

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.¹

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.² 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.³ 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.⁴ The ruling also has spurred threats from Congress to

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¹ 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>.

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

³ *Id.*

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

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introduce legislation to overturn *Riegel* and allow such state lawsuits to go forward.⁵

The case before the Court concerned the Evergreen Balloon Catheter, a medical device produced by Minneapolis, Minn.-based Medtronic, Inc.⁶ In 1996, an Evergreen catheter burst inside Charles Riegel as he underwent an angioplasty at a New York hospital.⁷ Riegel entered the hospital because he had suffered a myocardial infarction, and his right coronary artery was both heavily calcified and “diffusely diseased.”⁸ 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.⁹ The label also warned that the catheter should not be inflated beyond a pressure of eight atmospheres.¹⁰ 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.¹¹

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.¹² 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.¹³

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

⁵ *Id.*

⁶ *Riegel*, 128 S. Ct. at 1005.

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *Riegel*, 128 S. Ct. at 1005.

¹¹ *Id.*

¹² *Id.*

¹³ *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.¹⁴ The United States Court of Appeals for the Second Circuit affirmed the dismissals, and the U.S. Supreme Court granted certiorari.¹⁵

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.¹⁶ 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.”¹⁷ 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.¹⁸

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.¹⁹ Before making a decision, the FDA can refer the product to a panel of outside experts or request additional data.²⁰

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

¹⁴ *Riegel*, 128 S. Ct. at 1005-06.

¹⁵ *Id.*

¹⁶ *Id.* at 1003, 28 U.S.C. § 301 *et seq.*

¹⁷ 28 U.S.C. § 360k(a)

¹⁸ *Riegel*, 128 S. Ct. at 1003.

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

²⁰ *Riegel*, 128 S. Ct. at 1004.

assurance” of the product’s “safety and effectiveness.”²¹ 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.²² 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.”²³ 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.²⁴ 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 1996.²⁵ 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.²⁶ 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.”²⁷ 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.²⁸

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

²¹ *Id.*, 28 U.S.C. § 360e(d).

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

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

²⁴ *Riegel*, 128 S. Ct. at 1005.

²⁵ *Id.*

²⁶ *Id.* at 1007.

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

²⁸ *Id.*

grant greater power. . .to a single state jury than to state officials acting through state administrative or legislative. . .processes.”²⁹ 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.³⁰ 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.³¹ 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.³²

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.”³³ 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.”³⁴ Hence, the Court said, state tort law is even less deserving of protection.³⁵ 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.”³⁶

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.³⁷ However, the Court rejected that argument, stating that nothing in the

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

³⁰ *Riegel*, 128 S. Ct. at 1004.

³¹ *Id.*

³² *Id.*

³³ *Id.* at 1008.

³⁴ *Id.*

³⁵ *Riegel*, 128 S. Ct. at 1008.

³⁶ *Id.* at 1009.

³⁷ *Id.* at 1009-10.

statutory text supports such a reading.³⁸ The Court found that all such general tort claims question the regulatory decisions of the FDA and must be dismissed.³⁹ 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.⁴⁰ Such a claim would be “parallel” to the federal rules, and wouldn’t impose “additional requirements.”⁴¹

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.⁴² 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.⁴³ In none of the media reports did Congress stress the need to limit state liability claims.⁴⁴ 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.⁴⁵

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.”⁴⁶ She further stated the Court’s decision in *Riegel* “has the ‘perverse effect’ of granting broad immunity ‘to an

³⁸ *Id.* at 1010.

³⁹ *Id.*

⁴⁰ *Riegel*, 128 S. Ct. at 1011.

⁴¹ *Id.*

⁴² *Id.* at 1013.

⁴³ *Id.* at 1014-15.

⁴⁴ *Id.* at 1015.

⁴⁵ *Riegel*, 128 S. Ct. at 1013.

⁴⁶ *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."⁴⁷

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.⁴⁸ 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."⁴⁹ 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.⁵⁰

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.⁵¹ 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.⁵² 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.⁵³ "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."⁵⁴

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

⁴⁷ *Riegel*, 128 S. Ct. at 1016 (quoting *Lohr*, 518 U.S. at 487).

⁴⁸ *Id.* at 1015.

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

⁵⁰ *Id.* at 1013 n.1.

⁵¹ Feder, *supra* note 5.

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

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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.⁵⁵ 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.⁵⁶ Both were congressional leaders in the passage of the original MDA in 1976.⁵⁷

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.⁵⁸ 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.⁵⁹ 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.⁶⁰

⁵⁵ *Id.*

⁵⁶ Feder, *supra* note 5.

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.*

Texas Wine Decision Adds New Fuel to the Fire on Interstate Shipping After *Granholm*

By Thomas A. McCann

As part of the latest judicial wrangling over interstate wine sales, a Texas district court judge has struck down the state's laws barring out-of-state retailers from selling wine directly to Texas consumers.⁶¹ However, the judge also ruled that Texas could continue requiring the out-of-state retailers to buy all the wine they sell in Texas from Texas-licensed wholesalers.⁶²

The ruling adds further confusion to states' regulation of wine merchants in the aftermath of a landmark 2005 U.S. Supreme Court ruling. In *Granholm v. Heald*, the Court struck down state laws that restricted direct sales from wineries to consumers across state lines.⁶³ However, that decision addressed only the tip of the iceberg when it comes to the nation's complex state-based system of regulating alcohol sales, which dates back to the end of prohibition in the 1930s.⁶⁴ The system, which had the byproduct of protecting in-state alcohol vendors from out-of-state competition, began to crumble with the advent of the Internet and online stores.⁶⁵ The Texas decision extends *Granholm* beyond wine producers to out-of-state retailers.⁶⁶

In the Texas case, a group of Texas wine consumers banded together with two wine retailers, one based in Florida and the other in California, to sue the state of Texas and the Texas Alcoholic Beverage Commission ("TABC"), arguing that the state laws at issue discriminated against interstate commerce in violation of the dormant

⁶¹ *Siesta Vill. Mkt. v. Perry*, 530 F. Supp. 2d 848, 874 (N.D. Tex. Jan. 14, 2008).

⁶² *Id.*

⁶³ *Granholm v. Heald*, 544 U.S. 460 (2005).

⁶⁴ David Kesmodel, *Wine Sellers Win One in Texas*, WALL ST. J., Jan. 18, 2008, at B5.

⁶⁵ Kesmodel, *supra* note 64.

⁶⁶ *Id.*

Commerce Clause.⁶⁷ Also intervening in the case were two licensed Texas wholesalers, who defended the statute's constitutionality and contested a temporary injunction that was allowing non-Texas retailers to compete against them in the state until the case was resolved.⁶⁸ The plaintiffs argued that the Texas statute allowed in-state retailers to sell and ship wine to at least some Texas residents, but denied that same right to out-of-state businesses.⁶⁹ The Texas statute at issue stated "any person in the business of selling alcoholic beverages in another state or country who ships or causes to be shipped any alcoholic beverage directly to any Texas resident. . . is in violation of this code."⁷⁰ A recent amendment to the code further restricted the rights of in-state retailers by forbidding any Texas retailers from shipping products to consumers outside of their specific county.⁷¹ However, the amendment did nothing to alleviate the limitations to the out-of-state competitors.⁷²

U.S. District Judge Sidney A. Fitzwater declared that a Texas statute implicates the dormant Commerce clause "if it discriminates against interstate commerce either facially, by purpose or by effect."⁷³ If a law does discriminate, it may still be valid if it advances a legitimate local purpose that cannot be adequately served by reasonable nondiscriminatory alternatives.⁷⁴ However, even if the a Texas statute does not discriminate, it still could be struck down if it is "clearly excessive" in relation to the benefits of the statute.⁷⁵

The defendants argued that the prohibition on Texas retailers from selling outside their own counties made the advantage to Texas retailers too small and insignificant to be sufficiently discriminatory.⁷⁶ However, the district court disagreed, saying that the benefits Texas retailers had inside their counties under the law

⁶⁷ *Siesta Vill. Mkt.*, 530 F. Supp. 2d at 852; U.S. Const. art. I, § 8, cl. 3.

⁶⁸ *Siesta Vill. Mkt.*, 530 F. Supp. 2d at 853.

⁶⁹ *Id.* at 859.

⁷⁰ Tex. Alco. Bev. Code § 107.7(f).

⁷¹ Tex. Alco. Bev. Code § 22.03.

⁷² *Siesta Vill. Mkt.*, 530 F. Supp. 2d at 863-4.

⁷³ *Id.* at 862.

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *Id.* at 864.

were far from insignificant.⁷⁷ The judge said the law did not prevent a Texas retailer from setting up brick-and-mortar shops in multiple counties and then shipping products directly to consumers in those counties. Out-of-state retailers would have access to none of those markets.⁷⁸ Also, the court stated that even the benefit to selling within a single county is large, noting that Harris County, which includes Houston, has a population that exceeds that of 24 other states.⁷⁹

The court stated “there is no ‘*de minimis*’ defense to a charge of discriminat[ion]” and that “[a] law that relies on the requirement of a physical, in-state location to afford some retailers the right to sell and ship wine to Texas consumers, while denying that same right to others who are located out-of-state, is therefore constitutionally suspect, regardless whether that right expands to the entire state or is restricted to a single county.”⁸⁰

The State of Texas and the intervenor wholesalers offered several justifications for the Texas statutes. The defendants argued that requiring in-state premises was necessary to protect consumer safety in conducting on-site inspections; that the laws were needed to prevent access by minors to alcohol; and that the laws were indispensable for the state’s tax revenue gathering because Internet retailers were much harder to tax.⁸¹ The court rejected each of these arguments, declaring they were not sufficient to justify a discriminatory law.⁸² As for protecting minors, the court said a state could just as easily require an adult signature on delivery and a label stating such instructions on each package.⁸³

Thus, the court struck down the Texas “citizenship requirement” forbidding out-of-state retailers from selling to Texas consumers, but it did not invalidate the state laws that require all alcohol retailers to sell through a licensed Texas wholesaler.⁸⁴

⁷⁷ *Siesta Vill. Mkt.*, 530 F. Supp. 2d at 864.

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.* at 864-5.

⁸¹ *Id.* at 866-7.

⁸² *Siesta Vill. Mkt.*, 530 F. Supp. 2d at 867.

⁸³ *Id.*

⁸⁴ *Id.* at 874.

Despite the plaintiffs' arguments that this provision too was unconstitutional, the court said out-of-state retailers are free now either to sell to Texas consumers through a Texas wholesaler or to apply for Texas wholesaler permits themselves through the TABC.⁸⁵ The court acknowledged that the Texas agency's requirements were not ideal, but "[t]he fact that the remaining constitutional components of the Texas regulatory scheme may be somewhat awkward when applied to out-of-state wine retailers does not require that the Texas Legislature enact a separate system that regulates them."⁸⁶

The court said the wholesaler requirement applies equally to Texas and out-of-state retailers.⁸⁷ The court stated that if an out-of-state retailer has a problem with Texas' complex three-tier system for wine wholesale and retail sales, it must take up the issue with the Texas Legislature.⁸⁸

The out-of-state retailers are planning to appeal the part of the ruling that would require them to buy wine from Texas wholesalers, but they otherwise were happy with the court's decision, according to media reports.⁸⁹ Tom Wark, executive director of the Specialty Wine Retailers Association, based in Sacramento, Calif., told the *Wall Street Journal* that the court decision may influence pending wine shipping legislation in several other states, including Maine, Tennessee and Virginia.⁹⁰ The ruling also could have major implications for interstate sales of beer and distilled spirits, and other consumer products.⁹¹ Furthermore, legal experts contend that several conflicting decisions around the country concerning alcohol retailers make the issue "ripe for resolution by the Supreme Court."⁹²

The issue of interstate wine sales is a hot one right now. Several additional lawsuits around the country are contesting other versions of allegedly discriminatory wine commerce laws.⁹³ Several

⁸⁵ *Id.* at 871.

⁸⁶ *Id.* at 869.

⁸⁷ *Siesta Vill. Mkt.*, 530 F. Supp. 2d at 870.

⁸⁸ *Id.* at 871.

⁸⁹ Kesmodel, *supra* note 4.

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ Lynn Marek, *Legal Battle Over Wine Shipments Has Ripened*, NAT'L L. J.,

of the other states' contested laws require a prospective wine purchaser to meet face-to-face with a winery representative on the seller's premises to order a wine shipment, making phone and Internet orders impossible.⁹⁴ Such laws require courts now to decide what to do "when a state law makes interstate commerce difficult, but not impossible," according to James Tanford, a professor at Indiana University School of Law-Bloomington, who is working with lawyers to challenge the laws.⁹⁵ Lawsuits of this sort currently are pending before the U.S. Courts of Appeals for the Second, Sixth and Seventh Circuits.⁹⁶ In the Indiana case pending before the Seventh Circuit, the Southern District of Indiana struck down Indiana's requirement that there be a face-to-face transaction prior to a wine shipment, but upheld other state restrictions on out-of-state wineries.⁹⁷

Some commentators think the courts are steering toward better evening the playing field for interstate wine competition, but others are not so sure.⁹⁸ "The courts are starting to understand *Granholm* and what it meant and what it didn't mean," according to Craig Wolf, an attorney representing wine wholesalers. "So far, the prevailing winds have been in favor of the states."⁹⁹

Jan. 21, 2008, at 6.

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Baude v. Heath*, No. 07-03323 (7th Cir. argued Feb. 22, 2008).

⁹⁸ *Marek*, *supra* note 93.

⁹⁹ *Id.*