

WISCONSIN SUPREME COURT

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JOSEPH BLUNT, SR. and  
MARGARET BLUNT,

Plaintiffs-Appellants-Petitioners,

Appeal No. 2006AP1506  
Circuit Court Case No. 2005CV3879

STATE OF WISCONSIN  
DEPARTMENT OF HEALTH  
AND FAMILY SERVICES,

Subrogated-Plaintiff,

v.

MEDTRONIC, INC.,

Defendant-Respondent.

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**BRIEF OF AMICUS CURIAE  
THE PRODUCT LIABILITY ADVISORY COUNCIL  
IN SUPPORT OF DEFENDANT-RESPONDENT  
MEDTRONIC, INC.**

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## **INTRODUCTION AND STATEMENT OF INTEREST**

The Product Liability Advisory Council, Inc. (“PLAC”) is a non-profit association consisting of 124 voting members and several hundred non-voting (sustaining) members. PLAC’s voting members are all companies that design, manufacture or market products, including such complex products as automobiles, trucks, chemicals, pharmaceuticals, electronics, and life-saving medical devices such as those at issue in this case. Three of PLAC’s member companies are headquartered in Wisconsin, and virtually all PLAC member companies sell products in the State. (App.1, list of PLAC’s corporate members). PLAC’s sustaining members are several hundred of the leading product liability defense attorneys in the country.

PLAC’s interest in this case stems from the direct experience of its members, who must frequently address conflicts between duties imposed by federal regulatory authorities and the common law standards applied in product liability cases in States across the country. One of PLAC’s primary objectives is to ensure that the development of products liability law is informed by the views and experiences of product manufacturers. Since 1983, PLAC has filed over 825 *amicus curiae* briefs in federal and state courts, including Wisconsin, in its effort to achieve this objective.

The primary issue here is whether the express preemption clause of the Medical Device Amendments of 1976 (“MDA”), 21 U.S.C. §360k(a), preempts state law negligence and strict liability claims involving a Class III medical device, approved by the Food and Drug Administration (“FDA”) as safe and effective pursuant to the FDA’s premarket approval (“PMA”) process, and marketed at the same time as another PMA-approved model of the device. Under *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), the Blunts’ tort claims are preempted. If this Court were to reverse, it would be in contravention of *Riegel* and also threaten the many sound public policies underlying preemption which benefit the people of Wisconsin.

#### **FACTS PERTINENT TO THIS *AMICUS* BRIEF**

In December 2002, defendant Medtronic, Inc. (“Medtronic”) received FDA approval to market an implantable cardioverter defibrillator (“ICD”), the Marquis VR Model 7230, which was powered by a Chi 4420L battery (“Device with Battery”). (Initial Br. at 8-9); *Blunt v. Medtronic, Inc.*, 2007 WI App. 191, ¶2, 305 Wis. 2d 354, 738 N.W.2d 143.

In October 2003, Medtronic received approval from the FDA to market a Marquis VR Model 7230 device with a modified Chi 4420L battery (“Device with Modified Battery”), a product that was also deemed

safe and effective for its intended use pursuant to the PMA process. *Id.*, ¶3.

Medtronic learned that some patients implanted with the Device with Battery experienced shorting problems (9 out of 87,000 patients) and the manufacturer reported this information to the FDA. *Blunt*, ¶20; (Initial Br. at 7). The agency determined that a recall was not necessary nor did it require that Medtronic take any action. *Id.*

In May 2004, Blunt was implanted with the Device with Battery. *Id.*, ¶4.

In February 2005, Medtronic voluntarily alerted patients and their physicians of a potential 0.01% risk of shorting associated with the Device with Battery and voluntarily withdrew it from the market. *Blunt*, ¶20; (Response Br. at 12). The FDA was notified of the steps that Medtronic had taken and did not withdraw its approval of the Device with Battery nor did it require that the device be recalled. (Initial Br. at 8); *Id.*, ¶¶20-21.

After consulting with his physician, Blunt opted to undergo surgery to remove the Device with Battery. *Id.*, ¶4; (Initial Br. at 7). Blunt and his wife subsequently sued Medtronic for negligence, strict liability and loss of consortium.

## ARGUMENT

### **I. Under *Riegel*, Claims Against the Manufacturer of a Class III PMA Medical Device Are Preempted When the Device Is Designed and Manufactured in Compliance with FDA Requirements.**

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*Riegel* disposes of the two primary arguments that the Blunts advanced below, that (1) the PMA process does not impose federal safety requirements, *Blunt*, ¶¶9-10, and (2) common law claims challenging the safety and effectiveness of an approved Class III PMA medical device would not impose conflicting state requirements *Id.*, ¶14.

Contrary to the Blunts' position, *Riegel* emphasized that the PMA process “is federal safety review” and that “[p]remarket approval ... imposes ‘requirements’ under the MDA” for design, manufacture, marketing and reporting. *Reigel*, at 1004, 1007 (emphasis in original). The PMA process provides an authoritative determination by the FDA that the approved device offers “a reasonable assurance of safety and effectiveness.” *Id.* at 1007

State law claims challenging the safety of a PMA device manufactured in compliance with federal requirements are preempted if they would impose a “requirement” that is “different from, or in addition to” a federal requirement “relating to [the] safety and effectiveness” of the device. *Id.* at 1009-10 (citing 21 U.S.C. §360k(a)). To prevail in a negligence claim, a plaintiff must establish that the defendant breached a

duty of care by marketing a product that was unsafe because it “posed a foreseeable risk of injury.” *Morden v. Continental AG*, 2000 WI 51, ¶¶ 45-48, 235 Wis. 2d 325, 611 N.W.2d 659. To prevail in strict liability, a plaintiff must establish that the defendant marketed a device that was “unreasonably dangerous to the user or consumer.” *Haase v. Badger Mining Corp.*, 2004 WI 97, ¶25, 247 Wis. 2d 143, 682 N.W.2d 389. The gravamen of both types of claims turns on the safety of the product, and a common law verdict would necessarily impose safety requirements that are “different from, or in addition to” the federal requirements for the device.

*Riegel* unequivocally recognized that “[s]afety and effectiveness are the very subjects of ... common-law claims” asserting negligence and strict liability, *Riegel*, 128 S.Ct. at 1007, and that “excluding common-law duties from the scope of pre-emption would make little sense” because state tort law requiring a device to be safer than a model approved by the FDA “disrupts the federal scheme no less than state regulatory law to the same effect.” *Id.* at 1008. The Blunts’ position rests on the untenable assumption that a lay jury can determine whether a PMA-approved device is safe and, therefore, impose on the market the withdrawal of a device that a jury deems to be unsafe. That is not what the MDA provides, and rightly so. Federal specialists in health care,

science, device design and marketing have the sole authority to determine whether a given device is safe and effective.

*Riegel* clearly upholds federal preemption of the claims asserted here, and its dictates must be followed. *State v. Ward*, 2000 WI 3, ¶39, 231 Wis. 2d 723, 604 N.W.2d 517 (“On federal questions, the determinations of the United States Supreme Court are binding upon state courts.”); *Alberte v. Anew Health Care Services, Inc.*, 2000 WI 7, ¶7, 232 Wis. 2d 587, 605 N.W.2d 515 (same). Because *Riegel* is materially indistinguishable from this case, this Court must necessarily construe the MDA’s preemption clause in a similar manner and reach a similar result.

**II. The Blunts’ Mistaken Notion of Federal “Requirements” Does Not Preclude Preemption.**

To avoid the plain meaning of *Riegel*, the Blunts present an arcane approach to the statutory concept of a “requirement” that “relates to the safety and effectiveness of the device.” 21 U.S.C. § 360k(a). The Blunts do not dispute that a jury verdict in their favor would prohibit the manufacturer from marketing a PMA-approved device. (Initial Br. at 16). They nonetheless contend that preemption is not warranted because there is no federal “requirement” for Medtronic to market the Device with Battery. *Id.* As a result, the Blunts conclude, a state requirement banning the sale of a PMA-approved device is not different from, or in addition to a federal requirement. (Initial Br. at 16; Reply at 6).

The Blunts' position sidesteps the whole point of preemption – to maintain consistent federal safety requirements for design, manufacture and labeling of a covered device. *Riegel*, 128 S. Ct. at 1007. The fact that there is no federally imposed obligation to *sell* an approved device is irrelevant to the fact that common-law claims for negligence and strict liability would impose different or additional safety requirements on a device with specific, federally approved safety requirements.

In *Riegel*, the Court made clear that the relevant federal requirements are those imposed by the FDA pursuant to the PMA process and that the ability to market an approved device is contingent on scrupulous adherence to “the specifications in [the device’s] approval application.” *Id.* Here, a state verdict in favor of the Blunts would contravene a federal determination that the Device with Battery provides a reasonable assurance of safety and effectiveness. The Blunts want the Court to avert its gaze from the relevant federal requirements and look, instead, to non-existent requirements (like the absence of a federal mandate requiring Medtronic to market the Device with Battery) or requirements that are specific to the Device with Modified Battery, which is a device approved under a separate PMA Supplement, and have no bearing on the device in this case. Their ploy should be rejected.

### **III. The Blunts' Claims Are Not Exempted "Parallel" Claims.**

Although *Riegel* construed the MDA broadly, it recognized that “§360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.” *Id.* at 1011. Given that “parallel claims” may be exempted from preemption, it is not surprising that the Blunts try to fit their claims under this rubric, arguing that common law claims challenging the safety and effectiveness of a Class III medical device are not preempted if “the FDA has approved several different designs for a medical device and/or its components, and state law approves at least one of them” because “the state requirement parallels the federal requirement – it does not impose conflicting or additional burdens on the manufacturers.” (Initial Br. at 18).

It is not entirely clear why the Blunts believe that PMA approval of several different ICD designs somehow removes one of those designs from the reach of preemption. *Riegel* instructs that a manufacturer cannot be held liable for marketing a device that meets PMA requirements for safety and effectiveness, and thus it cannot be penalized for marketing multiple models of a device where each model and its components were subjected to the scrutiny of the PMA process, deemed by FDA to be safe and effective, approved for sale, and such approval was never withdrawn.

In fact, *Riegel* itself involved a device that had been modified pursuant to a PMA Supplement application. *Id.* at 1005. *See also Kemp v. Medtronic, Inc.*, 231 F.3d 216, 227 (6<sup>th</sup> Cir. 2000) (rejecting the argument that there is a categorical distinction between a device approved solely on a PMA application and a device that has been approved through a PMA application coupled with a subsequent PMA supplement).

Whether considering the first design, second, third or tenth supplemental design, every design approved under the PMA process is subject to MDA preemption. *See, e.g., Scott v. CIBA Vision Corp.*, 38 Cal. App. 4th 307, 321 (Cal. Ct. App. 1995) (negligence and strict liability claims involving an earlier design were preempted because the challenged product was “subject to class III MDA regulation at the time of the injury and ... the FDA had in fact approved the product for marketing, both in its original and in its new and improved packaging”). There is no principled reason for any other result. Here, the fact that the Device with Battery had PMA approval at the time it was implanted entirely disposes of the Blunts’ claims.

Finally, *Riegel* makes it abundantly clear that “parallel claims” are those “premised on a violation of FDA regulations.” *Riegel*, 128 S.Ct. at 1011. It defies logic to conclude that any of the Blunts’ claims fall into this category predicated as they are on Medtronic’s adherence to federal requirements, not its violation of them.

#### IV. Public Policy Favors Preemption.

MDA preemption applies only to a narrow category of sophisticated medical devices that share fundamental characteristics, including the ability to save lives.<sup>1</sup> Carving out exceptions will have numerous untoward effects on public health. At a bare minimum, they would result in higher health care costs because increased exposure to liability would need to be factored into the price of the product. As manufacturers move resources away from developing and marketing life-saving devices to defense and liability costs, innovations in medical technology will be hampered. *See, e.g.,* W. Kip Viscusi, *The Social Costs Of Punitive Damages Against Corporations In Environmental And Safety Torts*, 87 *Geo. L. J.* 285, 326 (1998) (“High damage levels suppress innovation across the board. Firms in effect stop innovating because of the substantial penalty that they suffer for new and uncertain product introductions .... Once damages become excessively high, either product development will stagnate or firms will withdraw from the market altogether.”)

One goal of preemption is to avoid such results. *Riegel’s* broad sweep embodies Congress’s “solicitude for those who would suffer

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<sup>1</sup> ICDs, for example, are associated with a 31 percent reduction in the risk of death for people who have had a heart attack. A. Moss, M.D., *et al.*, *Prophylactic Implantation of a Defibrillator in Patients with Myocardial Infarction and Reduced Ejection Fraction*, 346 *New Eng. J. Med.* 877 (2002).

without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations.” 128 S.Ct. at 1009. *See also*, M.C. Levy & G.J. Wartman, *Amicus Curiae Efforts to Reform Product Liability at the Food and Drug Administration: FDA’s Influence on Federal Preemption of Class III Medical Devices and Pharmaceuticals*, 60 Food & Drug L. J. 495, 508 (2005) (“allowing failure-to-warn claims to proceed even though a product has met the stringent FDA labeling requirements can harm the public’s health by encouraging manufacturers to withdraw products or to issue new warnings that overemphasize the risks and lead to ‘underutilization of beneficial treatments’”) (quoting *Horn v. Thoratec Corp.*, 376 F.3d 163, 178 (3d Cir. 2004)).

Upholding preemption gives incentives to manufacturers to develop devices that meet regulatory requirements because compliance with those requirements establishes preemption. A manufacturer’s resources can properly be used to develop medical devices rather than be allocated to defending jury trials. As explained in *Kemp v. Pfizer, Inc.*, 835 F.Supp. 1015, 1023 (E.D. Mich. 1993), “[if] manufacturers knew that their umbrellas would be snatched from them whenever it began to rain, then they would have no incentive to take the risk and venture outside.”

The public and the quality of health care also benefit when multiple devices with the same medical function are marketed. Individuals and their doctors may prefer one device over another because

of perceived differences in safety or effectiveness, differences in cost, preferences for a longer-marketed model that received wider patient exposure than a newer model, or many other reasons. A lay jury does not and should not have the authority to decide otherwise, by limiting the range of available devices or imposing a restricted market where only one form of device serving the same function is available.

PMA approval is and should be enough to sustain marketing. The public should have full access to the array of devices that are deemed “safe and effective” by federal regulators who specialize in making that determination. Safety requirements imposed *via* Wisconsin state tort law jeopardize access in Wisconsin to the choice of life-saving medical devices that are safe and effective and available to other Americans across the country. The FDA itself has pointed out the harm to public health when state actions

encourage, and in fact require, lay judges and juries to second-guess the balancing of benefits and risks of a specific device to their intended patient population – the central role of FDA – sometimes on behalf of a single individual or group of individuals. That individualized redetermination of the benefits and risks of a product can result in relief – including the threat of significant damage awards or penalties – that creates pressure on manufacturers to add warnings that FDA has neither approved, nor found to be scientifically required, or withdrawal of FDA-approved products from the market in conflict with the agency’s expert determination that such products are safe and effective. This situation can harm the public health by retarding research and development ....

Brief for FDA as *Amicus Curiae* Supporting Respondents, *Horn v. Thoratec Corp.* 376 F. 3d 163 (3d Cir. 2004), 2004 WL 1143720, at \*25-26 (May 14, 2004).

Similarly, to allow claims like the ones here to proceed would result in multiple lay juries imposing a patchwork quilt of requirements challenging the safety and effectiveness of devices that the federal government has already approved for marketing, thereby undermining the MDA. *Accord* H.R. Rep. No. 853, 94th Cong., 2d Sess. 45 (1976) (“[I]f a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened.”). Wisconsin juries could take entirely different views, indeed contradictory views, of the very same device. As the Court pointed out in *Riegel*, “tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation” because juries see “only the costs of a more dangerous design, and [are] not concerned with its benefits; the patients who reaped those benefits are not represented in courts.” *Riegel*, 128 S.Ct. at 1008.

Upholding preemption does not interfere with Wisconsin’s ability to seek an exemption, which is the proper way for Wisconsin to avoid the reach of the MDA’s preemption clause should it choose to do so. Because the MDA allows States to apply for exemptions to the express preemption clause, States are not left without recourse to challenge

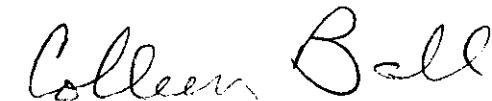
federal approval of a device. Pursuant to §360k(b), state requirements may be exempted from preemption if “required by compelling local conditions” and as long as the state requirements are more, not less, stringent than those mandated at the federal level. *See also* 21 C.F.R. §808.5 and 21 C.F.R. §808.20.

**CONCLUSION**

Wherefore, PLAC respectfully requests that this Court uphold the decision below.

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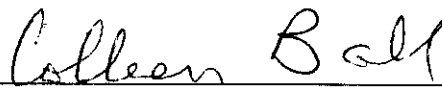
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**FORM AND LENGTH CERTIFICATION**

I hereby certify that this brief conforms to the rules contained in Wisconsin Statutes § 809.19(8)(b) and (c)(2) for a brief produced with a proportional serif font. The length of this brief is 2,997 words.

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Corporate Members of the Product Liability Advisory Council      App.1

# Corporate Members of the Product Liability Advisory Council

as of 6/19/2008

Total:120

3M  
ACCO Brands Corporation  
Altec Industries  
Altria Corporate Services, Inc.  
American Suzuki Motor Corporation  
Andersen Corporation  
Anheuser-Busch Companies  
Arai Helmet, Ltd.  
Astec Industries  
BASF Corporation  
Bayer Corporation  
Beretta U.S.A Corp.  
BIC Corporation  
Biro Manufacturing Company, Inc.  
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Boeing Company  
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Bridgestone Americas Holding, Inc.  
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Brown-Forman Corporation  
CARQUEST Corporation  
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Continental Tire North America, Inc.  
Cooper Tire and Rubber Company  
Coors Brewing Company  
Crown Equipment Corporation  
Daimler Trucks North America LLC  
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E.I. DuPont De Nemours and Company  
Easton-Bell Sports, Inc.  
Eaton Corporation  
Eli Lilly and Company  
Emerson Electric Co.  
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Estee Lauder Companies  
Exxon Mobil Corporation  
Ford Motor Company  
Genentech, Inc.  
General Electric Company  
General Motors Corporation  
GlaxoSmithKline  
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International Truck and Engine Corporation  
Isuzu Motors America, Inc.  
Jarden Corporation  
Johnson & Johnson  
Johnson Controls, Inc.  
Joy Global Inc., Joy Mining Machinery  
Kawasaki Motors Corp., U.S.A.  
Kia Motors America, Inc.  
Koch Industries  
Kolcraft Enterprises, Inc.  
Komatsu America Corp.  
Kraft Foods North America, Inc.  
Leviton Manufacturing Co., Inc.  
Lincoln Electric Company  
Magna International Inc.  
Mazda (North America), Inc.  
Medtronic, Inc.  
Merck & Co., Inc.  
Michelin North America, Inc.  
Microsoft Corporation  
Mine Safety Appliances Company  
Mitsubishi Motors North America, Inc.  
Mueller Water Products  
Nintendo of America, Inc.  
Niro Inc.  
Nissan North America, Inc.  
Nokia Inc.  
Novartis Pharmaceuticals Corporation  
Occidental Petroleum Corporation  
PACCAR Inc.  
Panasonic  
Pfizer Inc.  
Porsche Cars North America, Inc.  
PPG Industries, Inc.  
Purdue Pharma L.P.  
Putsch GmbH & Co. KG  
The Raymond Corporation  
Remington Arms Company, Inc.  
Rheem Manufacturing  
RJ Reynolds Tobacco Company

## **Corporate Members of the Product Liability Advisory Council**

as of 6/19/2008

Total:120

Sanofi-Aventis  
Schindler Elevator Corporation  
SCM Group USA Inc.  
Shell Oil Company  
The Sherwin-Williams Company  
Smith & Nephew, Inc.  
St. Jude Medical, Inc.  
Subaru of America, Inc.  
Synthes (U.S.A.)  
Terex Corporation  
Textron, Inc.  
TK Holdings Inc.  
The Toro Company  
Toshiba America Incorporated  
Toyota Motor Sales, USA, Inc.  
TRW Automotive  
UST (U.S. Tobacco)  
Vermeer Manufacturing Company  
The Viking Corporation  
Volkswagen of America, Inc.  
Volvo Cars of North America, Inc.  
Vulcan Materials Company  
Watts Water Technologies, Inc.  
Whirlpool Corporation  
Wyeth  
Yamaha Motor Corporation, U.S.A.  
Yokohama Tire Corporation  
Zimmer, Inc.