United States Court of Appeals
For the First Circuit

No. 21-1145

WILLIAM PLOURDE, individually and as administrator of the estate of Allison Plourde; FREDA MERRILL,

Plaintiffs, Appellants,

v.

SORIN GROUP USA, INC.; SORIN GROUP CANADA, INC.; CARBOMEDICS, INC.,

Defendants, Appellees,

LIVANOVA PLC,

Defendant.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
[Hon. Allison D. Burroughs, U.S. District Judge]

Before
Lynch, Thompson, and Kayatta,
Circuit Judges.

David Randolph Smith, with whom Adam Combies, Matt Hanson, David Randolph Smith & Associates, and Combies Hanson, P.C., were on brief, for appellants.

Katy E. Koski, with whom Jennifer H. Wang, Lea G. James, and Foley & Lardner LLP were on brief, for appellees.

January 11, 2022

THOMPSON, Circuit Judge. Today's appeal raises a knotty and important question of Massachusetts law on which Massachusetts should have the last word and for which Massachusetts offers us a way to get it.

Thanks to diversity jurisdiction, we federal judges can hear and decide issues of Massachusetts law. See 28 U.S.C. § 1332. We are not experts in that area, however, though Massachusetts's high court — the Supreme Judicial Court ("SJC") — is. See Lehman Bros. v. Schein, 416 U.S. 386, 391 (1974). And we have no business "steering state law into uncharted waters." See Siedle v. Putnam Invs., Inc., 147 F.3d 7, 12 (1st Cir. 1998) (quotation marks omitted). On consequential matters — like defining or restricting state causes of actions — any decision by us will not bind Massachusetts courts: they can (under principles of federalism) reach their own conclusions, "tell[ing] us that we are all wet . . . and wip[ing] away what we have written" should they so choose. See Candelario Del Moral v. UBS Fin. Servs. Inc. of P.R., 699 F.3d 93, 101 (1st Cir. 2012). Contrastingly, the SJC is the final decider of Massachusetts law, binding us and lower Massachusetts courts with its rulings. See Mullaney v. Wilbur, 421 U.S. 684, 691 (1975). So — as discussed shortly — when we (as here) face a serious question of Massachusetts law with no on-point authority, we can ask the SJC for help.

And this we can do because an SJC rule says that the SJC may answer certified legal questions (as they are called) from us that "may be determinative of the cause then pending . . . to which it appears to" us that "there is no controlling [SJC] precedent." See Mass. S.J.C. R. 1:03. Plus our own caselaw says that certification is "particularly appropriate" when "the answers to these questions may hinge on policy judgments best left to the Massachusetts court" and which could benefit future litigants too (be they in state or federal court). See In re Engage, Inc., 544 F.3d 50, 53 (1st Cir. 2008). The SJC has been gracious in answering our certified questions before. And convinced that this case meets all the prerequisites — we never want to abuse this process "lest we wear out our welcome," see Transcon. Pipeline Corp. v. Transp. Ins. Co., 958 F.2d 622, 623 (5th Cir. 1992) — we politely ask the SJC's favor in answering the question certified below in Part III.

The SJC's rule requests "a statement of all facts relevant to the question certified," a description of "the nature of the controversy in which the question arose," and a declaration of "the question of law to be answered." See Mass. S.J.C. R. 1.03. We proceed accordingly.

I

A

Appellants William Plourde and Freda Merrill had a child in 1991, a daughter they named Allison.[1] Allison was born with DiGeorge Syndrome, a chromosomal disorder associated with heart defects. Her doctors also later diagnosed her with aortic arch and ventricular septal defects.

In June 2012, Allison's medical team explained that she would die if she did not get a heart-valve replacement. A doctor described the different valve options available. And that same month — June 2012 — he implanted a Mitroflow Model LX heart valve in her body. The Mitroflow is a "bioprosthetic" valve, consisting of "a single piece of bovine pericardium sewn onto a polyester stent." Appellees listed in the case caption — referred to collectively as "Sorin" — manufacture and sell the Mitroflow.

B

We pause in narrating the case's background to summarize some legal concepts that play a major role here (their significance will become clear later).

The Mitroflow is a class III medical device under the Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Medical

[1] We use Allison's first name from now on not out of disrespect but to distinguish between William and Allison Plourde.

Devices Amendments of 1976.[2] The FDCA divides the realm of medical devices into three classes, according to the amount of regulation believed necessary to provide reasonable assurance of each device's safety and effectiveness. See 21 U.S.C. § 360c(a)(1). Class III devices, the most strictly regulated of the classes, are devices "that either 'presen[t] a potential unreasonable risk of illness or injury,' or which are 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health.'" Medtronic, Inc. v. Lohr, 518 U.S. 470, 477 (1996) (alteration by Lohr Court and quoting 21 U.S.C. § 360c(a)(1)(C)). Because these devices are so risky, a manufacturer looking to put them on the market must prove their safety and efficacy to the liking of the Food and Drug Administration ("FDA") — through a complex and costly premarket approval ("PMA") process. See 21 U.S.C. § 360e(a); see also Lohr, 518 U.S. at 477.

During the PMA process, the FDA — spending an average of 1200 hours on each application — analyzes the product's design, manufacturing, and labeling (among other things). See 21 U.S.C.

[2] Acronyms are a staple of opinions in this area of the law. And while we prefer simple words to awkward initialisms, we use some abbreviations here "because doing so nets out on the side of clarity and helps keep the opinion flowing." See United States v. Iriele, 977 F.3d 1155, 1156 n.1 (11th Cir. 2020).

§ 360e(c)(1); see also Lohr, 518 U.S. at 477. After getting PMA approval, manufacturers must comply with certain requirements, including informing the FDA of incidents where a device "[m]ay have caused or contributed to a death or serious injury." See 21 C.F.R. § 803.50(a)(1). And if they fail to comply, the FDA can withdraw approval. Id. § 814.82(c).

The scheme Congress created reflects a weighing of competing policy concerns. See, e.g., Caplinger v. Medtronic, Inc., 784 F.3d 1335, 1336 (10th Cir. 2015) (Gorsuch, J., for the court). On the one hand Congress wanted to "ensur[e] that proposed medical devices are carefully scrutinized for safety." Id. But on the other Congress hoped to "preserv[e] the freedom of patients and doctors to use potentially life-saving technology as they see fit without delay." Id. A flash point in the "legislative process" concerned "to what extent (if any) should states be able to layer additional rules on top of Congress's[.]" Id. Using its power under the Constitution's Supremacy Clause, id.,[3] Congress struck a balance it thought reasonable:

> Except as [authorized by the FDA], no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —

[3] See generally La. Pub. Serv. Comm'n v. FCC, 476 U.S. 355, 368 (1986) (explaining that the Supremacy Clause — U.S. Const. art. VI, cl. 2 — empowers Congress to preempt state law with national law).

> (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 [the FDCA].

See 21 U.S.C. § 360k(a). To paraphrase that provision's crucial part, a state-law claim is expressly preempted under § 360k(a) when the FDCA imposes a federal requirement on the device *and* the contested state or local rule imposes any obligation that differs from or adds to those in the FDCA.[4] Importantly, though, "[n]othing in § 360k denies [states] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." See Lohr, 518 U.S. at 495; accord Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008) (finding state-law claims expressly preempted because they alleged that the at-issue device "violated state tort law notwithstanding compliance with the relevant federal requirements" (ergo, the state requirements implicit in these claims differed from or added to the federal requirements) — but stressing how "§ 360k does not prevent a State from providing a damages remedy for claims premised

[4] With apologies to Professor Karl Llewellyn, who said "[n]ever paraphrase a statute." See https://chicagounbound.uchicago.edu/cgi/viewcontent.cgi?article=1622&context=lsr.

on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements" (quoting Lohr, 518 U.S. at 495)).

A state-law claim not expressly preempted by the FDCA may be impliedly preempted, however. See Buckman Co. v. Pls.' Legal Comm., 531 U.S. 341, 352-53 (2001). With exceptions not applicable here, § 337(a) of the FDCA provides that "proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." See 21 U.S.C. § 337(a). That language shows "that Congress intended that the [FDCA] be enforced exclusively by the Federal Government." See Buckman Co., 531 U.S. at 352. So § 337(a) preempts any state-law claim that exists "solely by virtue" of an FDCA infraction — like, for example, a claim against a manufacturer for violating the FDCA's ban on making false statements to the FDA during the PMA process. See id. at 353. On the flip side, a state-law claim based on "traditional state tort law" that happens to "parallel" the FDCA is outside of § 337(a)'s preemptive scope. See id.

Working in tandem, § 360k(a) and § 337(a) leave plaintiffs with a

> narrow gap through which [their] state-law claim must fit if it is to escape express or implied preemption: the plaintiff[s] must be suing for conduct that *violates* the FDCA (or else [their] claim is expressly preempted by [§ 360k(a)], but [they] must not be suing

> *because* the conduct violates the FDCA (such a claim would be impliedly preempted [by § 337(a)]).

Dumont v. Reilly Foods Co., 934 F.3d 35, 42 (1st Cir. 2019) (quoting In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010)) (quotations omitted and emphases in original).

C

Now back to this action.

The FDA gave Sorin the necessary approval for the Model LX, including signing off on the device's label — which warned that "[c]linical experience described in the medical literature suggests that . . . patients . . . who are 55 years of age or less may experience accelerated calcification of bioprosthetic heart valves." Allison's implanting surgeon knew about these risks and had a practice of explaining them to his patients and their families (appellants write that "although he was aware of calcification in younger patients, he was not aware of rapid valve deterioration . . . in one to two years").

About 18 months after the implantation, Allison — in January 2014 — had emergency surgery to remove the Mitroflow valve and replace it with a mechanical one. Sadly, she never regained consciousness and died weeks later after doctors took her off life support.

Appellants sued Sorin in Massachusetts state court. Plourde v. Sorin Group USA, Inc., 517 F. Supp. 3d 76, 80 (D. Mass. 2021). As relevant to this appeal, their complaint alleged negligence and failure-to-warn claims predicated on Sorin's not reporting adverse events to the FDA concerning Mitroflow malfunctions in young patients. Had Sorin made the required reports, the theory goes, Allison's doctor would not have recommended or implanted the Mitroflow.

Sorin removed the lawsuit to federal court under diversity jurisdiction and then moved to dismiss for failure to state a claim. See id.; see also Plourde v. Sorin Group USA, Inc., No. 17-cv-10507, 2018 WL 1542361, at *1 (D. Mass. Mar. 29, 2018). Of relevance here, the district judge ruled that "to the extent Plaintiffs allege that [Sorin] had a duty under Massachusetts law to report studies and adverse events that occurred after the [v]alve received premarket approval [from] the FDA, those claims are not preempted" — though the judge quickly added that "at this time," she "ma[de] no determination as to whether Massachusetts law actually imposes such a duty." See Plourde, 2018 WL 1542361, at *8.

The judge later issued an order granting summary judgment to Sorin. See Plourde, 517 F. Supp. 3d at 95. Pertinently for present purposes, the judge concluded that appellants "failed

to identify a parallel duty under Massachusetts law that would have required [Sorin] to make reports to the FDA coextensive with the requirements of federal law." Id. at 92. Based on that ruling, the judge deemed their negligence and failure-to-warn claims preempted. See id. at 88-92.

II

The core of appellants' case — as we just stated, and as they themselves concede — is that Sorin allegedly failed both to report adverse events to the FDA (which forms the basis of their negligence claim) and to warn the FDA of adverse events (which forms the basis of their failure-to-warn claim). The parties focus most of their energy on the question whether Massachusetts law imposes a duty on medical-device manufacturers to report adverse events to the FDA that does no more than parallel the FDCA and FDA regulations. Appellants answer yes. Sorin answers no. We summarize their key arguments broadly.

A

Surveying Massachusetts's legal landscape, appellants see a non-preempted duty of care that Sorin owed to Allison — a duty they say Sorin breached by "failing to comply with federal/FDA adverse event reporting requirements."

Appellants, for starters, highlight Massachusetts's common-law duty requiring manufacturers to act with reasonable

care to prevent foreseeable injury — such as by "warn[ing] consumers of the dangers arising from the use of their products where the manufacturers know or should have known of the dangers." See Rafferty v. Merck & Co., 93 N.E.3d 1205, 1211 (Mass. 2018); accord H.P. Hood & Sons, Inc. v. Ford Motor Co., 345 N.E.2d 683, 688 (Mass. 1976); see also Back v. Wickes Corp., 378 N.E.2d 964, 970-71 (Mass. 1978) (explaining that Massachusetts holds a manufacturer to the expectable knowledge of an "ordinary, reasonably prudent manufacturer in like circumstances"). To appellants' way of thinking, "[a] reasonably prudent manufacturer" in Sorin's shoes "would not violate a federally mandated duty to report adverse events to the FDA."

From there, appellants principally cite to and quote from two Massachusetts cases: a superior court decision, Brown v. DePuy Spine, Inc., Nos. BRCV2006-00208, BRCV2006-00209, BRCV2006-00211, & BRCV2006-00630, 2007 WL 1089337 (Mass. Super. Ct. Apr. 9, 2007); and an SJC decision, Dunn v. Genzyme Corp., 161 N.E.3d 390 (Mass. 2021). The Brown plaintiffs sued a medical-device manufacturer under Massachusetts law for (among other claims) "breach[ing] its duty to comply with FDA regulations." See 2007 WL 1089337, at *1. Denying the company's preemption-based bid for summary judgment, the superior court ruled — in words our appellants spotlight — that "[a]ll of the plaintiffs' claims

are based on traditional state causes of action; plaintiffs do not seek recovery merely for a violation of federal law." Id. at *10. Likewise invoking Massachusetts law, the Dunn plaintiff sued a medical-device manufacturer for negligent failure to warn (among other theories). See 161 N.E.3d at 392. The SJC reversed the superior court's decision denying the company's dismissal motion, holding that the plaintiff had insufficiently pled her claims. See id. at 393. But in doing so, the SJC noted — in language our appellants emphasize — that her "claims . . . all can be interpreted as coextensive with the comprehensive Federal requirements imposed on [the company] under the [FDCA]." See id. at 396. Appellants read these decisions as imposing a state duty to warn on medical-device manufacturers that parallels duties found in the FDCA.

Also as part of their multifaceted approach, appellants note that Massachusetts follows section 388 of the Restatement (Second) of Torts — which imposes a duty on manufacturers to warn third parties if a product "is or is likely to be dangerous." And according to them, a breach of that duty can constitute "a parallel non-preempted claim to the federal duty to report adverse events to the FDA."

B

Unsurprisingly (given how the parties are in the throes of appellate litigation), Sorin's overarching argument is that "the Commonwealth does not recognize" — as appellants contend — "an independent state law duty to make [adverse-events] reports to the FDA."

To that end, Sorin first attacks appellants' use of Massachusetts cases discussing a manufacturer's general duty of care to avoid foreseeable dangers. Seeking to downplay their significance, Sorin labels these decisions "inapposite" because they do not deal "with the duties of device manufacturers under Massachusetts law."

Sorin then says that Brown — the superior court opinion — is not an authoritative guide to Massachusetts law, insisting, for example, that Brown simply noted that *if* a parallel state-law duty to report or warn the FDA exists, the plaintiffs' claims *might* survive preemption. As support, Sorin harps on the Brown court's saying that "there ha[d] not yet been any significant discovery" and that "[w]here an underlying question of law is subject to doubt, the preferable practice is to decide the question on a full record of facts." See 2007 WL 1089337, at *13. And Sorin adds that a different superior court opinion — Phillips v. Medtronic, Inc. — more recently held that a Massachusetts tort claim based on

a failure to report to the FDA is "impliedly preempted because it is premised solely on a duty created by the [FDCA] which did not exist in the common law." See No. SUCV2009-05286-A, 2012 WL 3641487, at *10 (Mass. Super. Ct. July 10, 2012). Turning next to Dunn — the SJC decision — Sorin insists that the high court there did not hold that the plaintiff's state-law claims paralleled federal requirements. We assume what Sorin has in mind is the italicized part of the quotation (set out above) — plaintiff's "claims . . . all *can be interpreted* as coextensive with the comprehensive Federal requirements imposed on [the company] under the [FDCA]." See 161 N.E.3d at 396 (emphasis added).

Sorin next brings up the learned-intermediary doctrine, a common-law rule adopted in Massachusetts that (generally speaking) allows medical-device manufacturers to discharge their duty by warning physicians of the risks instead of the patients themselves. See, e.g., Knowlton v. Deseret Med., Inc., 930 F.3d 116, 120 n.2 (1st Cir. 1991) (applying Massachusetts law). As Sorin sees it, given this doctrine, Massachusetts law cannot require manufacturers to also warn the FDA — "[t]he FDA," argues Sorin, "is not a healthcare provider and therefore not a learned intermediary."

Which segues into Sorin's attempt to counter appellants' Restatement-based theory. Quoting Massachusetts caselaw, Sorin

asserts that when it comes to the duty to warn, "a manufacturer may be absolved from blame because of a justified reliance upon . . . a middleman" to communicate risks, see MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 68 (Mass. 1985) (quoting Carter v. Yardley & Co., 64 N.E.2d 693, 697 (Mass. 1946)) — but "only in the limited instances in which the manufacturer's reliance on an intermediary is reasonable," see id. (citing Restatement (Second) of Torts § 388 cmt. n). And to hear Sorin tell it, while "manufacturers may discharge their duty to warn the patient by adequately warning doctors directly," nothing in "[s]ection 388" or in "Massachusetts case law supports the proposition that a manufacturer can reasonably rely on the FDA to communicate [adverse events] to physicians much less to patients."

III

As intimated several pages ago, we try not to bother our busy state colleagues with every difficult state-law issue that comes our way, see Patel v. 7-Eleven, Inc., 8 F.4th 26, 29 (1st Cir. 2021) — if there is "a reasonably clear and principled course, we will seek to follow it ourselves," see Pino v. United States, 507 F.3d 1233, 1236 (10th Cir. 2007) (Gorsuch, J., for the court). But the caselaw outlined in Part II gives us no definitive guidance. And we "hesitate to 'trade judicial robes for the garb of prophet' . . . when an available certification procedure

renders the crystal ball or divining rod unnecessary." See Boardman v. United Servs. Auto Ass'n, 742 F.2d 847, 851 (5th Cir. 1984) (quoting John R. Brown, *Certification — Federalism in Action*, 7 Cumb. L. Rev. 455, 455 (1977)). So given the absence of any SJC decision directly on point — and in the spirit of "cooperative judicial federalism," see Lehman Bros., 416 U.S. at 391 (indicating that state (and not federal) courts should decide state-law policy when doable) — rather than hazard a guess about the meaning of state law in this "importan[t] and complex[]" area that may be outcome-determinative, see In re Engage, 544 F.3d at 57, we opt to certify, see Pyle v. S. Hadley Sch. Comm., 55 F.3d 20, 22 (1st Cir. 1995) (relying on Lehman Bros. for the notion that "uncertainty or difficulty regarding state law . . . may be enough to counsel certification where that procedure is available"); see generally In re Engage, 544 F.3d at 57 (certifying a question to the SJC after noting that "[t]his is not a case in which the policy arguments line up solely behind one solution" (quotation marks omitted)).

Satisfied that this case meets the SJC's certification standard and ours, we respectfully pose the following question to the only court that can give an authoritative answer — which will allow us and the parties to be certain that we are applying *genuine* state law:

> Does a manufacturer's failure to report adverse events to a regulator — such as one like the FDA — give rise to liability under Massachusetts law?

Our question is similar to a question the Second Circuit asked the Connecticut Supreme Court in a case involving "the scope of federal preemption of" that state's "tort law claims based on injuries caused by a medical device." See Glover v. Bausch & Lomb Inc., 6 F.4th 229, 232, 241, 244 (2d Cir. 2021) (querying "[w]hether a cause of action exists under the negligence or failure-to-warn provisions of the Connecticut Product Liability Act . . ., or elsewhere in Connecticut law," arising from "a manufacturer's alleged failure to report adverse events to a regulator like the FDA following approval of the device, or to comply with a regulator's post-approval requirements").[5] And we chose this phrasing to give the SJC maximum flexibility — we do not wish to handcuff the SJC's consideration of the issue and would welcome any additional comments about Massachusetts law the SJC may care to offer (assuming of course that the SJC accepts our request).

The clerk of this court shall forward to the SJC (under official seal) our opinion, as well as the parties' appellate briefs and appendices. We retain jurisdiction and award no costs

[5] The Connecticut high court "accepted" the certification request. See Order, Glover v. Bausch & Lomb Inc., No. 20-1156cv (Conn. Aug. 3, 2021).

at this time (we may revisit costs after we hear back from the SJC).