corp., St. Jude Medical Inc., Synthes Inc., and Stryker Corp.<sup>52</sup> Medtronic currently is defending another state lawsuit in Minnesota, where 600 plaintiffs are suing the company over a recalled heart defibrillator with electrical wires that were prone to developing deadly fractures.<sup>53</sup> "Medtronic probably already has summary judgment motions ready to go," Hunter Shkolnik, a plaintiffs' lawyer on the defibrillator case, told the *New York Times*. "The next six months will be consumed [with] fighting about such motions."<sup>54</sup>

Legal commentators have criticized the ruling for giving too much deference to FDA review procedures. The FDA handles 25 to

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<sup>47</sup> *Riegel*, 128 S. Ct. at 1016 (quoting *Loehr*, 518 U.S. at 487).

<sup>48</sup> *Id.* at 1015.

<sup>49</sup> *Id.* (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)).

<sup>50</sup> *Id.* at 1013 n.1.

<sup>51</sup> Feder, *supra* note 5.

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

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

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

50 new premarket approvals in a typical year, but the agency also gives a much more cursory review to hundreds of supplemental approval applications for changes and updates to the devices, and under *Riegel* these under-regulated products are immune from state tort claims.<sup>55</sup> In addition, U.S. Rep. Henry Waxman (D-Calif.) and U.S. Sen. Edward Kennedy (D-Mass.) announced after the ruling came down that *Riegel* was contrary to Congress' intent and that they would sponsor a bill to overturn it.<sup>56</sup> Both were congressional leaders in the passage of the original MDA in 1976.<sup>57</sup>

Lawyers said they would need to adapt their approach in future cases in the wake of the *Riegel* ruling. Among the suggestions are new lawsuits to attack devices sold in the market under the less-scrutinized "supplemental" approvals, as well as "parallel" tort claims based on violations of the FDA regulations themselves, including instances where manufacturers deceived federal regulators by providing false or insufficient data.<sup>58</sup> However, plaintiffs' attorneys expressed concern that many judges may dismiss their medical device tort claims before they can gain access to important discovery documents that would allow them to make such an argument.<sup>59</sup> Legal commentators also expressed dismay that the U.S. Supreme Court decision in *Riegel* takes away state tort claims as a real threat to unscrupulous health care companies and a vital consumer protection against unsafe medical products.<sup>60</sup>

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<sup>55</sup> *Id.*

<sup>56</sup> Feder, *supra* note 5.

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

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

<sup>59</sup> *Id.*

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