Appeal No. A12-609

IN THE COURT OF APPEALS OF THE STATE OF MINNESOTA

BARBARA LAMERE, trustee for the heirs and next-of-kin of Sergeant Major Thomas C. Lamere, deceased,

Plaintiff-Appellant,

v.

ST. JUDE MEDICAL INC., AND ST. JUDE MEDICAL S.C., INC.,

Defendants-Appellees,

APPELLANT'S PRINCIPAL BRIEF

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LEGAL ISSUES

This wrongful death action arises from a manufacturing defect in a heart valve that caused the valve to break, killing Thomas Lamere, in whom it was implanted. Plaintiff Barbara Lamere's claims rest on Minnesota tort principles that impose liability when a defect in manufacturing renders a product unreasonably dangerous and the defect causes injury. The Medical Device Amendments (MDA) to the federal Food, Drug, and Cosmetic Act (FDCA) contain a provision, 21 U.S.C. § 360k(a), which preempts any state requirement imposed on a medical device "(1) which is different from, or in addition to, any requirement applicable under [the MDA] 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 [the MDA]." The defendants assert that this provision preempts Minnesota tort law imposing strict liability for manufacturing defects. The case presents the following legal issues:

1. Whether Minnesota common-law manufacturing-defect claims impose "requirements" on medical device manufacturers that are "different from" or "in addition to" some "requirement" imposed by federal law and are thus preempted by the Medical Device Amendments, 21 U.S.C. § 360k(a).

The district court held in the affirmative on defendants' renewed motion for summary judgment. Preserved for appeal in plaintiff's oppositions to defendants' motion for summary judgment and renewed motion for summary judgment.

Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).

Riegel v. Medtronic, Inc., 552 U.S. 312 (2008)

2. Whether state common-law doctrines holding medical device manufacturers strictly liable for manufacturing defects are outside the scope of 21 U.S.C. § 360k(a) because they are parallel to Food and Drug Administration (FDA) regulations requiring medical device manufacturers to prevent manufacturing defects.

The district court held in the negative on defendants' renewed motion for summary judgment. Preserved for appeal in plaintiff's oppositions to defendants' motion for summary judgment and renewed motion for summary judgment.

Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).

Bass v. Stryker Corp., 669 F.3d 501 (5th Cir. 2012).

Bausch v. Stryker Corp., 630 F.3d 546, 555 (7th Cir. 2010).

Howard v. Sulzer Orthopedics, Inc., 382 F. Appx. 437 (6th Cir.2010).

STATEMENT OF THE CASE

The appellant in this case, Barbara Lamere, filed this wrongful death action in the District Court for the Second Judicial District seeking damages for injuries

caused by a manufacturing defect in a mechanical heart valve that resulted in the death of her husband. Ms. Lamere's complaint asserted, among other bases for liability, a claim based on strict product liability for manufacturing defects. App. A-1–A-10. The appellees, St. Jude Medical Inc. and St. Jude Medical S.C., Inc. (referred to collectively as "St. Jude"), moved for summary judgment, claiming that Ms. Lamere's manufacturing-defect claim is preempted by the MDA, under which St. Jude had received approval to market the heart valve. App. A-24. The District Court, Hon. Robert A. Awsumb, held that the manufacturing-defect claim was not preempted, but he dismissed Ms. Lamere's other claims on preemption grounds. Addendum 6a-27a. After the discovery period, St. Jude renewed the motion for summary judgment on the manufacturing-defect claim. App. A-48 The District Court, Hon. David C. Higgs, granted summary judgment to St. Jude on the ground that Ms. Lamere had not shown that her state-law manufacturing-defect claim was "parallel" to a specific federal requirement applicable to the device. Addendum 1a-5a. Final judgment was entered based on Judge Higgs' grant of summary judgment on March 21, 2012. Addendum 1a.

STATEMENT OF THE FACTS

I. Factual Background

This case arises from the death of Thomas C. Lamere (USMC Ret). On September 20, 2007, Mr. Lamere was doing yard work at his home when he

suffered acute heart failure. His wife, Barbara Lamere, found him lying unresponsive in their back yard and immediately called 911. Chu Aff., Orange County Sheriff-Coroner Report. When the paramedics arrived, they attempted to revive Mr. Lamere using EKG pads, but their efforts were unsuccessful. Mr. Lamere was pronounced dead soon thereafter. *Id*.

Dr. Richard I. Fukumoto performed an autopsy on Mr. Lamere, which revealed the cause of death to be displacement of a leaflet in Mr. Lamere's mechanical heart valve. Fukumoto Aff., Final Anatomical Diagnosis, at Microscopic Examination p. 3. In 1988, Mr. Lamere had undergone surgery to have his mitral heart valve replaced with a St. Jude Mechanical Heart Valve, Model No. 33M10, Serial Number 166155. Coyle Aff. ¶ 19. This type of mechanical heart valve was approved by the FDA in 1982, when it accepted St. Jude's application for premarket approval. *Id*. ¶ 16. The St. Jude Mechanical Heart Valve consists of a ring supporting two leaflets that open and close to regulate blood flow through the heart. The ring and leaflets are made of graphite and coated with pyrolitic carbon. App. A-2, Amended Complaint, ¶ 5.

Dr. Fukumoto stated in his autopsy report that a leaflet in Mr. Lamere's heart valve had broken. He wrote that "one of the prosthetic valve leaflets appears to have been completely displaced and is located in the left ventricle. This leaflet appears incomplete with evidence of a 0.4-0.5 cm missing fragment at one end."

Fukumoto Aff., Final Anatomical Diagnosis, at Gross Examination p. 2. Dr. Fukumoto concluded that "death in my opinion is due to acute heart failure from displacement of the mechanical heart valve leaflet," although he could not completely rule out "the remote possibility of displacement being caused by the embalming/trochar procedure." *Id*. p. 3.

Dr. Constantine Armeniades, a Rice University Professor in the Department of Chemical and Biomolecular Engineering, subsequently performed an examination of Mr. Lamere's mechanical heart valve using a scanning electron microscope. Addendum 29a, Armeniades Aff. ¶ 3. Dr. Armeniades' examination of the leaflet revealed that the outer layer of pyrolytic carbon had not completely fused and that, consequently, a series of pores and crevasses had formed on the leaflet's surface. These defects led to the formation of cracks, which caused the leaflet to fracture and separate. Addendum 29a, Armeniades Aff. ¶¶6-8. Based on this evidence, Dr. Armeniades concluded that "the fracture of the valve leaflet was caused by a manufacturing defect and that such manufacturing defect existed within the pyrolytic carbon component of the valve leaflet," and further that "the manufacturing defect occurred during the finishing process, where the valve leaflet is ground and polished in order to reduce the amount of surface porosity with the ultimate goal of eliminating porosity." Addendum 29a, Armeniades Aff. ¶¶ 4-5. He also concluded that the manufacturing defect "occurred due to the failure to

properly finish and polish the valve leaflet, and failure to detect its flaws during the post-manufacturing inspection," and that "the fracture of Sergeant Major Lamere's valve leaflet was not caused in the embalming process or the explantation of the valve." Addendum 29a-30a, Armeniades Aff. ¶¶ 9-10.

II. Statutory and Decisional Background

A. The Medical Device Amendments

In 1976, Congress enacted the MDA, 21 U.S.C. § 360c *et seq*., which "imposed a regime of detailed federal oversight" on companies that sell medical devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). The MDA was enacted in response to Congress's concern about health risks posed by medical devices including heart valves, catheters, defibrillators, pacemakers, and, most notably, the Dalkon Shield intrauterine device, which famously caused a high number of infections and deaths. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996); *Regulation of Medical Devices (Intrauterine Contraceptive Devices), Hearings Before a Subcommittee of the House Committee on Government Operations*, 93d Cong., 1st Sess. (1973); *Medical Device Amendments, 1973, Hearings Before the Subcommittee on Health of the Senate Committee on Labor and Public Welfare*, 93d Cong., 2d Sess., 270-361 (1973).

Congress intended the MDA to ensure that medical devices are safe for use by the public. To achieve this objective, it established a tripartite regulatory

scheme for new medical devices. The MDA divides medical devices into Class I, Class II, and Class III devices, in ascending order of risk, and establishes regulatory standards applicable to each class. *See* 21 U.S.C. § 360c. Class III devices that are not substantially similar to devices already on the market when the MDA was enacted must receive premarket approval (PMA) from the FDA. To obtain PMA, the MDA requires that the manufacturer of a medical device submit an application to the FDA that includes, among other things, "reports of all information … concerning investigations which have been made to show whether or not such device is safe and effective," "a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device," and "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device." 21 U.S.C. § 360e(c)(1). The FDA reviews the application and grants approval only if it finds a "reasonable assurance" of the device's "safety and effectiveness," 21 U.S.C. § 360e(d). In particular, the statute instructs the FDA to determine the safety and effectiveness of a device by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C).

By contrast, a Class III device that is substantially equivalent to a device already on the market when the MDA was enacted is not required to undergo

PMA, but may be marketed through what is referred to as the "§ 510(k) process," which does not involve rigorous FDA review and approval of the device's design, but only a determination that the device is equivalent to a device already on the market. *See Lohr*, 518 U.S. at 477-79.[1]

The MDA includes a provision that preempts certain state regulations related to the safety or effectiveness of covered medical devices. The preemption provision states in relevant part:

> [N]o 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). Section 360k(a) was aimed at preventing state governments from issuing regulations that would interfere with federal regulation by imposing further requirements on medical device manufacturers with respect to matters already subject to specific federal regulation. *See Lohr*, 518 U.S. at 490 n.12 (plurality opinion of Stevens, J.) (noting that "the very existence of the pre-emption statute demonstrates some concern that competing state requirements may unduly interfere with the market for medical devices," and that the legislative

[1] Although the device at issue in this case underwent PMA rather than the § 510k process, familiarity with both processes is necessary to an understanding of the U.S. Supreme Court's decisions concerning the preemptive effect of the MDA.

history suggests this concern "related more to the risk of additional federal and state regulation rather than the danger of pre-existing duties under common law"). The FDA subsequently promulgated regulations interpreting § 360k(a), which provide that state and 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." 21 C.F.R. § 808.1(d).

B. *Medtronic v. Lohr* and *Riegel v. Medtronic*

The United States Supreme Court has twice ruled on the scope of the MDA's preemption provision, in *Medtronic v. Lohr*, 518 U.S. 470, and *Riegel v. Medtronic*, 552 U.S. 312.

In *Lohr*, the Court considered the argument that § 360k(a) of the MDA preempted a variety of common-law tort claims stemming from a malfunctioning pacemaker—specifically, manufacturing-defect claims, design-defect claims, and failure-to-warn claims. The Court made three key holdings concerning such preemption. First, the Court unanimously held that design-defect claims are not preempted if the device in question was approved through the § 510(k) process. 518 U.S. at 492-94 (majority), 513 (O'Connor, J., concurring in part, dissenting in part). As explained above, the § 510(k) process grandfathers in new devices that are similar to devices that existed prior to the MDA, and thus focuses on

"substantial equivalence" to pre-existing devices rather than on substantive safety standards. *Id*. at 491-94. Claims based on the design of such devices are not preempted, the Court held, because the § 510(k) process does not impose specific federal requirements with respect to design. Therefore, absent a federal requirement, § 360k(a)'s prohibition on requirements different from or in addition to federal requirements is not triggered.

Second, the Court held, again unanimously, that even where a specific federal requirement is applicable to a medical device, state-law claims based on common-law duties are not preempted if those duties parallel federal requirements, even if the state common-law claims require proving additional elements beyond what is needed to establish a violation of under federal law. *Id.* at 494-97 (majority), 513 (O'Connor, J., concurring in part, dissenting in part). In such cases, the state-law claims fall outside the scope of the MDA's preemption provision because they do not impose "different" or "additional" requirements beyond those imposed by federal law.

Third, the Court held that the Lohrs' manufacturing-defect claims were not preempted by the MDA and the FDA's general manufacturing practices regulations, because such state-law claims do not conflict with *device-specific* federal requirements. *Id.* at 497-512. The Court explained that such claims, based on general state-law duties applicable to all manufacturers, were not preempted

because the FDA's manufacturing practices regulations were generic and, therefore, did not establish requirements "applicable to the device" within the meaning of the MDA's preemption provision. *See id.* at 498.

Later, in *Riegel*, the Court considered whether § 360k(a) preempts design-defect and failure-to-warn claims against manufacturers of devices (like the valve at issue in this case) that have undergone PMA, as distinguished from devices marketed through the § 510(k) process. The Court concluded that, in such cases, the MDA does preempt state-law design and warning claims. *Riegel*, 552 U.S. at 323-25. The Court distinguished the device at issue in *Lohr* by noting that, unlike the § 510(k) process, PMA is "focused on safety, not equivalence," *id.* at 323, and that approval imposes specific requirements dictating the design and labeling of the particular device. *Id.* State-law claims that would effectively require the manufacturer to use a design or labeling different from the federally approved one, the Court held, are preempted because they impose different or additional requirements. *Id.* at 325.

Riegel did not address manufacturing-defect claims because no such claims were before it. *Id.* at 321 n. 2. The Court thus left intact *Lohr*'s holding that manufacturing-defect claims are not preempted by § 360k(a). *Lohr*, 518 U.S. at 497-512; *Riegel*, 552 U.S. at 322. *Riegel* also reaffirmed *Lohr*'s holding that the MDA does not preempt state requirements that parallel federal requirements.

While the Court did not consider whether the claims in *Riegel* had federal parallels, because that argument had not been presented below, the Court reiterated *Lohr*'s holding 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 321-23, 330.

III. Procedural Background

Barbara Lamere filed her initial complaint in the District Court of the Second Judicial District, Ramsey County, on July 9, 2010. The complaint pleaded several causes of action, including strict liability for manufacturing defects, and sought to recover for wrongful death and loss of consortium. St. Jude filed a motion for summary judgment on October 8, 2010, arguing that each of Ms. Lamere's substantive claims was preempted by the MDA and that the statute of limitations had run. App. A-24. On February 7, 2011, the Honorable Robert A. Awsumb issued an order denying summary judgment on the statute of limitations question, dismissing all of the substantive claims except the manufacturing-defect claim on preemption grounds, and allowing the manufacturing-defect claim to proceed to discovery and trial. Judge Awsumb concluded:

> [The] manufacturing defect claim as to the particular device implanted into Lamere is not preempted. It would not impose requirements that are 'different from or in addition to' the federal requirements. Rather, it is a claim that this particular unit was not manufactured as approved by the FDA, but rather contains a unique defect caused by damage in the manufacturing process.

Addendum 27a.

Following the close of the discovery period, St. Jude filed a renewed motion for summary judgment on December 12, 2011. App. A-48. The motion made the same preemption argument that had been rejected in the February 7 order denying the earlier motion for summary judgment: that Ms. Lamere's manufacturing-defect claim is preempted by the MDA. The Honorable David C. Higgs granted summary judgment on that question in a January 18, 2012 order, stating that Ms. Lamere had failed to establish a "parallel" claim because she "failed to cite any federal requirement that was violated in the manufacture of Lamere's valve." Addendum 5a. This appeal is taken from the final judgment entered on March 21, 2012, based on the January 18 order. Addendum 1a.

STANDARD OF REVIEW

Minnesota appellate courts review legal questions that arise on appeal from grants of summary judgment de novo. *SCI Minn. Funeral Servs., Inc. v. Washburn-McReavy Funeral Corp.*, 795 N.W.2d 855, 861 (Minn. 2011).

ARGUMENT

The critical fact about this case is that Ms. Lamere's manufacturing-defect claim does not challenge, directly or indirectly, the FDA's premarket approval of the St. Jude heart valve that killed her husband. Ms. Lamere does not contend that the design or labeling approved by the FDA is flawed. Rather, her claim is that the

individual valve implanted in Mr. Lamere had defects—cracks and holes in its surface coating—that are not inherent in its design or part of its approved specifications, that were the result of improper execution of the production processes used by St. Jude to make the valve, and that ultimately led the valve to break, with fatal results. Imposing liability on St. Jude for its flawed execution of the FDA-approved design does not subject St. Jude to any requirement that is different from or in addition to any identifiable federal requirement that applies specifically to the product. To the extent that the manufacturing-defect claim can be said to impose any requirements on St. Jude, they run parallel to the federal requirements that it use good manufacturing practices to ensure that its products are not defective. The MDA's preemption provision does not deny persons injured by defectively manufactured products a state-law remedy under such circumstances.

I. Ms. Lamere's manufacturing-defect claim is not a "requirement" preempted by the Medical Device Amendments.

Under the U.S. Supreme Court's controlling decisions, *Lohr* and *Riegel*, manufacturing-defect claims such as Ms. Lamere's are not preempted by the MDA. In *Lohr*, the Supreme Court held that § 360k(a) does not preempt state common-law manufacturing-defect claims. Although the device at issue there was a § 510(k) device and the device at issue here is a PMA device, the same analysis applies because St. Jude has identified no device-specific federal manufacturing

requirements applicable to the device at issue that Ms. Lamere's manufacturing-defect claims add to or differ from..

The intermediate appellate court in *Lohr* had concluded that § 360k(a) preempted the plaintiff's manufacturing-defect claims because the claims "related to" the FDA's "good manufacturing practices" (GMP) regulations, 21 CFR §§ 820.20–820.198.[2] The Supreme Court reversed, explaining that the manufacturing-defect claims were not preempted because federal law imposed no specific requirements with respect to manufacturing the *particular device* at issue, and the application of generally applicable state-law duties to avoid manufacturing defects thus did not impose different or additional requirements on the manufacturer. *Lohr*, 518 U.S. at 499-502. The Court emphasized that preemption under § 360k(a) turns on the existence of *specific* federal and state requirements on the same subject matter and noted that "it is impossible to ignore [the statute's] overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." *Id.* at 500. The Court found no such specific conflict in the case before it. Rather, the relevant federal regulations "reflect important but entirely generic concerns about device regulation generally," and not "the sort of concerns regarding a specific device or

[2] The plaintiff in *Lohr* alleged manufacturing defect claims under both a strict liability theory and a negligence theory. The Court did not distinguish between the two in its analysis. *See Lohr*, 518 U.S. at 484, 497-502.

field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements." *Id*. The decision in *Riegel* reiterated the view that the touchstone of preemption is the existence of device-specific federal requirements. 552 U.S. at 322-23.

This aspect of *Lohr* controls here. As in *Lohr*, the general state-law duty not to distribute products with manufacturing flaws does not impose any requirements on St. Jude that are different from or in addition to federal requirements that are specifically applicable to the heart valve at issue.[3] Indeed, the same generic GMP regulations applicable to the device in *Lohr*, which the Supreme Court held do not establish requirements triggering preemption, also apply to the device at issue in this case.

Perhaps recognizing that the GMP regulations are an insufficient basis for preemption, St. Jude invokes the premarket approval of the heart valve implanted in Mr. Lamere as the source of the federal requirements that supposedly displace Ms. Lamere's manufacturing-defect claim. Yet St. Jude has not pointed to any *specific* manufacturing requirements imposed as part of the PMA as the basis for its claim of preemption, and, as *Lohr* teaches, a state-law duty cannot be "different

[3] Minnesota's common-law tort for manufacturing defects imposes a general duty on all manufacturers, including makers of medical devices, to keep defectively manufactured devices off the market or pay for the harm they cause. *See Lee v. Crookston Coca-Cola Bottling Co.*, 290 Minn. 321, 327-38, 188 N.W.2d 426, 431-32 (Minn. 1971).

from or in addition to" a specific federal requirement if such a requirement does not exist.

St. Jude asserts that it is "disingenuous" and "misleading" to ask it to point to any specific requirement concerning the kinds of manufacturing defects alleged in this case. Defendant's Reply Memorandum in Support of Renewed Motion for Summary Judgment at 3. But without such a requirement, reflecting "concerns regarding a specific device … that the statute or regulations were designed to protect from potentially contradictory state requirements," there can be no preemption. *Lohr*, 518 U.S. at 501; *see also Riegel*, 552 U.S. at 322-23 (finding preemption of design claims concerning PMA device because "[u]nlike general … duties, premarket approval is specific to individual devices."). Thus, Minnesota's imposition of strict liability when errors in manufacturing a product result in defects that are not inherent in the product's design does not create "a particular state requirement [that] threatens to interfere with a specific federal interest." *Lohr*, 518 U.S. at 500. Indeed, common-law claims for manufacturing defects *complement* FDA regulation by holding device manufacturers accountable for putting broken products on the market.

St. Jude's reliance on *Riegel* to support its claim of preemption is misplaced. In *Riegel*, the Supreme Court recognized that § 360k(a) applies to defective design and labeling claims brought against manufacturers of medical devices that have

gone through the PMA process. *Riegel*, 552 U.S. at 323-35. But that is because, as the Court explained, premarket approval imposes specific requirements applicable to the design and labeling of particular devices that state-law design-defect and failure-to-warn claims would effectively alter—exactly the element lacking here. Moreover, *Riegel* expressly stated that it did not address manufacturing-defect claims, as no such claims were before the Court. *Id.* at 321 n.2; *see also* Catherine J. Sharkey, *What Riegel Portends for FDA Preemption of State Law Products Liability Claims*, 103 Nw. U. L. Rev. 437, 451 (2009) ("Four caveats to the Court's opinion suggest categories of surviving claims. First, manufacturing-defect (as distinct from design-defect and failure-to-warn) claims are allowed to proceed.").

Further, the basis for the finding of preemption in *Riegel* does not extend to manufacturing-defect claims. *Riegel*'s preemption analysis rested heavily on the notion that the adequacy of the design and labeling of devices are matters specifically reviewed and approved by the FDA in the PMA process. Thus, the Court reasoned, state tort actions challenging design and labeling of a PMA device would empower juries to render decisions that conflict with the cost-benefit judgments made by the FDA in granting premarket approval, just as would state statutes or regulations imposing device-specific design or labeling requirements:

> A jury … 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. … [I]t is implausible that the MDA was meant to "grant greater power … to a single state jury than to state

> officials acting through state administrative or legislative lawmaking processes."

Riegel, 552 U.S. at 325 (citation omitted).

By contrast, a jury assessing liability for a manufacturing-defect claim engages in no second-guessing. It does not consider negligence in the design of a product or even consider whether the processes used to manufacture the product were sufficiently safe. Under Minnesota law, it merely determines (1) whether the particular specimen of the product, as manufactured, was in a defective condition unreasonably dangerous for its intended use, (2) whether the defect existed when the product left the defendant's control, and (3) whether the defect was the proximate cause of the injury sustained. *Bilotta v. Kelley Co., Inc.*, 346 N.W.2d 616, 623 n.3 (Minn. 1984). A manufacturing-defect claim, unlike the design-defect claim in *Riegel*, does not call into question the judgment of the manufacturer in marketing the type of device at issue or the judgment of the FDA in approving that marketing. It merely posits that the particular device that injured the plaintiff had a flaw—a flaw not inherent in the design approved by the FDA—that made it unfit for use.

As the United States Court of Appeals for the Fifth Circuit put it in a decision anticipating *Riegel*'s holding, the MDA preempts claims that rest on the premise that something that "the FDA required and approved through the PMA process [was] inadequate under state law" or that "require[] a showing that the

FDA requirements themselves were deficient." *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 931, 933 (5th Cir. 2006). But nothing in Ms. Lamere's manufacturing-defect claim conflicts with the FDA's decision to grant premarket approval to the device that killed her husband, nor does her claim imply the deficiency of any specific requirement imposed by the FDA on the device. *Riegel*, then, does not disturb the holding in *Lohr* that such claims impose no requirements with respect to the device that interfere with device-specific federal requirements under 21 U.S.C. § 360k(a).

Finally, FDA regulations preserve manufacturing-defect claims from preemption under § 360k(a):

> Generally, section 521(a) [21 U.S.C. § 360k(a)] does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

21 C.F.R. § 808.1(d)(6)(ii). The manufacturing-defect claim in this case, to the extent that it is a requirement, falls within the scope of the regulation—it prohibits the manufacture of adulterated devices by causing the makers of such devices to be strictly liable to those they have injured. *See Lee*, 290 Minn. at 327, 188 N.W.2d at

431 (listing one purpose of strict liability as "discouraging the marketing of defective products which constitute a menace to consumers not equipped to protect themselves"). Such regulations receive significant deference by the judiciary when interpreting a federal statute. *Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984); *Martin ex rel. Hoff v. City of Rochester*, 642 N.W.2d 1, 21 (Minn. 2002) (engaging in the *Chevron* analysis to determine whether an agency's interpretation of a federal statute receives deference).

II. Plaintiff's manufacturing-defect claim is a "parallel claim" that falls outside the preemptive scope of section 360k(a).

If the Court finds that manufacturing-defect claims in general may be preempted by the MDA, it should permit Ms. Lamere's claim to go forward on the ground that it is not "different from, or in addition to" any federal requirement because the duties on which it is based parallel federal duties. *See Lohr*, 518 U.S. at 495; *Riegel*, 552 U.S. at 330. The complaint in this case alleges that St. Jude produced and sold a heart valve with a defectively manufactured leaflet that fractured, killing Mr. Lamere. The leaflet fractured, according to Ms. Lamere's expert, because it contained a number of surface defects, including pores and crevasses, that were introduced during the polishing and finishing stages of its manufacture, and that were not detected in quality control. Addendum 29a-30a, Armeniades Aff. ¶¶ 4-10. Specifically, the observed defects "occurred due to the failure to properly finish and polish the valve leaflet, and failure to detect its flaws

during the post-manufacturing inspection." Addendum 29a-30a, Armeniades Aff. ¶¶ 9-10. A state common-law claim based on such manufacturing defects is not preempted because the same duty to avoid such defects exists under federal law.

The FDA has enacted a number of "good manufacturing practices" (GMP) regulations that provide general safety standards for the manufacture of medical devices. *See* 21 C.F.R. §§ 820.70, 820.72, 820.90. The GMP regulations prescribe practices generally applicable to the manufacture of medical devices, and are designed to prevent defects that would result in unsafe products entering the market. *See* 21 C.F.R. § 820.1 ("The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act."). The GMP regulations require manufacturers to establish and carry out production and control processes to "ensure" that devices with manufacturing flaws are not released into the marketplace. *See* 21 C.F.R. §§ 820.70(a), 820.90.

Applying Minnesota common law to hold St. Jude strictly liable for a manufacturing defect that resulted in the implantation in Mr. Lamere of a heart valve that contained dangerous pores and crevasses *not called for in its approved design specification* is entirely consistent with the provisions of the GMP regulations. Both the common-law duty not to sell a product with a manufacturing defect and the federal regulations requiring manufacturers to take steps to ensure

the absence of such defects have the same aim: preventing injuries resulting from the flawed production of devices, including PMA devices whose design has been approved by the FDA. Moreover, Minnesota manufacturing-defect principles do not require manufacturers to do anything different from or in addition to what they are required to do under federal law. Ms. Lamere's manufacturing-defect claim thus runs parallel to the requirements imposed by the GMP regulations and, under both *Lohr* and *Riegel*, is not preempted.

Reliance on the GMP regulations to establish parallelism between a state-law claim and federal requirements has ample support in case law construing the MDA's preemption provision. Several federal courts of appeals have rightly held that when state common law manufacturing-defect claims are premised on conduct that violates GMP regulations, there is no preemption under § 360k(a). *See Bass v. Stryker Corp.*, 669 F.3d 501, 510 (5th Cir. 2012) ("Bass has sufficiently pleaded parallel claims in his first amended complaint, to the extent that the claims are based upon manufacturing defects resulting from violations of federal regulations."); *Bausch v. Stryker Corp.*, 630 F.3d 546, 556 (7th Cir. 2010) (plaintiff's claims are "not expressly preempted by federal law" to the extent they are based on alleged violations of 21 C.F.R. § 820.90); *Howard v. Sulzer Orthopedics Inc.*, 382 F. Appx. 436, 440-41 (6th Cir. 2010) (unpublished) (holding that a tort claim escaped preemption because of 21 C.F.R. § 820.70(h), which

requires actual removal of excess manufacturing material, not merely a process to ensure removal); *see also Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 159-60 (S.D.N.Y. 2011) (same).

Although the Eighth Circuit declined to find that an alleged manufacturing-defect claim was parallel to GMP regulations in one case, it did so because the court found that the claim was not really a claim that particular specimens of the device at issue had manufacturing defects, but rather a claim that all devices employing the FDA-approved design were defective. *See In re Medtronic, Inc.*, 623 F.3d 1200, 1207 (8th Cir. 2010) ("[A]s pleaded and argued, the manufacturing defect claims are not parallel, they are a frontal assault on the FDA's decision to approve a PMA Supplement after weighing the product's benefits against its inherent risks."). Here, by contrast, Ms. Lamere's claim in no way challenges the FDA's decision to grant PMA to St. Jude's heart valve. It is a claim that the particular specimen of the valve implanted in Mr. Lamere was not properly made. The weight of authority supports Ms. Lamere's position that her manufacturing-defect claim escapes preemption because it parallels the requirements of the FDA's GMP regulations.

III. There is a strong presumption against reading federal laws to preempt state-law causes of action.

Finally, in recognition that the states are independent sovereigns in our constitutional system, courts must take special care to avoid reading a federal

statute to preempt a state law cause of action unless the statute is clear. The Supreme Court has long "presumed that Congress does not cavalierly pre-empt state-law causes of action." *Lohr*, 518 U.S. at 485; *see also Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) ("Congress legislated here in field which the States have traditionally occupied. … So we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."); *Hillsborough County, Fla. v. Automated Med. Laboratories, Inc.*, 471 U.S. 707, 715 (1985) (citing "the presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause"). This presumption against preemption should be especially strong in the present case, because the federal statute at issue was enacted not to grant immunity to the medical-device industry but "to provide for the safety and effectiveness of medical devices intended for human use." 90 Stat. 539 (1976) (preamble to Act). To interpret the preemption provision so expansively as to cut off liability for injuries resulting from manufacturers' production errors would run contrary to the primary purpose of the Act.

CONCLUSION

For the foregoing reasons, this Court should REVERSE the decision below granting summary judgment and REMAND for trial on the disputed issues of fact.

Respectfully submitted,

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CERTIFICATE OF WORD COUNT

The text of this brief consists of 5,871 words, as counted by the Microsoft Word 2010 word processing program used to generate the brief. The brief complies with the typeface requirements of Rule 132.01 because it is composed in a proportional 14-point font.

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