

**COURT OF APPEALS
DECISION
DATED AND FILED**

July 31, 2007

David R. Schanker
Clerk of Court of Appeals

NOTICE

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Appeal No. 2006AP1506

Cir. Ct. No. 2005CV3879

STATE OF WISCONSIN

**IN COURT OF APPEALS
DISTRICT I**

JOSEPH BLUNT, SR. AND MARGARET BLUNT,

PLAINTIFFS-APPELLANTS,

**STATE OF WISCONSIN DEPARTMENT OF HEALTH AND FAMILY
SERVICES,**

SUBROGATED-PLAINTIFF,

v.

MEDTRONIC, INC.,

DEFENDANT-RESPONDENT.

APPEAL from an order of the circuit court for Milwaukee County:
RICHARD J. SANKOVITZ, Judge. *Affirmed.*

Before Wedemeyer, P.J., Fine and Curley, JJ.

¶1 WEDEMEYER, P.J. Joseph Blunt, Sr. and Margaret Blunt appeal from an order dismissing their claim against Medtronic, Inc., following a summary

judgment hearing. The Blunts argue that the trial court erred in granting summary judgment to Medtronic. Specifically, they contend that their negligence and product liability claims are not pre-empted by 21 U.S.C. § 360k(a) (2000)¹ because the premarket approval of the defibrillator device does not constitute a specific federal requirement warranting pre-emption of state tort claims, a common law jury verdict does not constitute a state requirement, and even if it did, it would not be in conflict with the federal requirement. Because we conclude that the Blunts' claim is pre-empted, we affirm.

BACKGROUND

¶2 On December 17, 2002, the FDA approved Medtronic's request to market the Marquis 7230, an implantable cardioverter defibrillator, which used the Chi 4420L battery design. The medical device is capable of delivering a variety of therapies to patients suffering from chronic cardiac disease. In January 2003, during laboratory bench testing on the battery used in the Marquis 7230, Medtronic observed a potential shorting problem, which would cause the battery to fail. As a result, it worked to eliminate that potentiality, resulting in an improved battery for the defibrillator.

¶3 On October 6, 2003, Medtronic requested approval from the FDA to implement three design changes to the Chi 4420L battery to minimize the potential for internal shorting and to improve the robustness of the battery. The FDA approved the request to market the Marquis 7230 with the battery modifications on October 23, 2003. In early 2004, there were reports for the first time from the

¹ All references to the U.S.C. are to the 2000 version unless otherwise noted.

field that individual patients, who had received the original defibrillator, were experiencing the battery shorting problem.²

¶4 On May 19, 2004, Joseph Blunt underwent surgery, at which time the original Marquis 7230 defibrillator was implanted. In February 2005, Medtronic advised physicians of a possible battery shorting problem in the original Marquis 7230. As a result, Blunt and his physician decided as a precautionary measure to remove the previously implanted defibrillator and replace it with the improved version.

¶5 Subsequent to that surgery, the Blunts elected to file this lawsuit against Medtronic, alleging negligence, strict product liability, and a loss of consortium and companionship. Medtronic moved for summary judgment arguing that because the medical device had been approved by the FDA via the extensive premarket approval process, the Blunts' claims were pre-empted. The Blunts opposed the motion, contending that pre-emption should not apply here because: (1) the FDA's approval did not result in a specific federal design requirement; (2) a jury verdict in this case would not result in a state requirement different from the federal requirement applicable to the device; and (3) the Blunts' claims are based on state laws of general applicability. The trial court concluded that pre-emption applied and granted the motion for summary judgment. The Blunts filed a motion seeking reconsideration, which was also denied. They now appeal.

² There is an apparent dispute as to exactly when the first field reports occurred. The Blunts represent that these reports occurred as early as February 2004, while Medtronic indicated that the first confirmed field report occurred in April 2004. Resolution of this issue is not material to our decision.

DISCUSSION

¶6 This case arises following the grant of summary judgment, and therefore the summary judgment review process applies. In reviewing a grant of summary judgment, we employ the same methodology as the trial court. *Green Spring Farms v. Kersten*, 136 Wis. 2d 304, 315, 401 N.W.2d 816 (1987). We first examine the pleadings and affidavits to determine whether a claim for relief has been stated. *Id.* If a claim for relief has been stated, we then determine whether any factual issues exist. *Id.* If there is no genuine issue as to any material fact, and if the moving party is entitled to a judgment as a matter of law, we will affirm the trial court’s decision granting summary judgment. *Id.*

¶7 The sole issue in this case is whether the Blunts’ common law tort claims are pre-empted by federal law. The doctrine of pre-emption stems from the Supremacy Clause of the United States Constitution, U.S. CONST. art. VI, cl. 2, and operates to prevent state laws from conflicting with controlling federal laws. *Miezin v. Midwest Express Airlines, Inc.*, 2005 WI App 120, ¶9, 284 Wis. 2d 428, 701 N.W.2d 626. Our review on this issue is *de novo* as it involves a question of law. *Id.*, ¶7.

¶8 In 1976, the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act, *see* 21 U.S.C. § 360c, *et seq.*, were passed “to provide for the safety and effectiveness of medical devices intended for human use.” Pub. L. No. 94-295, 90 Stat. 539 (1976) (preamble). Medical devices were categorized into three groups related to the degree of risk posed by the device. Class I devices, such as ice packs and tongue depressors, which posed no risk, were subject only to general control regulations. *See* THOMAS R. MCLEAN, *Cybersurgery—An Argument for Enterprise Liability*, 23 J. LEGAL MED. 167, 187 (2002). Class II

devices, such as oxygen masks, were subject to specific controls and general controls. *Id.* Class III devices, such as the defibrillator, were subject to a much more rigorous review by the FDA before the device could be marketed for sale. 21 U.S.C. § 360e(d)(2). The manufacturer of a Class III device is required to submit an application for permission to the FDA before marketing the device. *See Id.* The trial court, in its decision below, described the process:

The manufacturer must submit the design of the device, manufacturing specifications, quality control procedures, a sample of the device and its proposed literature, instructions, labeling and advertising, and results of laboratory and clinical studies and trials. The FDA may approve the device for the use specified in the application if [the] manufacturer gives the FDA “reasonable assurance” that the device is safe and effective. 21 U.S.C. § 360e(d)(2). The FDA spends an average of about 1,200 hours per PMA application reviewing these materials....

If the FDA is satisfied with the assurances of the manufacturer, it issues “Conditions of Approval” that incorporate the design of the product. In other words, by virtue of FDA approval, the manufacturer becomes required to comply with the design, manufacturing specifications, etc. which it submitted to the FDA. 21 C.F.R. § 814.39. If any changes to the device are to be made, the manufacturer must return to the FDA for permission.... The end result ... appears to be a highly particularized set of requirements for Class III devices.

(Internal quotations omitted.). This process is referred to as “premarket approval,”³ or the PMA. The Medical Devices Amendments of 1976 also contain an express pre-emption provision, which provides:

³ Medtronic in its brief and at oral argument before the court provided the following description of the premarket approval process:

-[S]ubmission of a detailed application, including clinical data, manufacturing processes, and proposed labeling. 21 U.S.C. § 360e(c). A PMA application must include the following:

(continued)

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.

21 U.S.C. § 360k(a). The FDA thereafter promulgated regulations regarding the express pre-emption provision imposing some qualifications:

-A complete description of the device, its functional components, and the principles of its operation;

-A complete description of the methods, facilities and controls used for the manufacture, processing, packaging and storage of the device of sufficient detail so that the FDA “can make a knowledgeable judgment about the quality control used in the manufacture of the device”;

-A complete description of the properties of the device relevant to diagnosis and treatment of a disease or medical condition;

-The results of all nonclinical laboratory studies (including microbiological, toxicological, immunological, biocompatibility, stress, wear, shelf life);

-The results of all clinical studies;

-The results of all published reports concerning the safety and effectiveness of the device; and

-Copies of all proposed labeling, instructions, literature and advertising.

See 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814.20(b)

In addition, a manufacturer is obligated to comply with the design, labeling and manufacturing requirements that are approved by the FDA. 21 C.F.R. §§ 814.39, 814.80.

State 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, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements....

The following are examples of State or local requirements that are not regarded as preempted...:

State or local requirements of general applicability where the purpose of the requirement relates either to other products ... in which the requirements are not limited to devices.

21 C.F.R. § 808.1(d), (d)(1).

¶9 The qualifications have generated much discussion in cases, as in this one, where a person files a state lawsuit involving a medical device. There has been a great multitude of litigation across the country as to whether the state common law claim is pre-empted or not. Resolution of this issue is dependent upon whether the premarket approval process constitutes a federal requirement specifically applicable to a particular device, and whether the state common law tort suit would constitute a state requirement different from or in addition to the federal requirement. Twelve decisions across nine federal circuits have concluded that the premarket approval process for Class III devices constitutes a federal requirement specifically applicable to a particular device and that the state common law tort suit would constitute a state requirement in conflict—therefore, pre-emption applies. *See, e.g., Riegel v. Medtronic, Inc.*, 451 F.3d 104 (2d Cir. 2006); *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919 (5th Cir. 2006); *McMullen v. Medtronic, Inc.*, 421 F.3d 482 (7th Cir. 2005), *cert. denied*, 547 U.S. 1003 (2006) *cert. granted*, ___ S. Ct. ___; *Cupek v. Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005); *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004); *Brooks v.*

Howmedica, Inc., 273 F.3d 785 (8th Cir. 2001); *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001); *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000); *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997). One federal circuit court of appeals held that the premarket approval process does not constitute a specific federal requirement and therefore pre-emption is not triggered. See *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999).

¶10 Not surprisingly, Medtronic argues that this court should follow the majority of the federal circuits and conclude that pre-emption applies. The Blunts contend that the *Goodlin* court presents the correct approach and that the trial court's ruling applying pre-emption should be reversed. After a comprehensive review, we conclude that the majority view on this issue is more persuasive.

¶11 In 1996, the United State Supreme Court issued a decision, *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), wherein the state common law claims were not pre-empted by federal law. The Blunts rely on *Lohr* to support their claim that the FDA's approval does not result in a specific federal requirement. *Lohr*, however, is not dispositive because the medical device in *Lohr* was approved by the FDA through a less stringent, "substantially equivalent" approval process pursuant to 21 U.S.C. § 360(k), rather than the thorough and rigorous premarket approval process under 21 U.S.C. § 360e(c), utilized with respect to the defibrillator at issue in the instant case. In an *amicus curiae* brief filed in the Third Circuit Court of Appeals, the FDA explained the difference between the two approval processes:

A manufacturer can obtain an FDA finding of 'substantial equivalence' by submitting a pre-market notification to the agency in accordance with Section 510(k) of the [Act]. 21 U.S.C. § 360(k). A device found to be 'substantially equivalent' to a predicate device is said to be 'cleared' by FDA (as opposed to 'approved' by the

agency under a PMA). *A pre-market notification submitted under Section 510(k) is thus entirely different from a PMA, which must include data sufficient to demonstrate to FDA that the device is safe and effective. See Lohr, 518 U.S. at 478-79, 116 S.Ct. 2240 (“The § 510(k) notification process is by no means comparable to the PMA process.”).*

The number of medical devices that receive PMA review each year is dwarfed by the number of those that are marketed pursuant to cleared Section 510(k). In fiscal year 2003, for example, original PMAs represented only 54 of the 9,872 major submissions received. The previous fiscal year, original PMAs accounted for 49 of 10,323 total submissions.

Horn, 376 F.3d at 167 (citing the FDA’s *Amicus Curiae* Letter Brief) (emphasis in original).

¶12 After analyzing the *Lohr* decision and the difference between the “cleared” and “approved” FDA approval processes, the *Horn* court held that a medical device, which was approved via the premarket approval process “would give rise to preemption under § 360k(a),” *Horn*, 376 F.3d at 169, because the premarket approval process results in a specific federal requirement. The trial court, in the instant case, reached the same conclusion:

Comparing the *Goodlin* line of cases with the [*Horn*] line of cases, I find myself more persuaded by the latter. Congress authorized preemption to avoid conflicts with “any requirement applicable under this chapter to the device.” It did not specify who must author the requirement or that the requirement incorporate any particular “substance” that could not be achieved by a mandatory review-and-approval process that in fact requires certain devices to be manufactured and marketed in certain ways. Therefore, I conclude that the result of the PMA process involving the ICD implanted in Mr. Blunt was a federal requirement that may preempt this lawsuit, depending on the other factors in the equation.

We agree with and adopt both the trial court’s analysis and that set forth in the *Horn* line of cases. The premarket approval process involves “an exhaustive

inquiry into the risks and efficacy of a device,” and “imposes federal requirements based on the highly detailed and prescriptive nature of the PMA process and the approval order that results from it.” *Id.* at 171-72.

¶13 It is undisputed here that the defibrillator at issue underwent the aforescribed premarket approval process. The application with all the paperwork went to the FDA for approval. The FDA, presumably, complied with its obligations and conducted a thorough review of the documentation submitted and determined that the medical device could be marketed to the public. We must agree with the majority of the circuit courts, who have already ruled on this issue, that such process does constitute a specific federal requirement.

¶14 The next step in our pre-emption analysis is to determine whether the jury verdict here would constitute a state requirement. The Blunts contend that the jury verdict in this case would not impose a state requirement different from the federal requirement, particularly here because at the time Blunt received his defibrillator, the better-battery version was available. Thus, if a jury finds that Blunt should have received the better-battery version, such a verdict would not conflict with the federal requirement approving that version. Medtronic responds that the common law tort claim does constitute a state requirement, which would conflict with the federal requirement as the FDA specifically approved the defibrillator’s original design, and therefore a jury verdict rendering that design defective would conflict with the federal requirement. Medtronic also points out that the majority of courts addressing this issue have concluded that the common law state claim constitutes a state requirement that conflicts with the federal requirement and therefore is pre-empted. *See Riegel*, 451 F.3d at 122; *Gomez*, 442 F.3d at 929-30; *McMullen*, 421 F.3d at 488-89; *Cupek*, 405 F.3d at 424;

Horn, 376 F.3d at 176; *Brooks*, 273 F.3d at 796; *Papike v. Tambrands, Inc.*, 107 F.3d 737, 741 (9th Cir. 1997).

¶15 The trial court, in analyzing the law on this issue, again concluded that Wisconsin should follow the consensus of the foreign jurisdictions, reasoning:

... a consensus of sorts seems to have developed in the Supreme Court itself. Just last term, the Court held that the term “requirements” in a somewhat similar preemption provision of a different statute (the Federal Insecticide, Fungicide and Rodenticide Act...) could be read to bar damage actions premised on common law. In *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 ... (2005), the court wrote:

The Court of Appeals did ... correctly hold that the term “requirements” in § 136v(b) reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties. Our decision in *Cipollone* supports this conclusion. See 505 U.S., at 521 ... (“The phrase ‘[n]o requirement or prohibition’ sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules”) ... While the use of “requirements” in a preemption clause may not invariably carry this meaning, we think this is the best reading of § 136v(b).

....

Wisconsin appellate courts have yet to weigh in on these issues. However, because a clear majority of courts in other jurisdictions have reached a consensus, I believe that our appellate courts would join their ranks.... Based on the weight of precedent, I conclude that a jury verdict premised on the Wisconsin common law of negligence and strict liability would constitute a state law “requirement” under Section 360k(a), and, therefore, a lawsuit challenging the design or function of a medical device approved for marketing by the FDA, such as the Blunts’, is preempted.

¶16 The trial court was correct in its analysis of the case law emerging on this issue and we agree that based on the consensus of the precedent *and* the

logic attached to its conclusion, that the Blunts' common law claim is a state requirement, which is pre-empted by the federal requirement.

¶17 Although there is some dispute as to whether a jury verdict following a common law tort suit results in a state requirement, we are persuaded that such conclusion is correct. State law actions can constitute a state requirement if the verdict rendered in such action would impose a requirement on a manufacturer that is not required by the FDA during the premarket approval process. In the instant case, a jury verdict in the Blunts' favor would result in a jury finding that the original defibrillator implanted in Mr. Blunt was defective, either in its design or manufacture. Such a conclusion runs contrary to the FDA's approval of the original design as being safe to sell. Thus, the jury verdict would in effect threaten the federal premarket approval process by imposing on a manufacturer an obligation to modify what had previously been approved. While a common law tort suit may not traditionally fit into the term "state regulation" quite like a statute or regulation would, the practical effect of a jury verdict in this case would be the same. Stated another way, the State of Wisconsin would not be permitted to pass a statute or regulation requiring that Medtronic must sell only defibrillators with a particular battery if the FDA has not imposed such a requirement. There is really no difference between a statute or regulation on batteries in defibrillators and a jury verdict finding the battery in an FDA approved defibrillator to be defective. If the State cannot pass a statute or regulation on this issue because of pre-emption, we certainly cannot allow a lawsuit to circumvent pre-emption simply because it came through the judicial system instead of the legislative system. Based on the foregoing, we conclude that the common law tort claim in this case does constitute a state requirement.

¶18 The Third Circuit, in the *Horn* case, citing the FDA, set forth the logic behind this conclusion:

State common law tort actions threaten the statutory framework for the regulation of medical devices, particularly with regard to FDA's review and approval of product labeling. State actions are not characterized by centralized expert evaluation of device regulatory issues. Instead, they 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 and by encouraging 'defensive labeling' by manufacturers to avoid state liability, resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments.

....

[I]t is inappropriate for a jury to second-guess FDA's scientific judgment on such a matter that is within FDA's particular expertise. FDA determines the scope of a device, including the components it comprises, and the appropriate regulatory pathway for the device.... FDA subsequently determines whether the device meets the PMA approval standard. The agency makes a reasoned and deliberate decision as to the correct pathway of regulation and whether to approve the device. Juries lack the scientific knowledge and technical expertise necessary to make such judgments....

[T]he prospect of hundreds of individual juries determining the propriety of particular device approvals, or the appropriate standards to apply to those approvals, is the antithesis of the orderly scheme Congress put in place and charged the FDA with implementing.

Such uncertainty as to the status of medical devices would create chaos for both the regulated industry and FDA.

Horn, 376 F.3d at 178 (citation omitted). We agree with the reasoning set forth above and join the courts, which have concluded that the premarket approval process constitutes a federal requirement and the Blunts' common law tort claim in this suit would result in a state requirement in conflict with the federal requirement. The trial court aptly explained how a jury verdict in the Blunts' favor would conflict with the federal requirement:

I am persuaded that the result of this lawsuit would be the specific kind of substantive requirement for Medtronic ICDs that the statute and its regulations seek to avoid. An unfavorable verdict would pinpoint the battery system, call its design or manufacture into question and suggest that the design or manufacture, despite winning FDA approval, breaches the duty of care Medtronic owes its customers. In order to avoid being held liable to patients who wished to remove or replace their ICDs, Medtronic would have little choice but to alter its product. Although altering the product would not be mandated explicitly by government, Medtronic's lack of choice in the matter amounts, in my mind, to a requirement. Because this requirement arises as the result of state law applied specifically to Medtronic's product that results in a particularized obligation to change the product or be found liable, I believe the Blunts' lawsuit would have the effect of establishing a substantive requirement for Medtronic's ICD and therefore the lawsuit is preempted.

....

The Blunts essentially would be asking a jury in this court to find that the FDA process is insufficient, that what came to light during the supplemental process is indeed a defect in the Model 7230 and that the FDA should have ordered the Model 7230 off the market before it could be implanted in Mr. Blunt. A jury verdict implying as much would add requirements to the PMA process. Accordingly, preemption applies.

¶19 We adopt the trial court’s analysis quoted above as our own. In sum, we conclude that the premarket approval process, which occurred here, constitutes a specific federal requirement. It is undisputed that the defibrillator involved here was approved by the FDA for marketing only after the thorough and extensive premarket approval process was complete. We further conclude that the Blunts’ state common law tort suit constitutes a state requirement, which would result in a conflict with the federal requirement. The main basis for the Blunts’ claim is that the original battery design was defective due to the potential shorting mechanism. If a jury found in favor of the Blunts on that claim, it would result in a state requirement different from the federal requirement. It would result in a jury finding that the FDA’s approval of the design was erroneous. It would usurp the power Congress gave to the FDA, and thus must be pre-empted.

¶20 The Blunts contend that because the better-battery design was available for implantation in Mr. Blunt, the lawsuit would not result in a conflict with the federal requirement because the FDA approved two designs for this product and therefore Medtronic was not *required* to use the original design. We are not persuaded. A similar argument was rejected by the Seventh Circuit in *McMullen*:

In order for a state requirement to be parallel to a federal requirement, and thus not expressly preempted under § 360k(a), the plaintiff must show that the requirements are “*genuinely* equivalent.” State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law.

Id., 421 F.3d at 489 (citations omitted). Here, if the Blunts’ claims are not pre-empted, Medtronic could be held liable under Wisconsin common law even though it did not violate any federal law. The FDA approved both the original

defibrillator and the better-battery defibrillator. Both were available for implantation at the time Mr. Blunt received his device. Both were approved by the FDA at the time Mr. Blunt received his device. No restrictions were imposed on selling devices with the original design. The FDA has the authority to issue an immediate cease distribution order for all products found to cause “serious, adverse health consequences or deaths.” 21 U.S.C. § 360h(e)(1). The FDA may also order a recall. *Id.* At the time Blunt received his device, both versions were approved by the FDA. Thus, as the trial court concluded:

Because success for the Blunts in this case means the imposition on Medtronic of liability that the FDA, which did not order Medtronic to alter the design of the ICD implanted in Mr. Blunt nor withdraw it from the market, could not impose, the Blunts cannot show that their lawsuit would have an effect equivalent to that of pertinent federal regulations, and therefore it is preempted.

¶21 Based on the foregoing, we conclude that the trial court did not err when it concluded that the Blunts’ claims are pre-empted by federal law. We affirm the grant of summary judgment in favor of Medtronic.⁴

By the Court.—Order affirmed.

Recommended for publication in the official reports.

⁴ At oral argument, this issue of discovery was raised. Briefs addressing the issue of discovery were filed simultaneously following the Blunts request post oral argument to address discovery. Based on our review of those briefs and the disposition in this case, we are not convinced that the discovery issue needs to be addressed by this court. See *Gross v. Hoffman*, 227 Wis. 296, 300, 277 N.W. 663 (1938).

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¶22 FINE, J. (*dissenting*). The Majority asks and answers the wrong question. Assuming that state tort law can be pre-empted by 21 U.S.C. § 360k, *see* Majority, ¶¶8–19, *cf. Estate of Kriefall ex rel. Kriefall v. Sizzler USA Franchise, Inc.*, 2003 WI App 119, ¶¶3–4, 265 Wis. 2d 476, 484–487, 665 N.W.2d 417, 421–423 (Federal Meat Inspection Act, 21 U.S.C. §§ 601–695), the nub here is: Whether Medtronic is protected by the pre-emption doctrine when it had the *option* under federal law of selling two approved devices (for shorthand purposes, the good one and the not-so-good-one) but sold the not-so-good-one—knowing that it had a better device that was also approved—in order to clear its inventory of the obsolete, less-safe devices. In my view, it is not.

¶23 In its essence, the pre-emption doctrine is a rule against retrospective second-guessing. *See Gomez v. St. Jude Med. Daig Div., Inc.*, 442 F.3d 919, 930 (5th Cir. 2006).¹ But there is no danger of second-guessing here; when Medtronic

¹ The Majority quotes from the approval in *Horn v. Thoratec Corp.*, 376 F.3d 163, 178 (3d Cir. 2004), of a statement of policy submitted to *Horn* by the Food and Drug Administration in an amicus brief that permitting state-tort-law actions could have all sorts of dire consequences: “This situation can harm the public health by retarding research and development and by encouraging ‘defensive labeling’ by manufacturers to avoid state liability, resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments.” Majority, ¶18. The plurality in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 490–491 (1996), however, determined that those concerns were not as significant as Medtronic there argued:

While the Act certainly reflects some of these concerns, the legislative history indicates that any fears regarding regulatory burdens were related more to the risk of *additional* federal and state regulation rather than the danger of pre-existing duties under common law. *See, e.g.*, 122 Cong. Rec. 5850 (1976) (statement of Rep. Collins) (opposing further “redundant and burdensome Federal requirements”); *id.*, at 5855 (discussing

(continued)

sold the out-of-date defibrillator to Joseph Blunt, Sr., it *knew* that it was more dangerous (both because of its own tests *and* also reports it was getting from patients implanted with that model) than its new, improved model, which, when it sold the old one to Blunt, *had also been approved* by the Food and Drug Administration. Majority, ¶¶2–4. Yet, even though at oral argument, Medtronic’s lawyer admitted that the Food and Drug Administration “did not force us to clear the inventory out,” the Majority gives it pre-emption immunity for a purely economic decision that put patients like Blunt at risk.

¶24 In response to a hypothetical asked during oral argument, Medtronic’s lawyer said that pre-emption would shield it from liability even if the mortality rate were 80% (80 of 100 patients dying)! And, I see nothing in the Record or in the Majority opinion that leads me to believe that the answer of Medtronic’s lawyer would be any different if 85 persons out of one-hundred were to die, or 90, or 95, or if the total lethality was 100% (everyone dying).

efforts taken in [the Medical Device Amendments] to protect small businesses from the additional requirements of the Act). Indeed, nowhere in the materials relating to the Act’s history have we discovered a reference to a fear that product liability actions would hamper the development of medical devices. To the extent that Congress was concerned about protecting the industry, that intent was manifested primarily through fewer substantive requirements under the Act, not the pre-emption provision; furthermore, any such concern was far outweighed by concerns about the primary issue motivating the [Medical Device Amendments]’s enactment: the safety of those who use medical devices.

(Footnote omitted; emphasis by *Medtronic*.) Further, as we noted in *Estate of Kriefall ex rel. Kriefall v. Sizzler USA Franchise, Inc.*, 2003 WI App 119, ¶45, 265 Wis. 2d 476, 517, 665 N.W.2d 417, 437, “the United States Supreme Court has assumed that the agency’s view is entitled to *no* deference. *Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 744 (1996) (assuming, but not deciding, that ‘whether a statute is pre-emptive ... must always be decided *de novo* by the courts’).” (Emphasis by *Kriefall*.)

¶25 To say, as the Majority says in ¶20, that pre-emption gives Medtronic immunity for selling a less-safe product to clear its inventory merely because the Food and Drug Administration did not act immediately even though Medtronic both (1) had an approved device that was more safe, and (2) was under no preemption-compulsion to sell the less-safe device, transforms the valuable pre-emption shield into a dagger poised above the hearts of patients, contrary to the intent of Congress. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 491 (1996) (“[T]he primary issue motivating the [Medical Device Amendments]’s enactment [was] the safety of those who use medical devices.”). Accordingly, I respectfully dissent.²

² I recognize that an intermediate appellate court in California held that a manufacturer that sold a soft-lens cleaning solution in a package that could be mistaken for a soft-lens rinse was protected by federal pre-emption when the cleaning solution would hurt the eyes unless rinsed off before the lenses were used, even though the Food and Drug Administration had also approved less-confusing packaging when the old packages were apparently sold to the plaintiff. See *Scott v. CIBA Vision Corp.*, 38 Cal. App. 4th 307, 320–321 (Cal. Ct. App. 1995). We are, of course, not bound by *Scott*, and, in my view, it is wrong.

