

NO. A12-609

State of Minnesota
In Court of Appeals

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-Respondents.

**APPELLANT/CROSS-RESPONDENT'S
RESPONSE AND REPLY BRIEF**

OF COUNSEL:

Scott L. Nelson
Allison M. Zieve
PUBLIC CITIZEN LITIGATION
GROUP
1600 – 20th Street N.W.
Washington, D.C. 20009
Tel: (202) 588-1000
Fax: (202) 588-7795

Anthony J. Nemo (#221351)
Andrew Davick (#332719)
MESHBESHER & SPENCE, LTD.
1616 Park Avenue South
Minneapolis, MN 55404
Tel: (612) 339-9121
Fax: (612) 339-9188

Attorneys for Appellant

James T. Capretz
Anthony Chu
Don K. Ledgard
CAPRETZ & ASSOCIATES
5000 Birch Street, Suite 2500
Newport Beach, CA 92660-2139
Tel: (949) 724-3000
Fax: (949) 757-2635

(Counsel for Respondents appears on reverse)

Edward F. Fox (#003132X)

Carrie L. Hund (#277149)

BASSFORD REMELE

A Professional Association

33 South Sixth Street, Suite 3800

Minneapolis, MN 55402-3707

(612) 333-3000

Attorneys for Respondents

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ARGUMENT

Barbara Lamere’s manufacturing defect claim is based on the allegation that the heart valve that killed her husband had flaws—pits and crevasses that developed into cracks and ultimately caused the device to break—and that those flaws were not required by the valve’s federally approved specifications. St. Jude Medical’s contention that the claim is preempted by federal law because the device received premarket approval from the Food and Drug Administration (FDA) fails for two independent reasons.

First, although the Supreme Court has held that premarket approval preempts state-law claims that would impose requirements that differ from specific federal requirements imposed on a medical device as a result of the premarket approval process, St. Jude’s brief identifies no such specific requirements that are implicated by the manufacturing defect claim at issue here. That claim in no way challenges the adequacy of any FDA-approved feature of the device, but instead is based on defects in the particular valve that killed Mr. Lamere—defects that were not approved by the FDA.

Second, as explained in Ms. Lamere’s opening brief, even in cases (unlike this one) where a state-law tort claim relates to a subject as to which the premarket approval process has imposed specific federal requirements applicable to a medical device, the state-law claim is not preempted if it “parallels” federal requirements.

Here, even if Ms. Lamere's manufacturing defect claim did implicate some potentially preemptive federal requirements, it is saved from preemption because it parallels the FDA requirement that medical device manufacturers use procedures that ensure the absence of defects such as those at issue in this case.

St. Jude's cross-appeal, asserting that the district court erred in rejecting its statute of limitations defense, is as unavailing as its preemption arguments. Contrary to St. Jude's contention, Minnesota's wrongful death statute of limitations, Minn. Stat. § 573.02, as construed by the Minnesota Supreme Court, is not triggered until the decedent manifests an injury that could have supported a claim if he had lived, or until the date of death, whichever occurs first. The claim here is therefore timely. St. Jude's alternative argument that California's shorter statute of limitations should be applied if the claim is timely under the Minnesota statute fares no better. As the district court held, statutes of limitations are procedural matters to which the law of the forum applies. Moreover, the choice of law principles that Minnesota applies to questions of substantive law also dictate application of the Minnesota statute of limitations because whether to allow a tort claim that is timely under Minnesota law to proceed against a Minnesota defendant is a question as to which Minnesota's interests outweigh California's.¹

¹ The parties agree that the standard of review of the district court's summary judgment determinations is de novo. *SCI Minn. Funeral Servs., Inc. v. Washburn-McReavy Funeral Corp.*, 795 N.W.2d 855, 861 (Minn. 2011).

I. Ms. Lamere's manufacturing defect claim is not preempted.

A. St. Jude has identified no specific federal requirements that preempt the particular manufacturing defect claim asserted in this case.

St. Jude asks this Court to extend the preemption doctrine of *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), to Ms. Lamere's claim that the valve implanted in her late husband had a manufacturing defect—namely, the presence of cracks and fissures not called for in the device's approved specifications. Unlike the design-defect and failure to warn claims at issue in *Riegel*, however, Ms. Lamere's claim neither requires second-guessing the FDA's approval of the device nor implies any inadequacy in the federal requirements to which the device is subject. Indeed, Ms. Lamere's claims impose no requirements on St. Jude that are different from or in addition to specific requirements on the same subject that are imposed by federal law. Under *Riegel* and the Supreme Court's prior opinion in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), Ms. Lamere's manufacturing defect claims are not preempted.

Attempting to cast Ms. Lamere's claims as an assault on the FDA's approval of the heart valve, St. Jude clouds the issue with statements that, although true, are beside the point. For example, St. Jude points out that the FDA has never withdrawn its approval of the valve or required St. Jude to recall it. But Ms. Lamere does not assert that the valve was affected by some pervasive design defect

or that St. Jude's manufacturing processes were inadequate in some way that led to wide distribution of defective valves. Her claim is based only on the evidence that the *particular valve implanted in her husband* contained flaws when shipped from the manufacturer—namely, the cracks and fissures that, as Ms. Lamere's expert explains, made it susceptible to breaking, as it ultimately did, with fatal results. Manufacturing defects in a single valve would not be a basis either for the withdrawal of approval of the product design by the FDA or for a recall of other specimens of the device, not affected by the defect. Ms. Lamere's claims thus do not imply that the FDA should have taken any such regulatory actions, nor does the FDA's failure to do so have any bearing on the merits of her claims.

Equally irrelevant are St. Jude's observations that the FDA's approval of the device entailed approval of its manufacturing process as described in its application for premarket approval, and that the documentary trail concerning the device—the "Traveler" cited in St. Jude's brief—establishes that it conformed to all requirements imposed by the FDA as a part of that process. Ms. Lamere's claims do not contest the adequacy of any manufacturing process approved by the FDA. Under Minnesota's law of strict product liability, a manufacturing defect claim does not rest on alleged negligence or inadequacy of the manufacturing process, nor on any other form of fault on the part of the defendant, but solely on the shipment of a particular item containing a defect that renders it unreasonably

dangerous. *Bilotta v. Kelley Co., Inc.*, 346 N.W.2d 616, 623 n.3 (Minn. 1984). Ms. Lamere's claims thus do not impose manufacturing process requirements on St. Jude that are different from or in addition to any that are described in St. Jude's approved application to market the heart valve. As for the paper trail to which St. Jude refers, it establishes only that St. Jude carried out certain processes and inspections when it made the valve in question, and that it did not detect the flaws in the device that ultimately led to its failure. That evidence neither undermines Ms. Lamere's claim that the device was defective nor establishes that her claim would in any way impose requirements on St. Jude that are somehow different from or additional to specific requirements imposed by federal law.

Much more significant than St. Jude's assertions about its compliance with federal requirements is what St. Jude does *not* say. Nowhere does St. Jude contend that the FDA-approved specifications for the device call for or permit the presence of pores and crevasses that would weaken the device, develop into cracks, and make it more likely to break when placed into a patient's body. St. Jude's brief contains not the slightest suggestion that such pores and crevasses were an accepted part of the design of the product. St. Jude also points to no specific federal requirements with respect to how a valve should be manufactured or inspected to avoid pores and crevasses in its pyrolytic carbon surface. Nor does St. Jude argue that the FDA imposed specific requirements about whether a specimen

of the product that contained pores and crevasses *not* called for in the product's design could be sold for use in patients.

Absent such specific requirements, Minnesota law providing that a defendant is liable when a defectively manufactured product causes injury, as applied to the particular claims in this case, is not preempted. Both of the U.S. Supreme Court's governing cases on preemption of state tort law with respect to medical devices, *Lohr* and *Riegel*, hold that the existence of specific federal requirements with respect to the particular subject-matter addressed by a state tort claim is a prerequisite to preemption under 21 U.S.C. § 360k(a). *See Riegel*, 552 U.S. at 497-501; *Lohr*, 518 U.S. at 322-23. The absence of such specific requirements with respect to the subject of the manufacturing defect claim at issue here requires rejection of St. Jude's claim of preemption.

Contrary to St. Jude's assertion, Ms. Lamere's position does not rest on a misrepresentation of the holdings of *Lohr* and *Riegel*. To begin with, neither decision held any manufacturing defect claim preempted: *Lohr* specifically allowed a manufacturing defect claim to go forward, *see* 518 U.S. at 499-502, and *Riegel* did not consider preemption of manufacturing defect claims because no such claims were before it. *See* 552 U.S. at 321 n.2. Although *Riegel* at times referred generically to the claims that were before it as claims of strict liability and

negligence, nowhere did it purport to rule on whether a *type* of strict liability claim that was not in the case—i.e., a manufacturing defect claim—was preempted.

Nor does *Riegel* indicate that *Lohr*'s framework for analysis of preemption under § 360k(a) is inapplicable to this case. *Riegel* disagreed with the plurality portion of *Lohr* on one point: whether state common-law rules of liability impose “requirements” that are potentially subject to preemption under § 360k(a). *See Riegel*, 552 U.S. at 324. But on the point critical to this case—that preemption under § 360k(a) is triggered only by a *specific* federal requirement that a state-law requirement would add to or differ from—*Riegel* agrees with the holding of *Lohr*. *See Riegel*, 552 U.S. at 322-23. *Riegel* further holds that the premarket approval process (unlike the abbreviated “section 510k” process for grandfathered devices at issue in *Lohr*) imposes certain specific requirements on medical devices that receive such approval, most notably design and labeling requirements, *see id.*, and that state-law design defect and failure-to-warn claims are preempted *to the extent* that they would impose requirements different from or in addition to the specific design and labeling requirements imposed by federal law. *See id.* at 325.

Here, the claims at issue are different from those in *Riegel*, in that they do not seek to impose any requirements on St. Jude that add to or differ from specific requirements imposed by the premarket approval process. They do not require St. Jude to change the federally approved design of its product, its federally approved

labeling, or any step in the manufacturing or inspection process that may have been approved by the FDA. They merely require that St. Jude not ship a particular example of the valve that contains cracks and fissures not called for in the product's design specifications and that pose an unreasonable danger to patients.

As in *Lohr*, St. Jude's failure to point to any specific federal requirements pertaining to that subject-matter renders its claim that Minnesota manufacturing-defect law imposes different or additional requirements unavailing. *See Lohr*, 518 U.S. at 499-502. And unlike in *Riegel*, allowing such claims to proceed does not implicate the policies underlying the preemption provision because the claims pose no risk that a Minnesota jury will second-guess the FDA's determinations that the device's design is safe and effective, that its labeling provides adequate warnings, or that its manufacturing processes are, in general, adequate. *See Riegel*, 552 U.S. at 325, 329. A determination that a particular specimen of the device was manufactured with flaws that made it unsafe threatens no federal interests, and indeed advances the policies underlying federal law by enhancing the safety of patients and compensating them when they suffer injury.

This is not to say that no manufacturing defect claim can ever be preempted. A claim premised on the theory that an item was defectively manufactured when it in fact contained no flaws that were not accepted in the FDA-approved design would be preempted for the same reason a design-defect claim is preempted:

because it would represent a back-door attempt to impose design requirements in addition to those specifically imposed by the premarket approval process. Thus, in *In re Medtronic, Inc.*, 623 F.3d 1200 (8th Cir. 2010), the U.S. Court of Appeals for the Eighth Circuit held a purported manufacturing defect claim to be preempted when the claim was, in substance, a “frontal assault” on the FDA’s approval of the device because it amounted to an assertion that *any* device manufactured in accordance with the FDA-approved design was defective. *Id.* at 1207. Similarly, in *Walker v. Medtronic, Inc.*, 670 F.3d 569 (4th Cir. 2012), the U.S. Court of Appeals for the Fourth Circuit held that when the FDA had approved the design of a device with the specific understanding that the device could deviate from its expected range of performance, a claim that alleged no more than that a particular example of the device had experienced the contemplated failure was not sufficient to set forth a non-preempted manufacturing defect claim. Because such failures were inherent in the design approved by the FDA, the plaintiff was “actually contending that the device should have been designed differently” than its FDA-approved specifications required. *Id.* at 580.

The reasoning of such cases is wholly inapplicable here, where the manufacturing defect claim is not inconsistent with specific requirements imposed through the premarket approval process. As *Lohr* establishes and *Riegel* confirms, in the absence of specific federal requirements applicable to the particular subject

matter of a state-law claim, there is no basis for preemption under § 360k(a). Hence Ms. Lamere’s manufacturing defect claim is not preempted, and the court need not reach the question whether it also would avoid preemption as a parallel claim.

B. Ms. Lamere’s manufacturing defect claim is not preempted because it parallels federal requirements.

As the U.S. Supreme Court recognized in both *Lohr* and *Riegel*, even where a device is subject to specific, potentially preemptive federal requirements, there is no preemption of state-law claims that parallel federal standards applicable to the device, because such claims do not impose requirements “different from or in addition to” those imposed by federal law, as required for preemption under § 360k(a). In this case, even if Ms. Lamere’s manufacturing defect claim did implicate specific federal requirements, it would not be preempted because the claim parallels the federal requirements imposed on St. Jude by the FDA’s “Good Manufacturing Process” (GMP) regulations. Those regulations require that manufacturers employ manufacturing and inspection processes that ensure their products do not contain defects not contemplated in their specifications.

St. Jude contends that the GMP regulations are not federal requirements that “parallel” the state-law duties on which Ms. Lamere's claim is based because they are too “general.” The weight of federal *appellate* authority, and the better reasoned decisions, reject St. Jude’s argument. *See Bass v. Stryker Corp.*, 669 F.3d

501, 510 (5th Cir. 2012); *Bausch v. Stryker Corp.*, 630 F.3d 546, 556 (7th Cir. 2010); *Howard v. Sulzer Orthopedics Inc.*, 382 F. Appx. 436, 440-41 (6th Cir. 2010) (unpublished). As the Seventh Circuit explained in *Bausch*, the federal GMP requirements are binding on device manufacturers, and thus a state-law claim that parallels them does not impose different or additional requirements:

[F]ederal law is clear: for manufacturers of Class III medical devices, the Quality System Regulations and Current Good Manufacturing Practices adopted by the FDA under its delegated regulatory authority are legally binding requirements “under this chapter.” 21 C.F.R. § 820.1. “The failure to comply with any applicable provision in this part [of the regulations] renders a device adulterated under section 501(h) of the act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action.” 21 C.F.R. § 820.1(c).

630 F.3d at 555. Moreover, holding that the GMP regulations are too “general” to support a parallel claim “would also leave injured patients without any remedy for a wide range of harmful violations of federal law.” *Id.* Nothing in *Riegel*’s and *Lohr*’s discussion of non-preempted parallel claims supports St. Jude’s argument that state-law claims paralleling GMP requirements are preempted.²

² Indeed, the majority in *Lohr* held manufacturing defect claims not preempted in part because they paralleled applicable federal manufacturing standards, and the only federal manufacturing standards to which the device at issue in *Lohr* was subject were the GMP regulations. *See Lohr*, 518 U.S. at 494-97. The partial dissent agreed that manufacturing defect claims would not be preempted if they did not go beyond the requirements of the GMP regulations. *See id.* at 513-14 (O’Connor, J., concurring in part and dissenting in part).

St. Jude's assertion that Ms. Lamere did not preserve the argument that her claim is parallel to the GMP regulations is equally meritless. In her opposition to St. Jude's Motion for Summary Judgment, Ms. Lamere specifically invoked the GMP regulations and argued that her claims were parallel. *See* Plaintiff's Opp. to St. Jude Medical's Mot. for Sum. Jdgmt., at 13-15 (Oct. 19, 2010). Ms. Lamere's opposition to St. Jude's Renewed Motion for Summary Judgment invoked the arguments previously made in the original summary judgment opposition and repeated that the claim involved violation of federal requirements. *See* Plaintiff's Opp. to St. Jude Medical's Renewed Mot. for Sum. Jdgmt., at 2 (Dec. 12, 2011). Those arguments were more than sufficient to preserve Ms. Lamere's parallel claims argument. To be sure, as St. Jude points out, Ms. Lamere also argued below, as she argues in this Court, that she need not show a violation of federal law to sustain her manufacturing defect claim because the claim does not relate to a matter on which federal law imposes a specific preemptive requirement on the device at issue. Reliance on alternative arguments is, of course, a conventional practice in litigation and does not amount to a failure to preserve one or both alternatives.

Finally, St. Jude asserts that Ms. Lamere has not identified any federal requirement that parallels her manufacturing defect claim. On the contrary, Ms. Lamere has cited 21 C.F.R. §§ 820.70(a) and 820.90, which require device

manufacturers to develop production and inspection processes that “ensure” that products do not have defects not called for in their specifications and to identify “nonconforming product.” The evidence in the summary judgment record supporting Ms. Lamere’s manufacturing defect claim establishes that the particular device that killed her husband had manufacturing flaws (pores and crevasses creating an unacceptable risk that the device would develop cracks and ultimately break) and that those pores and cracks resulted from St. Jude’s manufacturing process and were not detected by its inspection procedures. Imposing liability on St. Jude for the presence in its product of flaws not called for in its specifications, and that its manufacturing processes failed to prevent or detect, imposes no requirements on St. Jude not contained in the cited GMP regulations. The manufacturing defect claim is thus a parallel claim and, under *Riegel* and *Lohr*, is not preempted by § 360k(a).

II. Ms. Lamere’s claim is timely under the applicable statute of limitations.

A. Minnesota’s wrongful death statute of limitations permitted Ms. Lamere’s claim to be brought within six years of the first manifestation of her husband’s injury or three years of his death, whichever period expired first.

Ms. Lamere’s wrongful death action was commenced within three years of her husband’s death and within six years of the date his injury first manifested itself—the day of his death. The action thus satisfies the relevant requirements of Minnesota’s wrongful death statute of limitations, Minn. Stat. § 573.02, which

provides that such an action “may be commenced within three years after the date of death provided that the action must be commenced within six years after the act or omission.” The district court correctly held that, under the circumstances of this case, the date when Mr. Lamere’s injury first manifested itself is the date of “the act or omission” under the statute. See Addendum to Appellant’s Principal Brief (Add.) 16a-17a.

St. Jude’s position on the statute of limitations set forth in § 573.02 is that it expired not only before Mr. Lamere died, but also before he could possibly have become aware that his heart valve was defective and, indeed, before it had even injured him, *see* Add. 16a, and thus before he or anyone acting on his behalf could have brought suit. As the district court correctly held, *see* Add. 12a-13a, St. Jude’s position is contrary to the construction given the statute by the Minnesota Supreme Court in a case presenting strikingly similar circumstances: *DeCosse v. Armstrong Cork Co.*, 319 N.W.2d 45 (Minn. 1982). There, considering the case of a plaintiff who died as a result of disease attributable to exposure to asbestos many years before, the Supreme Court held that the wrongful death statute of limitations would begin running on the earlier of (1) the date of manifestation of an injury that could be causally linked to the defendant’s conduct, or (2) the date of death. *Id.* at 48-49. In other words, the court held that in such latent-injury cases, the “act or omission” causing death would be deemed to have occurred when the injury first manifested

itself in a way that could be linked to the defendant's conduct, not when the defendant engaged in the wrongful conduct that ultimately injured the plaintiff and resulted in death.³

The action in this case is therefore timely. The manifestation of Mr. Lamere's injury and his death occurred simultaneously, so the triggers for the two limitations periods under the statute were the same. The action was brought less than three years after the date of death, and less than six years after the "act or omission" as that term was interpreted in *DeCosse*.

St. Jude wrongly insists that *DeCosse's* reasoning is inapplicable here. St. Jude's assertion that *DeCosse* has been limited to asbestos cases is incorrect: None of the decisions St. Jude cites so holds. What courts, including the Supreme Court, *have* said is that *DeCosse* is based on what the court there described as the "unique character of an asbestos-related disease." *Id.* at 48. The characteristics of asbestos-

³ Although *DeCosse* was decided after the limitations period had taken its present form, the case was governed by an earlier version of the statute under which the applicable limitations period was three years from the "act or omission" that caused death (as compared to the current three years from death or six years from the "act or omission," whichever expires first). However, because the case turned on the court's determination of when an "act or omission" occurred for purposes of the statute, and St. Jude's argument similarly depends on when an "act or omission" triggering the current limitation period takes place, the district court properly held that *DeCosse's* construction of the relevant statutory language remains authoritative. Moreover, the court in *DeCosse* took note of the statute's amendment, and discussed its significance in a way that suggested that the same meaning should be given to "act or omission" under both versions of the statute. *See id.* at 48.

related disease to which the court referred—namely that the injury and its causal relationship to the defendant’s conduct only become evident when disease has manifested itself—are equally present when, as here, a product with a latent defect is implanted in a patient, and the existence of the defect, the resulting injury, and their causal relationship to the defendant’s conduct only become evident when the product actually malfunctions and an injury to the patient becomes manifest. The critical basis of *DeCosse*’s holding—that “[i]t is when the disease manifests itself in a way which supplies some evidence of causal relationship to the manufactured product that the public interest in limiting the time for asserting a claim attaches and the statute of limitations will begin to run,” *id.* at 49—is as applicable in the circumstances of this case as in the asbestos setting.

Moreover, as the district court noted, *see* Add. 14a-15a, any suggestion that *DeCosse* applies only to asbestos cases is refuted by the Supreme Court’s subsequent decision in *Bonhiver v. Fugelso, Porter, Simich & Whiteman, Inc.*, 355 N.W.2d 138 (Minn. 1984). There, the court considered a wrongful death action involving a decedent who had slipped and fallen on stairs at the Duluth Campus of the University of Minnesota, and who subsequently died after having begun a personal injury action against defendants responsible for the design and construction of the stairs. Although the actual conduct of the defendants obviously predated the fall that resulted in the injuries, the Supreme Court observed that,

under the reasoning of *DeCosse*, the “act or omission” giving rise to the suit would be deemed to occur on “the date of [the decedent’s] fall” for purposes of applying the wrongful death statute of limitations. *Id.* at 141; *see also id.* at 142 (discussing *DeCosse*).⁴ Under the same reasoning, the relevant “act or omission” in this case occurred on the date when the heart valve failed and fatally injured Mr. Lamere.

Similarly, as the district court observed, *see* Add. 15a-16a, a federal district court applying § 573.02 to a case in which a child was killed by a defective garage door held that, as construed by the Minnesota Supreme Court, the statute’s reference to the “act or omission” that begins the running of six-year limitations period “refers to the date of the accident which causes death,” not “the date of the original negligent act of the defendant.” *Henry v. Raynor Mfg. Co.*, 753 F. Supp. 278, 280 (D. Minn. 1990). In *Henry*, the court thus concluded that the six-year limitations period began to run on the date when the defect in the garage door caused it to fail and fatally injured the child. Application of the same standard here

⁴ The holding of the court in *Bonhiver* was that a personal injury action that was timely filed before the plaintiff’s death and was converted to a wrongful death action after the plaintiff died was not subject to the statute of limitations in the wrongful death statute. *See id.* at 144. The court’s discussion of when the wrongful death statute of limitations would otherwise have expired, however, was important to its holding, because it would not have had to address the issue had it not first considered how the wrongful death statute of limitations would have applied had the action not been converted from a previously filed personal injury action.

would begin the running of the six-year period on the date when Mr. Lamere's heart valve failed.

St. Jude, on the other hand, points to no appellate decisions in which the limitations period triggered by the "act or omission" causing death has been deemed to begin running before the decedent has suffered any manifestation of injury. St. Jude's inability to do so is not surprising. Minnesota courts adhere to the view that statutes of limitation do not begin to run until a cause of action accrues, and a cause of action does not accrue until a plaintiff has suffered an injury causally attributable to a defendant's conduct that can support the filing of an action for damages. *See Broek v. Park Nicollet Health Servs.*, 660 N.W.2d 439, 442-43 (Minn. Ct. App. 2003). Thus, as the Supreme Court has put it, "a statute of limitations ... starts from the date of injury." *Hodder v. Goodyear Tire & Rubber Co.*, 426 N.W.2d 826, 830 (Minn. 1988).⁵

Construing the wrongful death statute to begin the running of the limitations period before Mr. Lamere had suffered an injury that could have supported *any* claim against the St. Jude would be contrary to this principle. Before his heart valve's latent defects had caused it to fail and injured him in some detectable way,

⁵ St. Jude asserts that the Minnesota Supreme Court has rejected a "discovery rule," but the cases it cites concern the separate issue of the time when a cause of action for medical malpractice accrues, and even in that context the cause of action does not accrue, and the statute of limitations does not begin to run, until the plaintiff suffers some actionable injury. *See Broek*, 660 N.W.2d at 444.

Mr. Lamere would not have had a tort claim against St. Jude, because, as in *Broek*, “[t]he record simply contains no evidence that [he] suffered any compensable injury before that time that could be attributable to [the defendant],” and “the law does not compensate the mere possibility of harm.” 660 N.W. 2d at 443-44. Applying the statute in the way St. Jude advocates would thus foreclose any possibility of a timely suit.

To be sure, as the Supreme Court has explained, the wrongful death statute, even as construed in *DeCosse*, will in some cases bar a claim less than three years after the claimant dies, and in some instances even before death. *See DeCosse*, 319 N.W.2d at 49 (noting that the statute as now written “presents the possibility that a wrongful death action could expire before death by limiting the bringing of actions to six years after the act or omission” and that “the legislature is expressing its intention to bar actions for *some* deaths caused by wrongful acts or omissions even if they are brought on the day of death” (emphasis added)). Thus, a person who suffers an actionable, manifested injury, delays filing suit for six years, and then dies cannot be the subject of a wrongful death action. Such a claimant, however, would have had ample opportunity to file a tort action during his lifetime. By contrast, the *DeCosse* rule will *not* bar a wrongful death action under circumstances where the victim would have had no opportunity to bring an action before death—that is, it will not bar claims where there was no injury that could

have been the subject of a lawsuit before the victim died. *DeCosse* thus reconciles the statutory language, with its evident intent to bar claims less than three years after death in *some* cases, with the overarching principle that a statute of limitations does not cut off the right to bring an action before any claim has accrued.

St. Jude's contention that this construction renders the statutory language meaningless is incorrect. Of course, on the facts of *this* case, where the injury first manifested itself simultaneously with death, and thus the date of the "act or omission" under *DeCosse* and the date of death are the same, the six-year limit does not come into play, because the statute allows only three years from the date of death. But that does not make the statutory language meaningless. In any case in which an injury causally attributable to the defendant's conduct manifests itself more than three years before death, the six-year limitation period triggered by the "act or omission" rather than the three-year period triggered by death will control, and where an injury manifests itself more than six years before death, a wrongful death claim will be barred even if filed on the date of death.

That reading of the statute will certainly bar fewer claims than St. Jude's, but it does not render the six-year limitation period meaningless or read it out of the statute. And there is no requirement that this Court construe the statute to *maximize* the number of claims that are barred. On the contrary, the Supreme Court in

DeCosse recognized that the concept of barring wrongful death claims before death “has been criticized as illogical and unjust,” 319 N.W.2d at 48. Although the court found that a reading of the statute that would bar claims before death in *some* cases to be unavoidable, *see id.*, its decision reflects an effort to avoid a reading of the statute that would unnecessarily expand the circumstances in which that result would occur, and to avoid altogether the still more illogical and unjust result of barring claims before the claimant suffered an actionable injury. The court’s holding that the action did not “*accrue*,” *id.*, and hence that the date of the “act or omission” beginning the running of the limitations period would not be deemed to occur, until the injury and its causal relationship to the defendant’s conduct had manifested itself, *id.* at 49, properly gave effect to the statutory language while avoiding a result at odds with the general principle that statutes of limitation do not bar claims before they accrue. St. Jude’s argument that the application of *DeCosse* here would run counter to the terms of the statute is nothing less than an attack on the Supreme Court’s holding in *DeCosse*.

St. Jude’s contrary construction of the statute would transform it from a statute of limitations to a statute of repose, which places an outside limit on the time in which an action may be brought, triggered by a defendant’s conduct rather than the resulting injury or the accrual of a cause of action. Unlike a statute of limitations, a statute of repose “has the potential of barring recovery even before

the cause of action accrues,” *Hodder*, 426 N.W.2d at 826 n. 3, or, more accurately, may prevent a plaintiff from ever *acquiring* a right of action. *Weston v. McWilliams & Assocs.*, 716 N.W.2d 634, 641 (Minn. 2006). Minnesota has some statutes of repose—notably Minn. Stat. § 541.051(1)(a), at issue in *Weston*, which bars claims, including wrongful death claims, that are based on improvements to real property and are brought more than 10 years after the completion of construction of such improvements. Although Minnesota courts have consistently referred to the 10-year period set forth in §541.051(1)(a) as a statute of repose, they have not similarly referred to the “act or omission” limitations period of § 573.02 as a statute of repose, but have consistently called it a statute of limitations. *See, e.g., DeCosse*, 319 N.W.2d at 47-52; *Bonhiver*, 355 N.W.2d at 152. *See also Henry*, 753 F. Supp. at 281-83 (finding wrongful death action not barred by six-year “statute of limitations” set forth in § 573.02, but foreclosed by 10-year “statute of repose” in § 541.051(1)(a)).

Finally, St. Jude’s citations of cases insisting upon strict compliance with the wrongful death statute’s limitations period on the ground that “[s]atisfaction of the limitation period is an absolute prerequisite to bringing suit,” *Bonhiver*, 355 N.W.2d at 142; *see also Gavenda v. Ortiz*, 590 N.W.2d 119, 122 (Minn. 1999), are irrelevant. The issue here is not whether Ms. Lamere is *excused* from compliance with the limitations periods of the statute, but whether she *has* complied. And

under the sensible reading of the statute adopted in *DeCosse*, she has strictly complied with the statute by bringing her action within three years of the date of death and six years of the “act or omission,” as the Minnesota Supreme Court interpreted that language.

B. Minnesota choice-of-law principles require application of Minnesota’s wrongful death limitations period, not California’s.

St. Jude contends that, assuming Minnesota’s wrongful death statute of limitations would allow Ms. Lamere’s claims, this Court should instead apply California’s two-year statute of limitations. But either under the district court’s view that statutes of limitation are procedural and subject to the law of the forum, or under St. Jude’s preferred approach of applying the five choice-influencing considerations used to resolve conflicts of substantive law, *see Jepson v. Gen. Cas. Co. of Wisc.*, 513 N.W.2d 467, 470 (Minn. 1994); *Milkovich v. Saari*, 295 Minn. 155, 203 N.W.2d 408 (1973), the result is the same: Minnesota’s limitations period governs.

St. Jude briefly invokes Minnesota’s “borrowing statute,” Minn. Stat. § 541.31, as support for its argument that California limitations law applies. In its motion for summary judgment on the statute of limitations issue, however, St. Jude did not argue that § 541.31 was applicable at all, or that it required use of California’s statute of limitations; rather, St. Jude asserted that no choice of law was required. *See Defendant’s Mem. of Law in Support of Mot. for Sum. Jdgmt.* 6-

7, 11 (Sept. 30, 2010). In its reply memorandum, St. Jude again failed to rely on § 541.31, instead arguing very briefly that if there is a conflict between Minnesota and California law, California law should apply because California is “the center of gravity of this case,” and citing the multi-factor choice-of-law approach of *Milkovich v. Saari, supra*. Defendant’s Reply Mem. in Support of Mot. for Sum. Jdgmt. 3-4 (Oct. 25, 2010).

Even if St. Jude had properly preserved the argument below, the borrowing statute does not support its request for application of California law. Section 541.31, which applies to “claims arising from incidents occurring on or after August 1, 2004,” Minn. Stat. § 541.34, provides that “if a claim is substantively based ... upon the law of one other state, the limitation period of that state applies.” Minn. Stat. § 541.31(1)(a)(1). Here, Ms. Lamere’s complaint invokes Minnesota substantive law, presenting claims explicitly based on Minnesota’s wrongful death statute and Minnesota product liability law. Aside from arguing for application of a California statute of limitations, St. Jude did not contest the applicability of Minnesota substantive law to Ms. Lamere’s claims when it moved for summary judgment on the limitations issue, nor has it even now pointed to any conflict of laws (again, other than the limitations question) that would call for application of California rather than Minnesota law to Ms. Lamere’s substantive

claims.⁶ The borrowing statute thus provides no support for St. Jude's invocation of California's statute of limitations. Indeed, its unambiguous statement that, except for claims substantively governed by the law of one or more other states, "[t]he limitation period of this state applies to all other claims," Minn. Stat. § 541.31(1)(b), supports the use of the Minnesota statute of limitations here.

Given St. Jude's failure to invoke the borrowing statute, the district court based its decision on a straightforward reading of the Minnesota Supreme Court's decision in *Fleeger v. Wyeth*, 771 N.W.2d 524 (Minn. 2009).⁷ There, the court rejected the view that the five-part choice-of-law test applicable to conflicts of substantive law should apply to conflicts of law over limitations periods. Rather, the court held, a multi-factor choice of law analysis applied only to conflicts of substantive law, while "the law of the forum applies to procedural conflicts." *Id.* at 527. Moreover, the court held, "The common law in Minnesota is clear. When directly faced with the issue, we have considered statutes of limitations to be procedural *without exception*. As a result, because we apply the *lex fori* to procedural conflicts, we have applied the Minnesota statute of limitations to cases

⁶ If St. Jude were to attempt to do so, the same considerations set forth in the choice of law analysis below, *see infra* at 27-32, would point toward application of Minnesota substantive law.

⁷ St. Jude itself pointed the district court toward *Fleeger* by citing it in its motion for summary judgment, without any suggestion that its analysis was inapplicable to statutory rights of action. *See* Defendant's Mem. of Law in Support of Mot. for Sum. Jdgmt. 6 (Sept. 30, 2010).

properly commenced here regardless of whether those cases have any connection to this state.” *Id.* at 528 (emphasis added).

St. Jude contends that the district court erred in applying *Fleeger*’s holding to the statute of limitations in the wrongful death statute, relying on earlier cases that indicate that statutes of limitations incorporated in laws creating statutory rights of action are substantive. Again, St. Jude waived this argument by not making it in the district court. *See* Defendant’s Mem. of Law in Support of Mot. for Sum. Jdgmt. 6-7, 11 (Sept. 30, 2010); Defendant’s Reply Mem. in Support of Mot. for Sum. Jdgmt. 3-4 (Oct. 25, 2010).

In any event, *Fleeger* does not make the distinction St. Jude seeks to draw.⁸ Instead, the distinction that *Fleeger* draws is between statutes of limitations, which limit the remedies for accrued rights of action and are considered procedural, and statutes of repose, which *prevent* the accrual of a right of action, and are considered substantive. *See id.* at 528. *Fleeger* relied in turn on the court’s earlier statement in *Weston v. McWilliams*, 716 N.W.2d at 641, that statutes of limitations, in contrast to statutes of repose, “are procedural in nature”—a statement that did

⁸ *Fleeger*’s reference to “common law” in connection with its statement that Minnesota considers statutes of limitations procedural “without exception” appears to refer to Minnesota *common law regarding conflict of laws*, rather than to a distinction between common-law and statutory rights of action. The quoted passage goes on to refer to the principle that the law of the forum applies to procedural conflicts and that the forum’s statute of limitations is controlling as “that common law rule.” *Id.* at 528.

not distinguish between limitations periods applicable to statutory rights of action and those applicable to common-law claims. As explained above, § 573.02 is a statute of limitations, not a statute of repose.

Even assuming, however, that the statute of limitations applicable to a wrongful death claim is a matter of substance rather than procedure, Minnesota choice of law principles would dictate application of Minnesota's limitations period to Ms. Lamere's claim under Minnesota's wrongful death statute. Minnesota's interests in applying its own law to the question whether to protect a Minnesota company from having to pay damages for injuries caused by a defective product it manufactured outweigh any interests California might have in the application of its shorter limitations period.

Minnesota has adopted an approach to choice of law that resolves conflicts of law based on consideration of five choice-influencing considerations: "(1) predictability of result; (2) maintenance of interstate and international order; (3) simplification of the judicial task; (4) advancement of the forum's governmental interest; and (5) application of the better rule of law." *Jepson*, 513 N.W.2d at 470.

Here, the first three of these factors have little impact. Minnesota courts have recognized that "[p]redictability of result as it relates to the tort aspect of a case is not of great importance ... because of the unplanned nature of ... accidents," *Jepson*, 513 N.W.2d at 470 (citations omitted), and that this consideration is

relevant “primarily to consensual transactions where the parties desire advance notice of which state law will govern in future disputes.” *Medtronic, Inc. v. Advanced Bionics Corp.*, 630 N.W.2d 438, 454 (Minn. Ct. App.2001) (citation omitted). Here, “advance notice” as to the resolution of a possible statute of limitations issue would not have been important to either party before the injury took place. *See Danielson v. National Supply Co.*, 670 N.W.2d 1, 7 (Minn. Ct. App. 2003).

As for “maintenance of interstate order,” this factor is generally satisfied as long as each state whose law may be implicated has “sufficient contacts with and interest in the facts and issues being litigated.” *Myers v. Gov’t Employees Ins. Co.*, 302 Minn. 359, 365, 225 N.W.2d 238, 242 (1974). That criterion is satisfied here because the issues relate to a Minnesota defendant’s claimed distribution of a defective product, an issue with which Minnesota has ample contacts and interest. The “interstate order” factor also considers whether the choice of a particular state’s law would manifest “disrespect” for another state, but that consideration is “neutral” because any choice concerning the limitations period would involve equal “disrespect” for whichever state’s law is not chosen. *Danielson*, 670 N.W.2d at 8.

“Simplification of the judicial task” also plays little role with respect to choice of a statute of limitations. The Minnesota rule, under which the action may

be brought within six years of the manifestation of an injury or three years from death (whichever comes first) presents no difficulty in application to the facts of this case. This factor, too, “does not favor any of the forums.” *Id.* at 8. That St. Jude has raised an issue concerning the construction of the Minnesota statute does not significantly alter the analysis: Resolving issues concerning the interpretation of Minnesota law is a familiar role for a Minnesota court.

In this case, the most significant factor is the fourth consideration: “advancement of the forum’s governmental interest.” St. Jude’s contention that California has the predominant interest in the limitations issue is manifestly incorrect. The principal interests at stake in the application of the statute of limitations are whether to protect the defendant against liability based on the passage of time since the claim accrued, or whether to permit compensation of an injured victim. The defendant in this case is a Minnesota corporation, and the wrongful death statute of limitations reflects a determination that the State of Minnesota does not consider protection of defendants against claims such as Ms. Lamere’s to be sound policy. No other state has a greater interest in protecting Minnesota companies against assertedly untimely claims than Minnesota. In particular, California, as its own case law suggests, has relatively little interest in protecting nonresidents against claims that would be permitted by their home states, or in denying its own residents a recovery that the defendant’s home state

would allow. *Cf. Hurtado v. Superior Court*, 522 P.2d 666, 670 (Cal. 1974) (holding, in a wrongful death case involving a Mexican plaintiff and a California defendant, that “Mexico has no interest in applying its limitation of damages— Mexico has no defendant residents to protect and has no interest in denying full recovery to its residents injured by non-Mexican defendants”).⁹

In addition, Minnesota has a strong interest “in promoting responsibility of sellers and producers” that is advanced by imposing liability when Minnesota companies cause injury through “the products they place into the stream of commerce.” *Danielson*, 670 N.W.2d at 9. Minnesota’s interest in promoting responsibility of its own corporate residents outweighs another state’s interest in applying a policy that would reduce that responsibility.

Further, Minnesota has long asserted an “overriding” interest in “compensating tort victims.” *Id.* at 8. As the Supreme Court stated in a case that, like this one, involved a nonresident plaintiff, “Minnesota places great value in compensating tort victims.” *Jepson*, 513 N.W.2d at 472.¹⁰ Similarly, in *Milkovich*,

⁹ Although the California Supreme Court has recently indicated that *Hurtado* does not mean that a state has *no* interest in protecting nonresident corporate defendants against untimely claims, *see McCann v. Foster Wheeler LLC*, 225 P.3d 516 (Cal. 2010), that holding did not come in a case, like this one, where the defendant’s home state had strong interests in allowing the assertion of the claim at issue, which supported the application of its law to the limitations issue.

¹⁰ In *Jepson*, the court found the interest to be overridden by other interests, not applicable here, in the predictability of contractual arrangements, but did not

which likewise involved a nonresident plaintiff, the Supreme Court gave preeminent weight to Minnesota’s interest in ensuring that “injured persons not be denied recovery on the basis of doctrines foreign to Minnesota.” 295 Minn. at 171, 203 N.W.2d at 417. Application of California’s limitations period to cut off a claim that Minnesota’s statute permits would conflict directly with Minnesota’s interest in compensating tort victims. *Danielson*, 670 N.W.2d at 8-9. By contrast, California has no comparable interest in *denying* compensation to tort victims; indeed, California courts have recognized that statutes limiting tort liability do “not reflect a preference that widows and orphans should be denied full recovery,” *Hurtado*, 522 P.2d at 670, but rather a weighing of other considerations that have lesser weight where nonresident defendants are concerned.

Because the first three considerations are neutral and the fourth—the governmental interests at issue—so strongly favors application of Minnesota law, the fifth consideration (which state has the better rule of law) requires little analysis, as it comes into play principally “when the choice-of-law question remains unresolved after the other factors are considered.” *Medtronic, Inc. v. Advanced Bionics Corp.*, 630 N.W.2d at 455. If any doubt about the proper choice of law remains after the consideration of the governmental interests, however, the

suggest that the interest was inapplicable because the plaintiff was a nonresident, though the defendant in the case made that argument. *Id.*

fifth consideration points strongly toward application of Minnesota law in this case. The Minnesota limitations period, which promotes compensation of victims and accountability of defendants, while also incorporating two limitations triggers to prevent assertion of stale claims, reflects the better rule of law. As the court in *Danielson* put it, “compensation of tort victims has far-reaching effects, such as avoiding victim reliance on public assistance, restoring injured parties to good health, paying healthcare providers and holding parties responsible for the products they make or sell,” and in comparison with other policies that would limit liability, “this state’s supreme court has identified fair compensation as the better policy.” *Danielson*, 670 N.W.2d at 9 (citing *Jepson*, 513 N.W.2d at 472-73.). Here, as in *Danielson*, that policy would be “better promoted” by application of Minnesota’s more generous limitations period; thus, “Minnesota has the better rule of law, and the Minnesota statute of limitations law should be applied.” *Id.*

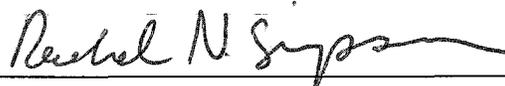
In sum, whether under the borrowing statute, under the trial court’s interpretation of *Fleeger*’s holding that the statute of limitations is a procedural issue subject to the law of the forum, or under St. Jude’s approach of applying the choice-influencing considerations applicable to the resolution of conflicts of substantive law, the Minnesota statute of limitations governs.

CONCLUSION

For the foregoing reasons, this Court should AFFIRM the district court's decision rejecting St. Jude's statute of limitations defense, REVERSE the decision below granting summary judgment to St. Jude on the issue of preemption, and REMAND for trial on the question of St. Jude's liability on Ms. Lamere's wrongful death claim.

Respectfully submitted,

MESHBESHER & SPENCE, LTD.



Anthony J. Nemo (#221351)

Andrew Davick (#332719)

Rachel N. Simpson (#390968)

1616 Park Avenue South

Minneapolis, MN 55404

Tel.: (612) 339-9121

Fax: (612) 339-9188

Attorneys for Appellant

OF COUNSEL:

Scott L. Nelson

Allison M. Zieve

PUBLIC CITIZEN LITIGATION
GROUP

1600 20th St. NW

Washington, DC 20009

Tel: (202) 588-1000

Fax: (202) 588-7795

James T. Capretz

Anthony Chu

Don K. Ledgard

CAPRETZ & ASSOCIATES

5000 Birch Street, Suite 2500

Newport Beach, CA 92660-2139

Tel: (949) 724-3000

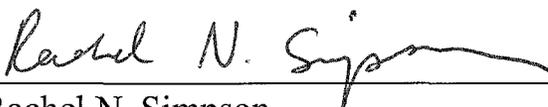
Fax: (949) 757-2635

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The text of this brief consists of 8,314 words, including all headings, footnotes and quotations, as counted by the Microsoft Word 2010 word processing program used to generate the brief, and therefore complies with the length limitation for an appellant/cross-respondent's response/reply brief as set forth in Rule 131.01(5)(d)(7)(C). 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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Rachel N. Simpson