SUPREME COURT

OF THE

STATE OF CONNECTICUT

S.C. 20607

MARJORIE GLOVER, ET AL.

v.

BAUSCH & LOMB, INC., ET AL.

BRIEF OF AMICUS CURIAE PRODUCT LIABILITY ADVISORY COUNCIL, INC. IN SUPPORT OF DEFENDANT-APPELLEES

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STATEMENT OF INTEREST OF AMICUS CURIAE

The Product Liability Advisory Council, Inc. ("PLAC") is a non-profit association whose corporate members represent a broad cross-section of American and international product manufacturers.[1] These companies seek to contribute to the improvement and reform of law in the United States and elsewhere, with emphasis on the law governing the liability of product manufacturers. PLAC's perspective derives from the experiences of a corporate membership that spans a diverse range of industries in the manufacturing sector. Hundreds of leading product liability defense attorneys are sustaining (nonvoting) members of PLAC. Since 1983, PLAC has filed more than 1,200 briefs as amicus curiae in both state and federal courts, including this Court, presenting the broad perspective of manufacturers seeking to improve the application and development of the law as it affects product liability.

PRELIMINARY STATEMENT[2]

This appeal presents an important opportunity for this Court to reject an unprecedented theory of liability and confirm long-standing limits on the types of product defect claims available under Connecticut law. The plaintiffs have brought state-law negligence and failure-to-warn claims based on defendants' alleged failure to report to the Food and Drug Administration ("FDA") adverse events that occurred in connection with Trulign Lens, a prescription medical device designed to treat cataracts. As the Second Circuit correctly held, these claims are preempted by federal law unless the plaintiffs can

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[1] A list of PLAC's corporate members is available at PLAC, *Corporate Member List* (June 2021), https://tinyurl.com/yn5xv862.

[2] In accordance with Practice Book Section 67-7, the Amicus states that no counsel for a party to this case wrote this brief in whole or in part and that no such counsel or a party contributed to the cost of the preparation or submission of the brief. No persons other than the Amicus, its members, or its counsel made such a monetary contribution.

identify an independent, pre-existing Connecticut tort cause of action based on a manufacturer's failure to report information to a governmental regulator such as the FDA. *Glover v. Bausch & Lomb Inc.*, 6 F.4th 229, 239 (2d Cir. 2021). But no court has recognized a tort law cause of action for failure to warn such a regulator under Connecticut law, and this Court should not create one now. In fact, any such a claim would be contrary to well-established principles of product liability law in this State.

ARGUMENT

The first certified question asks whether Connecticut law recognizes a cause of action in tort based on a manufacturer's alleged failure to report adverse events to a regulator.[3] The answer to that question is no.

First, Connecticut law recognizes product defect claims based on a manufacturer's failure to warn users, such as the implanting surgeons here. Plaintiffs cannot shoehorn their failure-to-warn-the-FDA claim into this line of cases. No Connecticut court has ever held that the duty to warn extends to a regulator such as the FDA. In the limited cases where Connecticut law recognizes that the warning will be communicated to someone other than the ultimate end user, the warning is provided to either the user's prescribing physician (in the case of prescription drugs and medical devices) or someone else in the product's chain of distribution who comes into contact with the user. The FDA does not fall into either category.

[3] PLAC's brief is limited to this first certified question. The plaintiffs also allege that defendants failed to comply with FDA's post approval requirements. But as the defendants correctly note, any duty to comply with these requirements arises exclusively from federal law. PLAC also agrees with the defendants that the exclusivity provision of the Connecticut Product Liability Act bars the plaintiffs' Connecticut Unfair Trade Practices Act claim because that claim is, at bottom, a product defect claim.

Second, Connecticut courts have also recognized a related "post-sale" duty to warn that extends to dangers discoverable after the sale of the product. Even assuming that there is a post-sale duty to warn that extends to medical devices, these cases are of no help to the plaintiffs because they invariably involve a duty to warn end users or, as is the case here, the intermediary prescribing physician.

Third and finally, creating what would be, in effect, a private right of action to enforce FDA reporting requirements would interfere with the FDA's exclusive authority to regulate medical devices. In *Ward v. Greene*, 267 Conn. 539 (2004), this Court relied on closely related concerns when declining to recognize an expansive private right of action under Connecticut's mandatory reporter statute. The same result should follow in this case.

I. CONNECTICUT LAW HAS NEVER RECOGNIZED A STATE TORT LAW CAUSE OF ACTION FOR A MANUFACTURER'S FAILURE TO WARN A REGULATOR

Connecticut law has long recognized that "[a] product may be defective because a manufacturer or seller failed to warn of the product's unreasonably dangerous propensities." *Tomer v. Am. Home Products Corp.*, 170 Conn. 681, 689 (1976). This was the rule at common law, and it remains the rule under the Connecticut Product Liability Act ("CPLA"), which "was intended to merge the various common law theories of products liability into one cause of action." *Gajewski v. Pavelo*, 36 Conn. App. 601, 611 (1994), *aff'd*, 236 Conn. 27 (1996); Conn. Gen. Stat. § 52-572q(a) (recognizing that product sellers may be held liable where "the product was defective in that adequate warnings or instructions were not provided"). But this duty to warn is owed only to the product's user, not to unrelated third parties. *Hurley v. Heart Physicians, P.C.*, 278 Conn. 305, 316 (2006) ("Generally, a manufacturer's duty to warn of dangers associated with its products … runs to the ultimate user or consumer of those products."); *Gajewski*, 36 Conn. App. at 613

("[The CPLA] … confers a cause of action on 'claimants' who have been harmed by defective products and refers to the 'expected product user.'"). That is why product warnings must be directed at the users of the product. *Giglio v. Connecticut Light & Power Co.*, 180 Conn. 230, 237 (1980) ("Warnings must specifically identify *for the user* the danger inherent in the product's use." (emphasis added); *Sharp v. Wyatt, Inc*., 31 Conn. App. 824, 849 (1993), *aff'd*, 230 Conn. 12 (1994) ("[O]ur warnings statute minimizes the risk that product sellers and purchasers will simultaneously rely on one another to provide warnings with the result that none is issued to the ultimate product user.").

While the duty to warn exists in a variety of contexts, the concern always has been whether the person actually using the product received sufficient warnings. *E.g.*, *Ames v. Sears, Roebuck & Co.*, 8 Conn. App. 642, 646 (1986) (duty to warn users of lawnmower); *Giglio*, 180 Conn. at 237 (duty to warn users of a gas operated home furnace); *Tomer*, 170 Conn. at 688 (duty to warn users of an anesthetic agent). The plaintiffs have not cited, and PLAC has been unable to identify, *any* case arising under Connecticut law that has extended this duty to a product's governmental regulator.

Significant precedent holds that no such Connecticut law duty exists. The duty to warn is "a duty to the plaintiff herself, not to some third party, who might then report the danger to the plaintiff. There is no general or background duty under Connecticut law to report risks *to a regulatory body*." *Norman v. Bayer Corp.*, No. 16-253, 2016 WL 4007547, at *4 (D. Conn. July 26, 2016); *accord Pratt v. Bayer Corp.*, No. 19-1310, 2020 WL 5749956, at *8 (D. Conn. Sept. 25, 2020) (following *Norman*); *D'Addario v. Johnson & Johnson*, No. 19-15627, 2020 WL 3546750, at *5 (D.N.J. June 30, 2020) (finding "no separate state law duty to warn the FDA") (applying Connecticut law); *Simoneau v. Stryker*

Corp., No. 13-1200, 2014 WL 1289426, at *10 (D. Conn. Mar. 31, 2014) (plaintiff "identifies no separate state law duty to warn *the FDA*"). Notably, every one of these claims was an attempt, as here, to contort Connecticut law to dodge federal preemption. "Absent the specific reporting requirements of the FDCA, no Connecticut court would have imposed a duty on defendants to report adverse events *to the FDA*, rather than alter the warning label or communicate with plaintiff and her doctor." *Norman*, 2016 WL 4007547, at *4.

Moreover, while there are certain exceptions to the general rule recognizing product users as the intended audience for product warnings, none apply here. To begin, in the context of an implantable medical device like the Trulign Lens, the learned intermediary doctrine provides that "adequate warnings to prescribing physicians obviate the need for manufactures of prescription products to warn ultimate consumers directly." *Vitanza v. Upjohn Co.*, 257 Conn. 365, 376 (2001) (quoting *Vitanza v. Upjohn Co.*, 48 F. Supp. 2d 124, 127 (D. Conn. 1999)).[4] The doctrine is grounded in "the principle that prescribing physicians act as 'learned intermediaries' between a manufacturer and consumer and, therefore, stand in the best position to evaluate a patient's needs." *Id.* Where it applies, the doctrine replaces the traditional warning to the user with a warning to the prescriber. *Id*.

The FDA or other regulators playing a similar oversight role do not fit the mold of a prescribing physician and are not positioned to personally communicate warnings to patients. *Cf. id.* at 391 (noting that the learned intermediary doctrine's "safeguards" include "the highly personal doctor-patient relationship and the fact that the product can be obtained legally only from a physician"). The FDA is not even under any obligation to

[4] Although initially affirmed in a case involve prescription drugs, the Court has since extended the learned intermediary doctrine medical devices. *Hurley*, 278 Conn. at 317; *Breen v. Synthes-Stratec, Inc.*, 108 Conn. App. 105, 114 (2008).

disclose adverse events to the public, so that the reports could trickle down to the user. 21 C.F.R. § 803.9 (FDA "may disclose" adverse event reports, but is not required to). In fact, even when the FDA does exercise its discretion to disclose reports, "it does so only passively by uploading the reports to a database," at which point end users or health care providers would have to "affirmatively access the database and search for adverse event reports" in order to learn the information. *Conklin v. Medtronic, Inc*., 431 P.3d 571, 578 (Ariz. 2018). The novel tort-law duty that plaintiffs advocate is wholly unmoored from traditional duty-to-warn principles designed to provide full information to product users.

Outside of the medical device context, there are limited cases where manufacturers may communicate warnings to someone other than the end user. But in these cases too, the recipient of the warning is in the chain of distribution and the warning still must "ultimately reach the 'ultimate product user.'" *Gajewski*, 36 Conn. App. at 615 (quoting *Sharp*, 31 Conn. App. at 849). For example, in *Gajewski*, the trial court instructed the jury that a gas furnace manufacturer's duty to warn ran to the installer of the product. *Id.* at 613. The Appellate Court explained that this instruction was "not that the manufacturer had a duty to warn [the installer] only," but that the jury could find that "the installer of the product who would come into direct contact with the ultimate product user, might have been the best way for the defendant … to warn the ultimate product user." *Id.* at 615.[5] Importantly, the person best able to recommend precautions in *Gajewski* was someone who would invariably come into contact with the ultimate product user—in that case the hiring

[5] The instruction was therefore consistent with § 52-572q(d), which provides that a "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." *Cf.* Restatement (Second) of Torts § 388 cmt. p (1965) (possible to exercise "reasonable care" by "informing the third person through whom the chattel is supplied").

homeowner—and be able to address the product's risks. That is not the case with the FDA or other administrative regulators that have no direct contact with the product's users. Accordingly, traditional principles of state tort law foreclose the type of failure-to-report claim the plaintiffs have alleged here.[6]

II. THE POST-SALE DUTY TO WARN DOES NOT ENCOMPASS A DUTY TO WARN REGULATORS

The plaintiffs also rely on cases recognizing a post-sale duty to warn. For example, in a pre-CPLA case, the Court agreed that an ammunition manufacturer's alleged failure to "indicat[e] by label or otherwise the danger to which the user would expose himself" was a "continuing course of conduct" for purposes of the statute of limitations. *Handler v. Remington Arms Co.*, 144 Conn. 316, 321 (1957). The plaintiffs suggest that these types of cases could also support a post-sale duty to warn the FDA.

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[6] This Court would not be alone in declining to recognize this cause of action. Surveying the laws of other states, many courts have reached precisely the same conclusion. *E.g.*, *Conklin*, 431 P.3d at 578 ("[A] manufacturer does not breach its duty to warn end users under Arizona law by failing to submit adverse event reports to the FDA."); *Norabuena v. Medtronic, Inc.*, 86 N.E.3d 1198, 1207 (Ill. App. Ct. 2018) ("Although Illinois recognizes that a manufacturer may satisfy its duty to warn by conveying information to third-party learned intermediaries, this is not synonymous with an affirmative duty to warn a federal regulatory body."); *Phillips v. Medtronic, Inc.*, No. SUCV2009-05286-A, 2012 WL 3641487, at *10 (Mass. Super. Ct. July 10, 2012) ("[A] claim based on failure to report adverse events … is impliedly preempted because it is premised solely on a duty created by the MDA which did not exist in the common law: the duty to provide information to a regulatory agency …."); *Kubicki v. Medtronic, Inc*., 293 F. Supp. 3d 129, 183 (D.D.C. 2018) ("Plaintiffs struggle mightily to avoid the implications of the undisputed fact that there is no D.C. common law claim that imposes liability for a manufacturer's failure to report to the FDA adverse incidents concerning an approved medical device."); *Kaiser v. Depuy Spine, Inc.*, 944 F. Supp. 2d 1187, 1192 (M.D. Fla. 2013) ("[P]rivate actions … that seek to enforce violations of FDA regulations are barred because Florida does not recognize such causes of action."); *Eng. v. Bayer Corp.*, 468 F. Supp. 3d 573, 580 (W.D.N.Y. 2020) ("[A]s a standalone claim, 'failure to report adverse events to the FDA' is not a cognizable cause of action under New York law.").

Not so. For one, it is unsettled whether the post-sale duty to warn applies to medical devices at all. Before the passage of the CPLA, this Court expressly declined to extend the post-sale duty to warn to strict product liability. *Prokolkin v. General Motors Corp.*, 170 Conn. 289, 299 (1976). And the CPLA itself specifies that warnings need only be given "at the time of manufacture." Conn. Gen. Stat. § 52-572q(b). In light of the statute's language, no court in this state has considered whether the CPLA nonetheless could allow for any post-sale duty to warn. *See Normandy v. Am. Med. Sys., Inc.*, No. X06CV156026580S, 2019 WL 3220558, at *9 (Conn. Super. Ct. May 29, 2019), *aff'd*, No. 20500, 2021 WL 3482928 (Conn. Aug. 9, 2021) (rejecting post-sale duty to warn claim because the defendant did not manufacture the medical device that allegedly harmed the plaintiff); *but see Densberger v. United Techs. Corp.*, 297 F.3d 66, 71 (2d Cir. 2002) (holding that the post-sale duty to warn is still cognizable in negligence actions under the CPLA).

More importantly, even assuming that the post-sale duty to warn applies to medical devices, that duty does not alter who is the required *recipient* of the warning. As with any duty to warn claim, the duty will typically run to the end user of the product. *E.g.*, *Handler*, 144 Conn. at 321 (duty to warn the user of the ammunition cartridge). And in the case of a medical device like the Trulign Lens, it is a duty to warn the prescribing physician. *Hurley*, 278 Conn. at 317. There is no precedent for rewriting the post-sale duty to warn to include a duty to warn a regulator such as the FDA—and no court has so held.

III. THIS COURT HAS ALREADY EXPRESSED CONCERN WITH THE CONSEQUENCES OF CONVERTING REGULATORY REPORTING REQUIREMENTS INTO PRIVATE RIGHTS OF ACTION

This appeal is not the first time this Court has considered whether Connecticut law recognizes a cause of action based on the alleged violation of a duty to report events to a

regulator. This Court has held that the mandated reporter statute does not establish in a wrongful death action a duty that extends beyond children who were, or should have been, the subject of a mandated report. *Ward*, 267 Conn. at 557.[7] The Court was rightfully concerned that expanding a mandated reporter's liability to include the potential future abuse of children unknown to the reporter would lead to over-reporting and interfere with the careful balance the legislature struck in passing the statute. *Id.* at 558–60.

Similarly here, Congress has decided to grant the FDA the exclusive authority to enforce applicable regulatory requirements, including the obligation to report adverse events. *E.g.*, *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions ….") (citing 21 U.S.C. § 337(a)). Allowing the FDA to police compliance with its own regulations permits the agency to "achieve a somewhat delicate balance of statutory objectives." *Id.* at 348. On the other hand, permitting private litigants such as the plaintiffs to bring a state law tort claim based solely on what they construe as alleged violations of federal reporting requirements threatens the FDA's ability to maintain this balance. At a minimum, recognizing such a claim would lead to substantial regulatory uncertainty for pharmaceutical and medical device manufacturers. Courts and juries would be asked to

[7] Courts analyzing similar statutes in other states have similarly held that these laws do not create common-law causes of action. *E.g.*, *Roe No. 1 v. Children's Hosp. Medical Ctr.*, 16 N.E.3d 1044, 1052 (Mass. 2014); *Becker v. Mayo Foundation*, 737 N.W.2d 200, 210 (Minn. 2007); *J.S. v. R.T.H.*, 714 A.2d 924, 934 (N.J. 1998).

assess their compliance with nuanced reporting requirements,[8] leading to a patchwork of inconsistent rulings construing reporting obligations in ways that are at odds with the FDA's regulatory enforcement.

In addition, creating a new cause of action for failing to make a report to a regulatory body could lead to similar consequences beyond the pharmaceutical and medical device industries. Other product manufacturers, and other regulated parties are subject to similar federal and state regulations that require them to make reports to their regulators. *E.g.*, 15 U.S.C. § 2064(b) (requiring manufacturers of consumer products to report product defects in certain circumstances); 15 U.S.C. § 2084 (requiring manufacturers of consumer products to report civil actions for death or grievous bodily injury); 31 U.S.C. § 5318(g) (requiring banks to report "suspicious activity"); 14 C.F.R. § 21.3(a) (requiring aircraft manufacturers to report any "failure, malfunction or defect"). Under the plaintiffs' proposed rule, even the most minor or technical failure to comply with any of these regulations could support a product defect (or other) claim under Connecticut law.[9] The Court should decline the plaintiffs' invitation to create the new, expansive state tort duties that the plaintiffs seek.

CONCLUSION

The Court should affirm that there is no cause of action under Connecticut law based on a manufacturer's alleged failure to report adverse events to a regulator like the FDA.

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[8] For example, the FDA's regulations provide that a manufacturer must report information that "reasonably suggests" that a device "may have caused or contributed to a death or serious injury." 21 C.F.R. § 803.50.

[9] *See Lundstedt v. Deutsche Bank National Trust Co.*, No. 13-1423, 2016 WL 3101999, at *5 (D. Conn. June 2, 2016) (no failure-to-report claim under the Bank Secrecy Act).

Dated: October 15, 2021

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing complies with all of the provisions of the Connecticut Rules of Appellate Procedure § 67-2, as follows:

§ 67-2(g):

(1) The electronically submitted brief has been delivered electronically to the last known e-mail address of each counsel of record for whom an e-mail address has been provided; and

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(1) A copy of the brief has been sent to each counsel of record in compliance with P.B. § 62-7;

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Dated: October 15, 2021

CERTIFICATE OF SERVICE

I hereby certify that on this date a copy of the foregoing was served by electronic mail upon all counsel of record, as follows:

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