UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term, 2020

Argued: March 23, 2021 Decided: July 20, 2021

Docket No. 20-1156-cv

MARJORIE GLOVER, CHARLES GLOVER,

Plaintiffs-Appellants,

JANE DOE, JOSEPH DOE,

Plaintiffs,

— v. —

BAUSCH & LOMB INCORPORATED, BAUSCH HEALTH COMPANIES INC. (F/K/A VALEANT PHARMACEUTICALS INTERNATIONAL, INC.), BAUSCH HEALTH US, LLC (F/K/A VALEANT PHARMACEUTICALS NORTH AMERICA LLC), BAUSCH HEALTH AMERICAS, INC. (F/K/A VALEANT PHARMACEUTICALS INTERNATIONAL), DOES 1 though 50, inclusive,

Defendants-Appellees.[*]

---

[*] The Clerk of the Court is respectfully directed to amend the caption as set forth above.

B e f o r e:

LYNCH and NARDINI, *Circuit Judges*.[**]

This appeal raises questions regarding the scope of federal preemption of state tort law claims based on injuries caused by a medical device. Plaintiff-Appellant Marjorie Glover suffered post-operative injuries after she was implanted with artificial lenses during cataract surgery. She and her husband sued the manufacturer of the lenses, Defendant-Appellee Bausch & Lomb, Inc., and related entities. The Glovers now appeal an order of the United States District Court for the District of Connecticut (Kari A. Dooley, *J.*) granting Defendants' motion to dismiss the Glovers' negligence and failure-to-warn claims and denying their motion for leave to amend the complaint to add a claim based on wrongful marketing. On appeal, the Glovers argue that the district court erred in concluding that their negligence and failure-to-warn claims are preempted by federal law and further erred in denying leave to amend their complaint as futile. We conclude that the Glovers' claims raise unresolved issues of state law that are appropriate for certification. We therefore reserve decision and certify two questions to the Supreme Court of Connecticut.

WENDY R. FLEISHMAN, Lieff Cabraser Heimann & Bernstein, LLP, New York, NY (Hugh W. Cuthbertson, Glenn A. Duhl, Zangari Cohn Cuthbertson Duhl & Grello P.C., New Haven, CT, *on the brief*), *for Plaintiffs-Appellants*.

ELLIOT H. SCHERKER , Greenberg Traurig, P.A., Miami, FL

[**] Judge Robert A. Katzmann, originally a member of the panel, died on June 9, 2021. The two remaining members of the panel, who agree, have determined the matter. *See* 28 U.S.C. § 46(d); 2d Cir. IOP E(b); *United States v. Desimone*, 140 F.3d 457, 458-59 (2d Cir. 1998).

(Brigid F. Cech Samole, Miami, FL, Lori G. Cohen, Atlanta, GA, Daniel I.A. Smulian, Robert J. Kirshenberg, Sarah H. Richardson, New York, NY, *on the brief*), *for Defendants-Appellees.*

GERARD E. LYNCH, *Circuit Judge*:

This appeal raises questions regarding the scope of federal preemption of state tort law claims based on injuries caused by a medical device. Plaintiff-Appellant Marjorie Glover suffered pain and loss of vision after she was implanted with Trulign Toric intraocular lenses ("Trulign Lenses") in both of her eyes to correct her vision following cataract surgery. She and her husband (together, "the Glovers") sued Defendant-Appellee Bausch & Lomb Incorporated and related entities (collectively, "B&L").[1] The district court dismissed the complaint, concluding, *inter alia*, that the Glovers' negligence and failure-to-warn claims under the Connecticut Product Liability Act ("CPLA") were expressly and impliedly preempted by the federal Food, Drug, and Cosmetic Act ("FDCA"). The court also denied leave to amend the complaint to add a claim under the

---

[1] Defendants-Appellees include Bausch & Lomb Incorporated, Bausch Health Companies Inc. (f/k/a Valeant Pharmaceuticals International, Inc.), Bausch Health US, LLC (f/k/a Valeant Pharmaceuticals North America LLC), Bausch Health Americas, Inc. (f/k/a Valeant Pharmaceuticals International), and Does, 1 through 50, inclusive.

Connecticut Unfair Trade Practices Act ("CUTPA") based on wrongful marketing, concluding that amendment would be futile because the wrongful marketing claim would also be preempted.

The Glovers appeal both decisions. They argue that their negligence and failure-to-warn claims are not impliedly preempted because Connecticut law includes a cause of action based on failure to warn a regulator, such as the FDA, of known safety risks and failure to comply with a regulator's post-approval safety requirements. Therefore, they contend, those claims proceed under traditional tort law and are not a veiled attempt to enforce federal requirements that Congress has not provided a private right of action to enforce. They further contend that their claims are not expressly preempted by the FDCA because they impose no requirements different from or in addition to those imposed by federal law. Finally, as to their CUTPA claim, the Glovers argue that amendment would not be futile because Connecticut law permits a CUTPA claim for wrongful marketing where a manufacturer "deceptively marketed and promoted" a product "despite possessing information that [the product] presented a substantial risk of causing" injury. Appellants' Br. 33. They argue that such a claim is not preempted for much the same reasons that their other claims are not

preempted, and further argue – responding to an argument that B&L made below and renews on appeal, which the district court declined to address – that their CUTPA claim is not barred by the exclusivity provision of the CPLA. As explained below, we conclude that both issues turn on questions of state law for which no controlling decisions of the Supreme Court of Connecticut exist. Therefore, we certify two questions to the Supreme Court and reserve decision on this case.

BACKGROUND

I. Factual and Legal Background

A. Regulation of Medical Devices

In 1976, Congress passed the Medical Device Amendments ("MDA") to the FDCA, which authorized federal regulation of medical devices. 21 U.S.C. § 360c *et seq*. The FDCA, as amended by the MDA, divides medical devices into three classes. As relevant here, Class III, the most stringently regulated class, encompasses devices for which lesser controls are not clearly sufficient to assure their safety and effectiveness, and which are "for a use in supporting or sustaining human life or . . . of substantial importance in preventing impairment

of human health" or which "present[] a potential unreasonable risk of illness or injury." *Id.* § 360c(a)(1)(C)(i)-(ii).

Class III devices are subject to a pre-market approval ("PMA") process, in which the manufacturer must present to the FDA information about the device's safety and effectiveness, as well as proposed labeling for the device. *Id.* § 360e(c)(1). The FDA must determine whether approval is appropriate, "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." *Id.* § 360c(a)(2)(C).

The FDCA and its implementing regulations provide that the FDA may approve a Class III device subject to additional post-approval conditions. *See* 21 C.F.R. §§ 814.80, 814.82. If a manufacturer fails to comply with the FDA's regulations or any post-approval conditions, the agency may withdraw approval. *Id.* § 814.82(c). Once a device has been approved, the manufacturer must submit a supplemental application before making any change to the device that would "affect[] safety or effectiveness." 21 U.S.C. § 360e(d)(5)(A)(i).

Finally, the FDCA contains a provision expressly preempting state law. The provision states that, save for exceptions not relevant here,

> no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Id. § 360k(a).

B. The Trulign Toric Intraocular Lens

B&L's Trulign Lens is a prescription medical device used to treat cataracts. A cataract occurs when the naturally clear lens in a patient's eye becomes cloudy. The Trulign Lens is surgically implanted in a patient's eye to replace the clouded natural lens. The Trulign Lens is an "accommodating" lens – a lens that can flex to change focus, allowing the patient to see clearly objects at different distances.

The Trulign Lens is classified as a Class III medical device under the FDCA. Accordingly, B&L was required to seek FDA approval for the device. Because B&L had already obtained approval for a predecessor device, the Crystalens Intraocular Lens, B&L sought approval for the Trulign Lens through a

PMA supplement.[2] The Glovers allege that during the PMA process for the Trulign Lens, B&L "downplay[ed]" risks of the device. J.A. 179. Specifically, they allege that B&L failed to alert the FDA to the extent of the risk of a condition called Z Syndrome, a post-operative complication which occurs when one side of the implanted lens pulls forward, while the other side remains in the normal position or is pushed backward, resulting in a "Z" shape. The Glovers assert that B&L was aware of several instances of Z Syndrome complications attributable to the predecessor device, Crystalens.

In 2013, B&L received approval from the FDA for the Trulign Lens, subject to certain post-approval conditions. The FDA required B&L to conduct a post-market safety study specifically regarding Z Syndrome risk, to submit the protocol for that study within 30 days of approval, and to submit progress reports regarding the study every six months for the first two years. The FDA also required that the results from that study be included in the labeling for the

[2] A PMA supplement "means a supplemental application to an approved PMA for approval of a change or modification in a class III medical device, including all information submitted with or incorporated by reference therein." 21 C.F.R. § 814.3(g).

Trulign Lens as data became available and that updated labeling be submitted to the FDA for approval.

Finally, B&L, like all manufacturers of medical devices, was required to submit adverse event reports "no later than 30 calendar days after" becoming aware of any information that:

> [R]easonably suggests that a device that [B&L] market[ed]:
> (1) May have caused or contributed to a death or serious injury or
> (2) Has malfunctioned and this device or a similar device that [B&L] market[ed] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

21 C.F.R. § 803.50(a).

C. Plaintiffs' Injuries

In September 2014, Marjorie Glover underwent two successive cataract surgeries during which her physician surgically implanted a Trulign Lens in each eye. Shortly after her surgeries, she began to experience significant loss in visual acuity, blurriness, hazing, halos, and eye pain. She was ultimately diagnosed with Z Syndrome in both of her eyes. Her vision is permanently impaired, and she has endured numerous procedures in the unsuccessful effort to correct her

condition. During these procedures, her doctors have been unable to remove some components of the Trulign Lenses from her eyes.

The Glovers allege that Glover's injuries were caused by the Trulign Lenses. They further allege that B&L was aware that there was a substantial risk that patients would develop Z Syndrome after the lenses were implanted and failed to inform the FDA of the extent of that risk during the PMA process. Finally, they allege that B&L failed to comply with the post-approval conditions set by the FDA, including by failing to begin the FDA-required Z Syndrome study until 2015, after Glover's lenses were already implanted, and by failing to inform the FDA of adverse events that occurred after approval. As a result, the Glovers allege, Glover and her physician were unaware of the risk of Z Syndrome when she chose to have the lenses implanted.

II. Procedural Background

In October 2017, the Glovers sued B&L in federal court in California. On B&L's motion, the case was transferred to the United States District Court for the District of Connecticut. The Glovers filed an amended complaint in March 2018 and a second amended complaint (the "SAC") in June 2018. In the SAC, the Glovers alleged claims for failure to warn and negligence under the CPLA, Conn.

Gen. Stat. §§ 52-572h and 52-572q, along with related loss of consortium, and other claims not at issue in this appeal.

On July 5, 2018, B&L moved to dismiss the SAC. The district court held oral argument on the motion on January 17, 2019. On July 16, 2019, before the motion was decided, the Glovers moved to amend their complaint to add a cause of action under CUTPA, Conn. Gen. Stat. § 42-110a, *et seq.*; B&L opposed the motion.

On March 11, 2020, the district court (Kari A. Dooley, *J.*) granted B&L's motion, dismissed the Glovers' claims with prejudice, and denied leave to amend the complaint. *Doe v. Bausch & Lomb, Inc.*, 443 F. Supp. 3d 259 (D. Conn. 2020). As relevant here, the district court concluded that the Glovers' failure-to-warn claim was both expressly and impliedly preempted by federal law. The court concluded that, to the extent the claim alleged that B&L failed to warn *Glover and her physicians*, it was expressly preempted by § 360k of the FDCA because federal law imposes no duty to warn patients and physicians of risks presented by medical devices, apart from those warnings included on FDA-approved labels. To the extent the claim alleged that B&L failed to warn *the FDA* of post-approval adverse events, the district court concluded that it was impliedly preempted

because any such claim was "wholly derivative of the FDCA" and the Glovers failed to identify a corresponding duty to warn the FDA under Connecticut law. *Id.* at 273.

The court concluded that the Glovers' negligence claim, which it understood – similarly to the failure-to-warn claim – as based on failure to report adverse events to the FDA, though "likely not expressly preempted," was impliedly preempted for much the same reason as the failure-to-warn claim. *Id.*

Finally, the district court denied leave to amend the complaint, concluding that amendment to add a claim under CUTPA would be futile because "[r]egardless as to whether the exclusivity provision of the CPLA bars CUTPA claims, . . . [the Glovers' claim] would be dismissed as expressly preempted by § 360k(a)." *Id.* at 275. The court reasoned that the CUTPA claim, if successful, would require B&L to give warnings different from or in addition to those approved by the FDA, which is impermissible under § 360k.

This appeal followed.

DISCUSSION

The Glovers appeal the dismissal of their failure-to-warn and negligence claims under the CPLA and the related loss of consortium claim, as well as the district court's denial of leave to amend their complaint to add a claim under CUTPA. They do not appeal the dismissal of their other claims. "We review *de novo* a district court's application of preemption principles." *Goodspeed Airport LLC v. E. Haddam Inland Wetlands & Watercourses Comm'n*, 634 F.3d 206, 209 n.3 (2d Cir. 2011) (internal quotation marks omitted).[3] We also review *de novo* a district court's denial of a request for leave to amend based on futility. *Orchard Hill Master Fund Ltd. v. SBA Commc'ns Corp.*, 830 F.3d 152, 156 (2d Cir. 2016).

The Glovers argue that the district court erred in dismissing their failure-to-warn and negligence claims under Connecticut law as impliedly preempted because they contend that Connecticut law "recognize[s] a medical device manufacturer's duty to timely and accurately report adverse events to the FDA"

---

[3] As the district court correctly noted, preemption is "an affirmative defense," *Ricci v. Teamsters Union Loc. 456*, 781 F.3d 25, 28 (2d Cir. 2015) (internal quotation marks omitted). However, preemption "can still support a motion to dismiss if the statute's barrier to suit is evident from the face of the complaint." *Id.* Here, because the district court concluded that the defense was apparent on the face of the complaint, and because the Glovers have not objected to the manner in which B&L raised the issue, we assume that the defense was properly raised.

and to comply with the FDA's post-approval requirements. Appellants' Br. 19. They further contend that their failure-to-warn claim does not create additional requirements for B&L beyond those imposed by the FDA and therefore that the district court erred in concluding that the claim was expressly preempted. Finally, as to their CUTPA claim, the Glovers argue that the district court erred in concluding that amendment would be futile, because the Supreme Court of Connecticut's recent decision in *Soto v. Bushmaster Firearms Int'l, LLC*, 331 Conn. 53 (2019), explicitly clarifies that CUTPA permits recovery for personal injuries caused by wrongful marketing, and such a claim would not be expressly preempted.

Because, as we explain below, the Glovers' arguments ultimately turn on questions of state law for which no controlling decisions of the Supreme Court of Connecticut exist, we reserve decision and certify two questions to the Supreme Court. *See* Conn. Gen. Stat. § 51-199b(d); 2d Cir. Local R. 27.2(a).

I. CPLA Claims

The Glovers contend that their negligence and failure-to-warn claims under the CPLA are based on "overlapping conduct," Appellants' Br. 27, namely, "B&L's failures to conduct a required post-approval study and to report adverse

events," which, they argue "not only constituted negligence, but also deprived Mrs. Glover and her doctors of accurate information," Appellants' Reply Br. 6. They argue that the district court erred in interpreting their failure-to-warn claim in part as a challenge to the FDA-approved labeling. On appeal, they explicitly limit their claims to those based on failure to comply with the FDA's post-approval requirements. Accordingly, we limit our analysis to that issue.[4] B&L contends that both claims, however interpreted, are preempted.

The MDA "swept back some state obligations and imposed a regime of detailed federal oversight" of medical devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315-16 (2008). Since its passage, the Supreme Court has several times addressed the scope of federal preemption of state law regulation of medical devices. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Court interpreted the FDCA's express preemption provision, § 360k, which prohibits claims based on state law that impose requirements "different from, or in addition to, any requirement applicable . . . to the device" under federal law. The Court concluded that § 360k did not preempt the *Lohr* plaintiffs' "manufacturing and

[4] However, to the extent that the SAC can be read to plead a labeling claim, we agree with the district court that any such claim is expressly preempted. *See* 21 U.S.C. § 360k; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 329 (2008).

labeling claims to the extent that they rest on claims that [the manufacturer] negligently failed to comply with duties equal to, or substantially identical to, requirements imposed under federal law" because "[n]othing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." 518 U.S. at 495, 497 (internal quotation marks omitted). Importantly, the Court explained that the scope of express preemption under the Act is limited: "§ 360(k) simply was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions." *Id.* at 491 (plurality opinion).

Shortly thereafter, in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Court addressed implied preemption. The FDCA provides that "all . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). In *Buckman*, the Court explained that the FDA has the sole authority "to police fraud consistently with the Administration's judgment and objectives." 531 U.S. at 350. The Court held that the *Buckman* plaintiffs' claims that the manufacturer had misled the FDA during the approval process were preempted because those "fraud-on-the-FDA" claims "exist[ed] solely by virtue of the FDCA disclosure requirements"

and permitting such claims to proceed would "skew[] . . . [the] delicate balance of statutory objectives" the FDA seeks to achieve in enforcing the FDCA's requirements. 531 U.S. at 352-53. To avoid implied preemption, the Court explained, claims must be based not on the FDCA, but on "traditional state tort law which . . . predated the federal enactments in question[]." *Id.*

Finally, in *Riegel*, the Court returned to the question of express preemption, holding plaintiffs' state common law claims preempted because they asserted that the device in question "violated state tort law notwithstanding compliance with the relevant federal requirements" and accordingly, imposed requirements in addition to those imposed by federal law, contravening § 360(k). 552 U.S. at 330. However, the Court again affirmed that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." 552 U.S. at 323. Such claims would not be expressly preempted because "the state duties in such a case parallel, rather than add to, federal requirements." *Id.*

Together, express and implied preemption under the FDCA, "operating in tandem, have created what some federal courts have described as a 'narrow gap' for pleadings." *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017),

quoting *In re Medtronic, Inc.*, 623 F.3d 1200, 1204 (8th Cir. 2010). "The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *In re Medtronic*, 623 F.3d at 1200, quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009).

Applying the Supreme Court's analysis from *Lohr*, *Buckman,* and *Riegel*, three of our sister circuits have concluded that state tort claims premised on a failure to comply with the FDA's post-approval requirements are *not* preempted. The Fifth Circuit, in *Hughes v. Boston Scientific Corp.*, concluded that a claim based on a manufacturer's failure to report adverse events to the FDA was not expressly preempted by the FDCA because it did not "purport[] to impose liability despite [the manufacturer's] compliance with FDA regulations." 631 F.3d 762, 770 (5th Cir. 2011). The court further concluded that the claim was not impliedly preempted because the plaintiff was not "attempting to assert a freestanding federal cause of action based on violation of the FDA's regulations" but rather "[wa]s asserting a Mississippi tort claim based on the underlying state duty to warn about the dangers or risks of [a] product." *Id.* at 775.

Similarly, in *Stengel v. Medtronic Inc.*, the plaintiffs alleged that the manufacturer "had a continuing duty to monitor the product after pre-market approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product" and that because the manufacturer "failed to comply with its duty under federal law, it breached its duty to use reasonable care under Arizona negligence law." 704 F.3d 1224, 1232 (9th Cir. 2013) (*en banc*) (internal quotation marks omitted). The Ninth Circuit concluded that plaintiffs' negligence claim was not expressly or impliedly preempted because "Arizona law contemplate[d] a warning to a third party such as the FDA," and therefore they had properly pleaded a "parallel" claim based on state, not federal law. *Id.* at 1233.

Finally, in *Bausch v. Stryker Corp.*, the Seventh Circuit concluded that the plaintiff had successfully pleaded a claim that was not preempted, though based on somewhat different factual allegations. 630 F.3d 546 (7th Cir. 2010). There, the plaintiff alleged that the FDA "conducted an inspection at the defendants' . . . manufacturing facility . . . [and] informed the defendants of numerous deficiencies in the [device's] manufacturing and inspection processes." *Id.* at 559.

Subsequently, "the FDA issued a letter to defendants . . . warning that the [device] was adulterated due to manufacturing methods not in conformity with industry and regulatory standards." *Id.* The plaintiff alleged claims based on Illinois strict product liability and negligence law, arguing that the defendants knew or should have known that the device was defective before it was implanted in her. *Id.* The court concluded that the plaintiff's claims were not expressly preempted because although the complaint "d[id] not specify the precise defect or the specific federal regulatory requirements that were allegedly violated," the court reasoned that "if the problem turns out to be a failure to comply with the FDA's legally enforceable conditions for approval of the device, section 360k will not protect the manufacturer." *Id.* at 560. The court also determined that the claims were not impliedly preempted because they "[we]re tort law claims based on manufacturing defects, not fraud on a federal agency." *Id.* at 557. The court explained that there was "no indication that Congress intended preemption of state claims based on violations of federal law, beyond the limitations set forth in the express preemption clause." *Id.*

In contrast, at least three circuits have concluded that claims arguably similar to the Glovers' claims here may not proceed. Examining those decisions

closely, however, it appears that those courts were doubtful that a traditional state-law cause of action existed for failure to report adverse events to a regulator like the FDA, and believed instead that the plaintiffs were attempting to directly enforce the FDCA, a type of claim clearly foreclosed by *Buckman* and by the text of the FDCA.

For example, the Eighth Circuit, in *In re Medtronic*, concluded that a claim that "[the manufacturer] failed to provide the FDA with sufficient information and did not timely file adverse event reports . . . [was] simply an attempt by private parties to enforce the MDA" and therefore was impliedly preempted. 623 F.3d at 1203. Similarly, the Eleventh Circuit, in *Mink*, determined that a tort claim based on failure to report adverse events to the FDA was impliedly preempted because the manufacturer's "duty [wa]s owed to the FDA," not the plaintiff, and the plaintiff's "theory of liability [wa]s not one that state tort law has traditionally occupied." 860 F.3d at 1330.[5] Finally, the Tenth Circuit, in *Brooks v. Mentor*

[5] However, earlier in the opinion the court concluded that the plaintiff's "'failure to report adverse events' theory [was] properly pled under Florida law." *Mink*, 860 F.3d at 1329. Accordingly, it may be that the *Mink* court was drawing a distinction between claims that are "properly pled" under state law but are nonetheless preempted, and those that are in an area "state tort law has traditionally occupied" and therefore are not preempted. *Id.* at 1329-30.

Worldwide LLC, concluded that because the plaintiffs "ha[d] not identified a state-law duty to comply with FDA-imposed post-approval requirements such as testing and reporting" and because "the government retains the exclusive right to enforce post-approval requirements for continued testing, including the right to revoke approval for noncompliance," those claims were impliedly preempted. 985 F.3d 1272, 1281 (10th Cir. 2021).

Considering these decisions, and the Supreme Court's precedents in *Lohr*, *Buckman*, and *Riegel*, it is clear that the Glovers' claims can proceed, if at all, only if the CPLA provides a cause of action based on a manufacturer's failure to report adverse events to a regulator like the FDA, or to comply with post-approval requirements set by that regulator. Critically, to avoid express preemption any such state-law cause of action may not impose requirements "different from, or in addition to" the requirements imposed by federal law. 21 U.S.C. § 360k. Moreover, the cause of action may not exist "solely by virtue of the FDCA disclosure requirements" and must be based on "traditional state tort law," or the claim will be impliedly preempted. *Buckman*, 531 U.S. at 353; *see also Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 95 (2d Cir. 2006) (applying *Buckman* and concluding that plaintiffs' claims were not preempted because they were

"asserting claims that sound in traditional state tort law"), aff'd sub nom. *Warner-Lambert Co., LLC v. Kent*, 552 U.S. 440 (2008).

The Glovers argue that their claims under the CPLA meet these requirements. They rely on the text of the CPLA's negligence and failure-to-warn provisions, and in particular § 52-572q(d), which provides in relevant part that "[a] product seller may not be considered to have provided adequate warnings or instructions unless they were devised to communicate with the person best able to take or recommend precautions against the potential harm." They argue that here, "the person best able to take or recommend precautions against the potential harm" is the FDA and, accordingly, under the CPLA, B&L has a duty to report adverse events to the FDA, and to conduct the post-approval testing that the FDA required.

B&L disagrees with the Glovers' interpretation of Connecticut law and contends that we should affirm the district court's conclusion that "[t]here is no general or background duty under Connecticut law to report risks *to a regulatory body*" like the FDA. Appellees' Br. 24, quoting *Doe*, 443 F. Supp. 3d at 273 (emphasis in original). B&L relies in part on Connecticut's learned intermediary doctrine, which provides that "adequate warnings to prescribing physicians

obviate the need for manufacturers . . . to warn ultimate consumers directly." *Vitanza v. Upjohn Co.*, 257 Conn. 365, 376 (2001); *see also Hurley v. Heart Physicians, P.C.*, 278 Conn. 305, 317 (2006) (applying the doctrine to medical devices). B&L argues that because the learned intermediary doctrine provides that manufacturers owe a duty to warn physicians rather than end consumers, Connecticut law has identified *physicians* as "the person[s] best able to take or recommend precautions against the potential harm," and thus cannot be interpreted to require manufacturers also to warn *regulators*.[6]

However, neither party points to any binding Connecticut authorities on the question of whether manufacturers have a duty to warn a regulator, nor are we able to locate any. The Glovers cite our decision in *Densberger v. United Technologies Corporation*, 297 F.3d 66 (2d Cir. 2002), for the proposition that there is a post-sale duty to warn sounding in negligence, which is cognizable under the CPLA. But that decision certainly does not address whether Connecticut law provides a cause of action for post-sale failure to warn a *regulator*. Both sides also point to a number of federal district court decisions that they contend support

[6] B&L also argues that we should affirm on the alternative ground that the Glovers failed to adequately plead causation. The district court did not reach that question and we decline to address it for the first time on appeal.

their respective positions.[7] But those decisions are inconclusive with regard to the question before us, and in any event are not authoritative sources of Connecticut law.

We also observe that many of the previous decisions of our sister circuits do not include extensive discussions of whether the relevant state law provided a cause of action for failure to report adverse events to a regulator. *See, e.g.*, *Hughes*, 631 F.3d at 769 ("[a]ssuming that a failure to warn claim may be pursued under

---

[7] B&L points to two cases concluding that there is no duty under Connecticut law to report risks to a regulatory body like the FDA. *Norman v. Bayer Corp*., No. 16-cv-253, 2016 WL 4007547 at *3-*4 (D. Conn. Jul. 26, 2016); *Pratt v. Bayer Corp.*, No. 19-cv-1310, 2020 WL 5749956 at *8 (D. Conn. Sept. 25, 2020). The Glovers, for their part, rely on several cases where the district court concluded that the plaintiff failed to identify a duty under state law, or failed to allege sufficient facts to support a claim, without deciding that no such duty *exists* under Connecticut law. The Glovers argue that those cases "signal[]" that "failure-to-warn claims, pled with enough specificity, would state a non-preempted parallel claim under Connecticut law," Appellants' Br. 19. *See Simoneau v. Stryker Corp.*, No. 13-cv-1200, 2014 WL 1289426, at *11 (D. Conn. Mar. 31, 2014) (noting that plaintiff "identifie[d] no separate state law duty to warn the FDA," but permitting plaintiff to replead); *Nagel v. Smith & Nephew, Inc.*, No. 15-cv-927, 2016 WL 4098715, at *7 (D. Conn. July 28, 2016) (concluding that the facts alleged were "insufficient to indicate that defendant failed to comply with FDA requirements regarding reporting adverse events that would provide the basis for a parallel state law claim"); *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 108 (D. Conn. 2014) (dismissing claims without prejudice where plaintiff failed to allege facts showing that defendants "violated any duty of continuing reporting pursuant to the FDA's premarket approval process").

Mississippi law" without expressly addressing that issue). That appears to be a significant omission, given that the preemption analysis turns on whether plaintiffs successfully pleaded a traditional state law cause of action that exists separately from the FDCA but does not impose requirements "different from, or in addition to" the requirements imposed by federal law. 21 U.S.C. § 360k.

The Ninth Circuit's decision in *Stengel* is particularly illuminating in that regard. Several years after the *Stengel* court concluded that "Arizona law contemplate[d] a warning to a third party such as the FDA," 704 F.3d at 1233, the Supreme Court of Arizona considered the issue and held that Arizona law in fact imposed no such duty to warn the FDA. In *Conklin v. Medtronic, Inc.*, 245 Ariz. 501, 508 (2018), the Supreme Court of Arizona explicitly disagreed with *Stengel*, explaining that "[b]ecause only federal law, not state law, imposes a duty on [a manufacturer] to submit adverse event reports to the FDA," a failure-to-warn claim was "at bottom . . . an attempt to enforce a federal law requirement" and therefore was impliedly preempted.[8]

[8] Intermediate courts of appeal in several other states have addressed whether the law of their state recognizes a duty to report adverse events to the FDA, reaching divergent conclusions. *See Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 428 (Cal. 2014) (concluding that, in light of a parallel California law duty, the plaintiff's "failure to warn claim based on [the manufacturer's] failure to file

Taking *Stengel* as a cautionary tale, we seek guidance on the issue of whether Connecticut law imposes a duty on a manufacturer, enforceable in tort, to warn the relevant regulator of potential dangers from its products. The answer to that question is potentially dispositive of this appeal because, if Connecticut law does not impose such a duty, then the Glovers' claims here are an effort to enforce the FDCA, which only the FDA may do. Accordingly, we certify the following question to the Supreme Court of Connecticut: *Whether a cause of action exists under the negligence or failure-to-warn provisions of the Connecticut Product Liability Act, Conn. Gen. Stat. §§ 52-572h, 52-572q, or elsewhere in Connecticut law, based on a manufacturer's alleged failure to report adverse events to a regulator like the FDA following approval of a product, or to comply with a regulator's post-approval safety requirements for the product.*[9]

---

adverse event reports with the FDA is not subject to express or implied preemption"); *Norabuena v. Medtronic, Inc.*, 2017 IL App (1st) 162928 (Ill. 2018) (concluding that plaintiffs' claims were impliedly preempted because "there is no Illinois requirement" that the manufacturer "report adverse events to the FDA").

[9] Because preemption is a question of federal law, *see Desiano*, 467 F.3d at 91, we certify only the question of whether Connecticut law recognizes such a cause of action, and not whether that cause of action would be preempted under the FDCA.

II. CUTPA Claims

The Glovers also appeal the district court's denial of their motion for leave to amend, through which they sought to plead an additional claim under CUTPA. They argue that amendment would not be futile because an intervening decision of the Supreme Court of Connecticut, *Soto v. Bushmaster Firearms Int'l, LLC*, 331 Conn. 53, 109 (2019), "held . . . as a matter of first impression, that CUTPA permits recovery for personal injuries" and that "the exclusivity provision of the CPLA does not bar plaintiffs' CUTPA personal injury claims." Appellants' Br. 31 (internal quotation marks and alterations omitted), and therefore, that they had a newly viable claim under CUTPA.

The Glovers' CUTPA claim is based on B&L's alleged "wrongful conduct of suppressing known safety risks associated with the Trulign Lens." Appellants' Br. 33. Specifically, the Glovers allege that "[a]t the time of Mrs. Glover's implants in 2014, consumers did not have access to any information about Z Syndrome complications associated with Trulign Lens usage" because of B&L's "failure to report these complications to the FDA and its failure to begin a safety study." *Id.* They further allege that "B&L deceptively marketed and promoted" the lens, "despite possessing information that Trulign Lens presented a substantial risk of

causing Z Syndrome complications." *Id.*

Before the district court, B&L argued that the Glovers' motion for leave to amend should be denied as futile, because their CUTPA claim was barred by the exclusivity provision of the CPLA and also because it was preempted by the FDCA. The district court denied the motion, concluding that the CUTPA claim was expressly preempted by § 360k(a) of the FDCA, and declining to decide whether it was barred by the CPLA's exclusivity provision.

On appeal, the Glovers argue that the district court erred in concluding that their CUTPA claim is preempted. B&L contends that the claim is preempted, for the same reasons the Glovers' CPLA claims are preempted, and that in any event, it is barred by the exclusivity provision of the CPLA because it is, at bottom, based on a defective product and under Connecticut law such claims may be brought only under the CPLA. Therefore, to determine whether the district court erred in denying the Glovers' motion, we must determine whether the CPLA's exclusivity provision bars their claim under CUTPA. If it does, then we need not address the question of whether the claim is preempted. Resolution of the question of Connecticut law is thus potentially dispositive; if the CUTPA claim is barred by the CPLA, the question of federal preemption will be moot.

The CPLA's exclusivity provision states that the CPLA is the exclusive remedy under Connecticut law "for harm caused by a product." Conn. Gen. Stat. § 52-572n. The Supreme Court of Connecticut has made clear that the provision bars claims not brought under the CPLA "that seek[] to recover damages for personal injuries, including wrongful death, or for property damages, including damage to the product itself, caused by the defective product." *Hurley v. Heart Physicians, P.C.*, 278 Conn. 305, 325 (2006). It permits claims not brought under the CPLA, including those brought under CUTPA, only if they are "for an injury not caused by the defective product, or if the party is not pursuing a claim for personal injury, death or property damage." *Id.* at 325-26.

In *Soto*, the plaintiffs, administrators of the estates of decedents killed in the Sandy Hook Elementary School shooting, sued Bushmaster, the maker of the semiautomatic rifle used in the shooting. 331 Conn. at 65. The court ruled, as relevant here, that the plaintiffs' CUTPA claim, which alleged that Bushmaster "marketed the [rifle] by promoting the gun's use for illegal purposes – offensive, military style assault missions" could proceed and, in particular, was not barred by the CPLA's exclusivity provision. *Id.* at 107-08. The court reasoned that plaintiffs had not alleged that the product was defective, and notably, that

"[t]here [wa]s no allegation . . . that the marketing for the [rifle] contained inadequate warnings that made the weapon unreasonably dangerous." *Id.* at 107. The Court noted that such claims would "represent veiled product liability claims" subject to the CPLA's express preemption provision. *Id.* at 109. The court further concluded, as a matter of first impression, that plaintiffs could seek damages for personal injuries under CUTPA. *Id.* at 110.

The Glovers' CUTPA claim may proceed only if it falls into the class of CUTPA claims permitted under *Soto* – those for "wrongful advertising," which are not "masked product defect claims." *Id.* at 109. The Glovers argue that their claim does fall into that category, because it alleges that B&L engaged in wrongful advertising insofar as it "deceptively marketed and promoted its Trulign Lens, despite possessing information that Trulign Lens presented a substantial risk of causing Z Syndrome complications," and that its marketing was "particularly aggressive." Appellants' Br. 33. That, they argue, is precisely the type of personal injury claim that *Soto* permits.

B&L argues that the Glovers' CUTPA claim is foreclosed by the exclusivity provision of the CPLA because unlike in *Soto*, the Glovers' claim is based on an allegedly defective product – the Trulign Lens – which caused Glover's injuries.

They argue that Connecticut courts have routinely dismissed such claims as barred by the CPLA's exclusivity provision.

Whether the Glovers' CUTPA claim may proceed turns on whether that claim is barred by the CPLA's exclusivity provision. That is a question of Connecticut law that the State's highest court has not answered.[10] Accordingly, we certify the following question to the Supreme Court of Connecticut: *Whether the Connecticut Product Liability Act's exclusivity provision, Conn. Gen. Stat. § 52-572n, bars a claim under the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. § 42-110a, et seq., based on allegations that a manufacturer deceptively and aggressively marketed and promoted a product despite knowing that it presented a*

---

[10] B&L points to several lower-court Connecticut decisions following *Soto*, which concluded that arguably similar CUTPA claims were barred by the exclusivity provision of the CPLA, despite *Soto*. *See Phillips-Moldex Co. v. Beaulieu Co., LLC*, 2019 WL 7499960, at *5 (Conn. Super. Ct. Dec. 6, 2019) (concluding that where the plaintiffs sought to bring a CUTPA claim based on the failure of their roof, "[u]nlike the plaintiffs in *Soto*, the plaintiffs in the present action are seeking to recover damages caused by a defective product"); *Appiah v. Home Depot U.S.A., Inc.*, 20-cv-489, 2020 WL 6263544, at *5 (D. Conn. Oct. 23, 2020) (dismissing CUTPA claim that defendant had "wrongfully market[ed] the subject tile for use in bathrooms and kitchens with the knowledge that such tile was unsafe and unsuitable for that purpose" because it was barred by the CPLA's exclusivity provision). However, these decisions do not offer an interpretation of Connecticut law binding on us, and in any event address claims arguably distinguishable from those presented in this case.

substantial risk of injury.

III. Certification

"Although the parties did not request certification, we are empowered to seek certification *nostra sponte*." *CIT Bank N.A. v. Schiffman*, 948 F.3d 529, 537 (2d Cir. 2020) (internal quotation marks omitted). "We have long recognized the appropriateness of according to state courts the opportunity to decide significant issues of state law through the certification process." *Corsair Special Situations Fund, L.P. v. Pesiri*, 863 F.3d 176, 183 (2d Cir. 2017). The rules of the Supreme Court of Connecticut provide that it "may answer a question of law certified to it by a court of the United States . . . if the answer may be determinative of an issue in pending litigation in the certifying court and if there is no controlling appellate decision, constitutional provision or statute of this state." Conn. Gen. Stat. § 51-199b; *see also* 2d Cir. R. 27.2(a) ("If state law permits, the court may certify a question of state law to that state's highest court.").

Certification is an exercise of our discretion. In considering whether to certify a question for review, we have "traditionally considered":

> [1] whether a state court decision has ever provided an authoritative answer[;] [2] the extent to which the question implicates the weighing of policy concerns of

> particular importance[;] and [3] if the Connecticut Supreme Court's answer may be determinative of the appeal.

Corsair, 863 F.3d at 183 (internal quotation marks, citations and alterations omitted).

All three factors counsel in favor of certification here. First, the Supreme Court of Connecticut has not, as noted above, provided an "authoritative answer" to either of the questions for which we seek certification. Second, the issues before us in this appeal implicate "policy concerns of particular importance" because they will determine the extent to which plaintiffs are able to proceed with tort claims based on allegedly defective medical devices under Connecticut law. Finally, as explained in the preceding sections, the Supreme Court's responses may well be determinative of the issues in this appeal. If Connecticut law does not recognize a cause of action based on failure to report adverse events to a regulator, or to comply with a regulator's post-approval safety conditions, then the Glovers' negligence and failure-to-warn claims are likely foreclosed by *Buckman*. Conversely, if Connecticut law does recognize such a cause of action, and the requirements imposed by Connecticut law are the same as those imposed by federal law, then the Glovers' claims may not be preempted.

Similarly, as to the second question, if the CPLA's exclusivity provision bars a CUTPA claim based on allegations that a manufacturer "deceptively" and "aggressive[ly]" marketed and promoted a product despite knowing that it presented a substantial risk of injury, then the Glovers' claim under CUTPA cannot proceed and the district court's judgment must be affirmed.

Accordingly, we reserve decision and respectfully certify the following questions to the Supreme Court of Connecticut.

Question 1:

Whether a cause of action exists under the negligence or failure-to-warn provisions of the Connecticut Product Liability Act, Conn. Gen. Stat. §§ 52-572h, 52-572q, or elsewhere in Connecticut law, based on 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.

Question 2:

Whether the Connecticut Product Liability Act's exclusivity provision, Conn. Gen. Stat. § 52-572n, bars a claim under the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. § 42-110a, *et seq.*, based on allegations that a manufacturer deceptively and aggressively marketed and promoted a product

despite knowing that it presented a substantial risk of injury.

We invite the Supreme Court of Connecticut to construe liberally and, if necessary, expand these certified questions to address related or other relevant issues in connection with this appeal. We retain jurisdiction over the case once the Supreme Court has either ruled on the certified questions or has declined certification.

CONCLUSION

It is hereby ORDERED that the Clerk of this Court transmit to the Clerk of the Supreme Court of Connecticut this opinion as our certificate, together with a complete set of briefs, appendices, and the record filed in this case by the parties. This panel retains jurisdiction for purposes of resolving this appeal after the disposition of the certification by the Supreme Court of Connecticut.

CERTIFICATE

The foregoing is hereby certified to the Supreme Court of Connecticut pursuant to Conn. Gen. Stat. § 51-199b and 2d Cir. R. 27.2(a), as ordered by the United States Court of Appeals for the Second Circuit.