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MARJORIE GLOVER ET AL. *v.* BAUSCH & LOMB, INC., ET AL.
(SC 20607)

Robinson, C. J., and McDonald, D'Auria, Mullins, Kahn, Ecker and Keller, Js.

Syllabus

Pursuant to the Connecticut Product Liability Act (CPLA) (§ 52-572q (a) and (d)), a product seller may be subject to liability for harm caused to an individual who proves that the product was defective insofar as adequate warnings or instructions were not provided, and the product seller may not be considered to have provided adequate warnings or instructions unless they were devised to communicate with the person or entity best able to take or recommend precautions against the potential harm.

Pursuant further to the CPLA (§ 52-572n (a)), "[a] product liability claim as provided [under that act] may be asserted and shall be in lieu of all other claims against product sellers, including actions of negligence, strict liability and warranty, for harm caused by a product."

The plaintiffs, M and her husband, sought to recover damages from the defendants in federal court in connection with two surgical procedures in which a medical device manufactured and marketed by the defendants, known as the Trulign Lens, was implanted in each of M's eyes for the purpose of treating her cataracts. M began to experience vision loss after the procedure, and her surgeon diagnosed her with a postoperative complication known as Z syndrome. M underwent multiple procedures to remove the artificial lenses and to correct her vision, but fragments of the lenses remained, causing permanent impairment to her eyesight. The plaintiffs alleged, inter alia, that the defendants were negligent and had failed to warn M and her surgeon of the inherent dangers of the Trulign Lens. In support of those claims, the plaintiffs alleged that the defendants were aware that the Trulign Lens had caused Z syndrome in numerous cases, that the defendants had failed to report all of those cases to the federal Food and Drug Administration (FDA) in a timely manner, as required by the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 301 et seq.), that the defendants had failed to comply with a condition of approval for the Trulign Lens imposed by the FDA requiring the defendants to conduct a postmarket safety study related to Z syndrome and to submit progress reports to the FDA, that, as a result of those failures, M and her surgeon were unaware of the true dangers of the Trulign Lens, and that, if they had known of those dangers, M would not have undergone the surgeries. The plaintiffs also alleged that, after M's surgeries, the labeling of the Trulign Lens was changed to reflect the true frequency of Z syndrome and to include instructions for minimizing risk and for treatment. The defendants moved to dismiss the plaintiffs' claims on the ground that they were preempted by federal law. Thereafter, the plaintiffs moved for leave to amend their complaint to add a claim that the defendants had violated the Connecticut Unfair Trade Practices Act (CUTPA) (§ 42-110a et seq.) by unscrupulously marketing and promoting the Trulign Lens for use despite knowing that it presented a substantial risk of injury. The United States District Court for the District of Connecticut granted the defendants' motion to dismiss the action, concluding, with respect to the negligence and failure to warn claims, that those claims were expressly or impliedly preempted by the FDCA, which, inter alia, prohibits claims based on state law that impose requirements "different from, or in addition to, any requirement applicable . . . to the [medical] device" under federal law. The District Court also denied the plaintiffs' motion for leave to amend their complaint on the ground that it would be futile insofar as the proposed CUTPA claim also would be preempted by federal law. The plaintiffs appealed from the District Court's judgment of dismissal to the United States Court of Appeals for the Second Circuit, which noted that the preemption analysis under the FDCA turns on whether the plaintiffs successfully pleaded a traditional state law cause

of action that existed separately from the FDCA but did not impose requirements different from, or in addition to, the requirements imposed by federal law. Because the Second Circuit found Connecticut law unclear with respect to whether a manufacturer has a duty to warn a regulator, such as the FDA, of a product's known safety risks, that court sought this court's advice, by way of certification pursuant to statute (§ 51-199b (d)), as to whether a cause of action exists under § 52-572q, or under some other 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 a failure to comply with a regulator's postmarket requirements. With respect to the plaintiffs' claim that the District Court had incorrectly determined that amending their complaint to include the unscrupulous marketing claim under CUTPA would be futile, the Second Circuit observed that the issue of whether the proposed CUTPA claim was barred by the exclusivity provision set forth in § 52-572n involved a question of state law for which there was no binding precedent and, accordingly, certified a question of law to this court concerning whether that provision bars a claim under CUTPA based on allegations that a manufacturer deceptively and aggressively marketed and promoted a product despite knowing that it presented a substantial risk of injury. *Held*:

1. The facts alleged by the plaintiffs, if accepted as true, gave rise to a cognizable claim under § 52-572q based on the defendants' alleged failure to report adverse events associated with the use of Trulign Lens to the FDA in order to prevent harm to users such as M: because the language of § 52-572q does not clearly and unambiguously indicate whether the CPLA, which embodies preexisting common-law causes of action, provides for a cause of action based on a manufacturer's alleged failure to report to a regulator adverse events related to a product, this court looked to case law construing the scope of the CPLA, as well as general common-law principles governing the existence of a duty to use care, and concluded that the defendants had a duty under the CPLA to comply with federal statutes and regulations requiring them to report to the FDA adverse events associated with the Trulign Lens and to comply with the FDA's postapproval requirements with respect to that product; moreover, nothing in the CPLA or in the case law construing the CPLA suggested that only physicians and other healthcare providers could be found to be in the best position to prevent harm to users of medical devices and, thus, the duty to warn was not limited to such individuals, it was appropriate to read the CPLA broadly to accomplish its remedial purpose of preventing injury from defective products, including medical devices that are inherently dangerous and that accordingly must be accompanied by adequate warnings, and the plaintiffs' allegations, when taken as true, which they must at this stage of the proceedings, were sufficient to raise the inference that the defendants knew or should have known that harm of the general nature that M suffered was likely to result from their failure to provide to the FDA in a timely manner information about the adverse effects of the Trulign Lens, as required by federal law; furthermore, other public policy factors supporting the imposition of a duty weighed in favor of the plaintiffs, and this court found the decisions of those jurisdictions construing product liability laws of various states as creating a duty to comply with federal law requiring manufacturers to report to the FDA adverse events associated with inherently dangerous medical devices to be more persuasive than the cases on which the defendants relied; accordingly, this court concluded that the plaintiffs could prevail at trial if they established that it is more likely than not that, if the defendants had complied in a timely manner with the requirements of federal law that they report adverse events to the FDA and perform a postmarket safety study, the FDA would have required the defendants to change the labeling of the Trulign Lens or otherwise have made the substance of the reports available to healthcare providers before M's surgeries, and if the plaintiffs also established that, as a result, she and her surgeon would not have chosen that device.
2. The exclusivity provision of the CPLA barred the plaintiffs' CUTPA claim that the defendants unscrupulously marketed and promoted the Trulign Lens for use despite knowing that it presented a substantial risk of injury: this court's precedent established that § 52-572n does not bar CUTPA claims based on the sale of a product when the plaintiff does not seek a remedy for personal injury, death, or property damage that

was caused by a defective product, or when the plaintiff seeks a remedy for personal injury, death, or property damage that was caused by the unscrupulous advertising of a product that was not defective, and the plaintiffs' CUTPA claim in the present case, which sought damages for personal injuries that allegedly were caused by unscrupulous advertising of the allegedly defective Trulign Lens, did not fall within the scope of either of those exceptions; moreover, this court declined to recognize an additional exception to the exclusivity provision for CUTPA claims, such as the CUTPA claim asserted in the present case, that seek damages for personal injuries caused by a defective product.

(*One justice concurring separately*)

Argued October 22, 2021—officially released June 7, 2022

Procedural History

Action to recover damages pursuant to the Connecticut Product Liability Act, and for other relief, brought to the United States District Court for the District of Connecticut, where the court, *Dooley*, *J.*, denied the plaintiffs' motion to amend the complaint and granted the defendants' motion to dismiss and rendered judgment thereon, from which the plaintiffs appealed to the United States Court of Appeals for the Second Circuit, which certified certain questions of law to this court.

Wendy R. Fleishman, pro hac vice, with whom were *Daniel E. Seltz*, pro hac vice, *Hugh W. Cuthbertson* and, on the brief, *Glenn A. Duhl* and *Leslie A. Brueckner*, pro hac vice, for the plaintiffs (appellants).

Jeffrey R. Babbin, with whom were *Daniel Smulian*, pro hac vice, *Robert M. Langer* and, on the brief, *Lori G. Cohen*, pro hac vice, for the defendants (appellees).

Sarah A. Ricciardi filed a brief for the Connecticut Trial Lawyers Association et al. as amici curiae.

John W. Cerreta, *James H. Rotondo* and *Matthew J. Letten* filed a brief for the Product Liability Advisory Council, Inc., as amicus curiae.

Opinion

ROBINSON, C. J. This case presents two questions of law certified to us by the United States Court of Appeals for the Second Circuit, pursuant to General Statutes § 51-199b (d),[1] regarding the interpretation the Connecticut Product Liability Act (CPLA), General Statutes § 52-572m et seq., and the Connecticut Unfair Trade Practices Act (CUTPA), General Statutes § 42-110a et seq. The plaintiff, Marjorie Glover,[2] brought this action in the United States District Court for the District of Connecticut, alleging that she had been injured by defective artificial lenses manufactured and marketed by the defendants, Bausch & Lomb, Inc., Bausch & Lomb Holdings, Inc., Valeant Pharmaceuticals International, Valeant Pharmaceuticals International, Inc., Valeant Pharmaceuticals North America, LLC, and the "Doe defendants."[3] The plaintiff alleged, inter alia, that the defendants had violated the CPLA by failing to warn her of the inherent dangers of the artificial lenses, thereby causing injuries to her eyes. After the operative complaint was filed, the plaintiff filed a motion for leave to amend the complaint to add a claim that the defendants had violated CUTPA by engaging in deceptive advertising. The District Court granted the defendants' motion to dismiss the plaintiff's claims pursuant to the CPLA on the ground that they were preempted by federal law. The court also denied the plaintiff's motion for leave to amend the complaint to add a CUTPA claim on the ground that the amendment would be futile because federal law would also preempt that claim.

The plaintiff appealed from the judgment of dismissal to the United States Court of Appeals for the Second Circuit. That court determined that the resolution of the plaintiff's claims depended on the interpretation of Connecticut law for which there was no controlling precedent in this court's decisions, and it requested certification of the following questions of law for our consideration: (1) "[w]hether a cause of action exists under the negligence or failure-to-warn provisions of the [CPLA, General Statutes §] 52-572q, or elsewhere in Connecticut law, based on a manufacturer's alleged failure to report adverse events to a regulator like the [United States Food and Drug Administration (FDA)] following approval of the device, or to comply with a regulator's [postapproval] requirements."[4] And (2) "[w]hether the [CPLA's] exclusivity provision, [General Statutes] § 52-572n, bars a claim under [CUTPA] based on allegations that a manufacturer deceptively and aggressively marketed and promoted a product despite knowing that it presented a substantial risk of injury." *Glover* v. *Bausch & Lomb, Inc.*, 6 F.4th 229, 244 (2d Cir. 2021). We accepted the certified questions of law and answer "yes" to both.

The record reveals the following factual allegations made by the plaintiff, which we construe in her favor

for purposes of answering the certified questions of law, and procedural history.[5] See, e.g., *Burton* v. *Dominion Nuclear Connecticut, Inc.*, 300 Conn. 542, 550, 23 A.3d 1176 (2011) ("[i]n ruling [on] whether a complaint survives a motion to dismiss, a court must take the facts to be those alleged in the complaint, including those facts necessarily implied from the allegations, construing them in a manner most favorable to the pleader" (internal quotation marks omitted)). The defendants manufacture a product known as the Trulign Lens, which was designed and marketed as a medical device that is surgically implanted in a patient's eye to treat cataracts. In September, 2014, the plaintiff, who resides in Connecticut, underwent two successive cataract surgeries during which her physician surgically implanted one Trulign Lens in each eye. Several weeks later, she began to experience significant loss of vision. Her physician ultimately diagnosed her vision problems as "Z syndrome," a postoperative complication unique to the Trulign Lens in which part of the lens moves forward toward the surface of the eye and part of the lens stays in place or moves backwards, creating a distinctive "Z" shape. The plaintiff was required to undergo multiple surgeries and other medical procedures and treatments in an unsuccessful attempt to correct the damage to her vision. Part of each lens was surgically removed, but fragments of the lenses remain, causing permanent impairment of both eyes.

The plaintiff brought this action against the defendants in the United States District Court for the Central District of California, where the defendants operated various offices and facilities. After the action was transferred to the United States District Court for the District of Connecticut, the plaintiff amended the complaint to include a claim that the defendants had violated the CPLA by failing to warn the plaintiff and her physicians about the dangers of the Trulign Lens, as well as other claims not relevant to the issues before us. In support of this claim, the plaintiff alleged in the operative complaint that the defendants were aware that the Trulign Lens had caused Z syndrome in numerous cases and that they had failed to report all of those cases to the FDA in a timely manner, as required by the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq.[6] The plaintiff further alleged that the defendants had failed to comply in a timely manner with an FDA condition of approval for the Trulign Lens requiring the defendants to conduct a postmarket safety study related to Z syndrome and to submit progress reports to the FDA. As a result of the defendants' failure to report all of the known cases of Z syndrome to the FDA and to conduct the safety study in a timely manner, the plaintiff alleged that she and her physician were unaware of the true dangers of the Trulign Lens at the time of surgery. She further alleged that, if she had known of the true risks, she would not have undergone the surgery.

Finally, she alleged that, after the surgery, the labeling of the Trulign Lens was changed to reflect the true frequency of Z syndrome and to include instructions for minimizing risk and for treatment.

The defendants moved to dismiss all of the plaintiff's claims on the ground that they were preempted by federal law. Thereafter, the plaintiff moved for leave to amend the complaint to include a CUTPA claim based on allegations of unscrupulous marketing. The District Court granted the defendants' motion to dismiss as to all counts. With respect to the failure to warn claim under the CPLA, the court observed that federal law "expressly preempts state law claims [when] . . . (1) the FDA has established requirements applicable to the particular medical device; and (2) the state law claims would impose requirements with respect to the device that are different from, or in addition to the federal requirements that relate to either . . . (i) safety or effectiveness; or (ii) any other matter included in a requirement applicable to the device." (Internal quotation marks omitted.) *Doe* v. *Bausch & Lomb, Inc.*, 443 F. Supp. 3d 259, 272 (D. Conn. 2020). In addition, the court observed that "a litigant's [state law] claim may be *impliedly* preempted when the [state law] claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist." (Emphasis in original; internal quotation marks omitted.) Id. Accordingly, the court concluded that, to the extent that the plaintiff claimed that the defendants had a duty to warn consumers or physicians of the dangers of the Trulign Lens, the claim was expressly preempted by federal law because it imposed a requirement that the FDCA did not imply. Id. With respect to the plaintiff's claim that the defendants violated the CPLA by failing to comply with federal law requiring them to report adverse events to the FDA, the court concluded that, "under Connecticut law, manufacturers do not have a duty to report adverse events to regulatory entities such as the FDA." Id., 273. The court therefore concluded that the claim was impliedly preempted because it was wholly derivative of the FDCA. Id. With respect to the plaintiff's CUTPA claim, the court concluded that, because the claim was premised on the allegation that the defendants had inadequately warned of the dangers associated with the Trulign Lens, and because the plaintiff had not alleged that the warnings provided deviated from those approved by the FDA, the claim was expressly preempted by the FDCA. Id., 275.

The plaintiff appealed from the judgment of dismissal to the United States Court of Appeals for the Second Circuit, contending that Connecticut law recognizes claims based on a failure to comply with (1) laws and regulations requiring a defendant to warn a government regulator, such as the FDA, of a product's known safety risks, and (2) the regulator's postapproval safety require-

ments. The plaintiff contended that, because this requirement of Connecticut law was both independent of and coextensive with the requirements of the FDCA, the failure to warn claim was neither impliedly nor expressly preempted. The plaintiff further claimed that amending the complaint to add a CUTPA claim would not be futile because it was based on allegations that the defendants had deceptively marketed and promoted the Trulign Lens despite knowing that it presented a substantial risk of injury.

The Second Circuit observed that the federal courts of appeals are split on the issue of whether federal law preempts failure to warn claims based on allegations that a defendant has failed to comply with a requirement to report adverse events to the FDA.[7] See *Glover* v. *Bausch & Lomb, Inc.*, supra, 6 F.4th 238. The court noted that "many of the . . . decisions of [its] 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," which it concluded was "a significant omission, given that the preemption analysis turns on whether [a plaintiff] 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." (Internal quotation marks omitted.) Id., 240–41. Because neither party had cited "any binding Connecticut authorities on the [issue] of whether manufacturers have a duty to warn a regulator"; id., 240; the court certified the following question of law to this court: "Whether a cause of action exists under the negligence or failure-to-warn provisions of the [CPLA, § 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 [postapproval] requirements." Id., 244.

Turning to the plaintiff's contention that the District Court had incorrectly determined that allowing her to amend the operative complaint to include a CUTPA claim would be futile because that claim would also be preempted, the Second Circuit observed that the defendants contended that the claim was barred by the exclusivity provision of the CPLA. See id., 243. Because that claim involved a question of state law for which there is no binding precedent, the Second Circuit certified the following question of law to this court: "Whether the [CPLA's] exclusivity provision . . . § 52-572n, bars a claim under [CUTPA] based on allegations that a manufacturer deceptively and aggressively marketed and promoted a product despite knowing that it presented a substantial risk of injury." Id., 244. This court accepted both certified questions of law.[8]

We begin with the first certified question: "Whether a cause of action exists under the negligence or failure-to-warn provisions of the [CPLA, § 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 [postapproval] requirements." Id. We answer this question "yes."

We note preliminarily that the certified question requires us to determine only whether the facts alleged by the plaintiff give rise to a cognizable claim under the CPLA and does not require us to determine whether any such claim would be preempted by federal law.[9] Nevertheless, because the issues are somewhat intertwined, to provide context for our analysis of the certified question, it is instructive at the outset to set forth the legal principles underlying the District Court's determination that the plaintiff's claims are preempted. "Congress enacted the [Medical Device Amendments of 1976 (MDA) to the FDCA] to extend the coverage of the [FDCA] to medical devices. The MDA divides medical devices into three classes according to user risk. Class I devices pose the least risk; Class III devices pose the most. Class I devices are subject to general controls such as labeling requirements. Class II devices are subject not only to general controls, but also to special controls such as performance standards, postmarket surveillance, and patient registries. If a device cannot be determined to provide a reasonable assurance of safety and effectiveness under Class I or II controls and . . . either [is] marketed as a life-supporting device or may cause an unreasonable risk of illness or injury, it is a Class III device. A Class III device is subject to a [premarket] approval process of the FDA. . . .

"The FDA's [premarket] approval process of a Class III device is rigorous. The FDA performs a risk-benefit assessment of the device and determines the adequacy of the manufacturer's proposed label. The FDA then denies, approves, or approves with conditions on distribution, marketing, or sale. Once the FDA approves a device, the manufacturer is required to report any information that reasonably suggests that the device (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that any recurring malfunction would be likely to cause or contribute to a death or serious injury." (Internal quotation marks omitted.) *Doe* v. *Bausch & Lomb, Inc.*, supra, 443 F. Supp. 3d 271, quoting *Stengel* v. *Medtronic, Inc.*, 704 F.3d 1224, 1226–27 (9th Cir. 2013), cert. denied, 573 U.S. 930, 134 S. Ct. 2839, 189 L. Ed. 2d 805 (2014).

"Causes of action brought pursuant to state law involving Class III medical devices, such as the Trulign Lens, may be expressly or impliedly preempted by federal law. First, the MDA contains an express preemption provision:

" '[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

" '(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

" '(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.' " *Doe* v. *Bausch & Lomb*, *Inc.*, supra, 443 F. Supp. 3d 271, quoting 21 U.S.C. § 360k (a) (2018).

"In *Riegel* v. *Medtronic*, *Inc.* [552 U.S. 312, 321–23, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008)], the [United States] Supreme Court [quoting 21 U.S.C. § 360k (a)] held that the MDA expressly preempts state law claims [when] . . . (1) the FDA has established requirements applicable to the particular medical device; and (2) the state law claims would impose requirements with respect to the device that are different from, or in addition to the federal requirements that relate to either . . . (i) safety or effectiveness; or (ii) any other matter included in a requirement applicable to the device." (Internal quotation marks omitted.) *Doe* v. *Bausch & Lomb*, *Inc.*, supra, 443 F. Supp. 3d 271–72. "Importantly, the [United States Supreme Court has] explained that the scope of express preemption under the [MDA] is limited: [21 U.S.C. § 360 (k)] simply was not intended to [preempt] most, let alone all, general common-law duties enforced by damages actions." (Internal quotation marks omitted.) *Glover* v. *Bausch & Lomb*, *Inc.*, supra, 6 F.4th 237, quoting *Medtronic*, *Inc.* v. *Lohr*, 518 U.S. 470, 491, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996).

"In addition, federal law impliedly preempts state law claims if those claims are based solely on violations of FDCA requirements. [See] *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341, 353, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001); see also *Norman* v. *Bayer Corp.*, [Docket] No. 3:16-cv-00253 (JAM), 2016 WL 4007547 [*2] (D. Conn. July 26, 2016) ([a] state claim is impliedly preempted under the FDCA if the conclusion that the state law has been violated is based solely on a violation of the FDCA . . .)." (Internal quotation marks omitted.) *Doe* v. *Bausch & Lomb*, *Inc.*, supra, 443 F. Supp. 3d 272. In *Buckman Co.*, the United States Supreme Court held that the "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.[10] . . . To avoid implied preemption . . . claims must be based not on the FDCA, but on traditional state tort law [that] . . . predated the

federal enactments in [question]." (Citation omitted; footnote added; internal quotation marks omitted.) *Glover* v. *Bausch & Lomb, Inc.*, supra, 6 F.4th 237. "In other words, a litigant's [state law] claim may be *impliedly* preempted when the [state law] claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist." (Emphasis in original; internal quotation marks omitted.) *Doe* v. *Bausch & Lomb, Inc.*, supra, 272, quoting *McConologue* v. *Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 101 (D. Conn. 2014).

"Between those claims that are expressly preempted and those that are impliedly preempted is an extremely narrow class of claims that are not preempted. The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by [21 U.S.C.] § 360k (a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such claim would be impliedly preempted under *Buckman* [*Co.*])." (Emphasis in original; internal quotation marks omitted.) *Doe* v. *Bausch & Lomb, Inc.*, supra, 443 F. Supp. 3d 272, quoting *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200, 1204 (8th Cir. 2010). "Plaintiffs must advance a state law claim that parallels federal law but [that] . . . is not wholly derivative of federal law." (Internal quotation marks omitted.) *Doe* v. *Bausch & Lomb, Inc.*, supra, 272.

With these background principles of federal law in mind, we turn to the question of whether the facts alleged by the plaintiff give rise to a cognizable claim under the CPLA. "Because [this] issue presents a question of statutory interpretation, our analysis is guided by General Statutes § 1-2z, the plain meaning rule. In seeking to determine the meaning of a statute, § 1-2z directs us first to consider the text of the statute itself and its relationship to the broader statutory scheme. If, after examining such text and considering such relationship, the meaning of such text is plain and unambiguous and does not yield absurd or unworkable results, extratextual evidence of the meaning of the statute shall not be considered. . . . The test to determine ambiguity is whether the statute, when read in context, is susceptible to more than one reasonable interpretation." (Citation omitted; internal quotation marks omitted.) *State* v. *Dudley*, 332 Conn. 639, 645, 212 A.3d 1268 (2019).

We begin with the text of § 52-572q, which is the duty to warn provision of the CPLA. Section 52-572q provides: "(a) A product seller may be subject to liability for harm caused to a claimant who proves by a fair preponderance of the evidence that the product was defective in that adequate warnings or instructions were not provided.

"(b) In determining whether instructions or warnings

were required and, if required, whether they were adequate, the trier of fact may consider: (1) The likelihood that the product would cause the harm suffered by the claimant; (2) the ability of the product seller to anticipate at the time of manufacture that the expected product user would be aware of the product risk, and the nature of the potential harm; and (3) the technological feasibility and cost of warnings and instructions.

"(c) In claims based on this section, the claimant shall prove by a fair preponderance of the evidence that if adequate warnings or instructions had been provided, the claimant would not have suffered the harm.

"(d) 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."

Nothing in the language of § 52-572q clearly and unambiguously indicates whether it provides for a cause of action based on a manufacturer's alleged failure to report to a regulator adverse events related to a product. "When a statute is not plain and unambiguous, we . . . look for interpretive guidance to the legislative history and circumstances surrounding its enactment, to the legislative policy it was designed to implement, and to its relationship to existing legislation and [common-law] principles governing the same general subject matter . . . ." (Internal quotation marks omitted.) *Fedus* v. *Planning & Zoning Commission*, 278 Conn. 751, 756, 900 A.2d 1 (2006).

We begin with a review of our case law construing the CPLA. The Appellate Court previously has recognized that the CPLA "was intended to merge the various [common-law] theories of [product] liability into one cause of action." (Footnote omitted.) *Gajewski* v. *Pavelo*, 36 Conn. App. 601, 611, 652 A.2d 509 (1994), aff'd, 236 Conn. 27, 670 A.2d 318 (1996). "A principal purpose of the [CPLA] is to protect people from harm caused by defective and hazardous products. In order to meet this purpose, it is necessary that the statute be read to reach *all conduct* [that] affects the safety of a product prior to its entry into the stream of commerce." (Emphasis in original; internal quotation marks omitted.) Id., 614. The CPLA defines "product liability claim" broadly to include "*all* claims or actions brought for personal injury, death or property damage cause by the manufacture, construction, design, formula, preparation, assembly, installation, testing, *warnings*, instructions, marketing, packaging or labeling of *any* product. . . ." (Emphasis added.) General Statutes § 52-572m (b). These terms "are *simply generic categories of conduct* [*that*] *must be read broadly and in relationship to one another in order to accomplish the purposes of the statute.*" (Emphasis in original; internal quotation marks omitted.) *Gajewski* v. *Pavelo*, supra, 614. "The statutory

scheme is intended to protect anyone who is injured by a defective product." Id.

Certain products, such as prescription drugs and medical devices, are inherently unsafe. See *Hurley* v. *Heart Physicians, P.C.*, 278 Conn. 305, 317, 898 A.2d 777 (2006). A manufacturer of such products can avoid liability under the CPLA for injuries that they cause only if the products are properly prepared and accompanied by proper directions and warnings. See id., 315. "Generally, a manufacturer's duty to warn of dangers associated with its products pertains only to known dangers and runs to the ultimate user or consumer of those products." (Internal quotation marks omitted.) Id., 316. This court has recognized an exception to this general rule, however, for warnings related to prescription drugs and medical devices. Id. The exception, known as the learned intermediary doctrine, provides that "adequate warnings to prescribing physicians obviate the need for manufacturers of prescription products to warn ultimate consumers directly. The doctrine is based on 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 and [to] assess [the] risks and benefits of a particular course of treatment." (Internal quotation marks omitted.) Id. Thus, the doctrine is a specific application of the more general rule set forth in § 52-572q (d), which this court has interpreted to mean that a manufacturer has a "duty . . . to provide suitable warnings to the person best able to take or recommend precautions against the potential harm." (Internal quotation marks omitted.) *Vitanza* v. *Upjohn Co.*, 257 Conn. 365, 382, 778 A.2d 829 (2001).

Because the CPLA embodies preexisting common-law causes of action, general common-law principles governing the existence of a duty to use care are also instructive in determining the scope of the duty set forth in § 52-572q (d).[11] See id., 381 ("[i]nterpreting a statute to impair an existing interest or to change radically existing law is appropriate only if the language of the legislature plainly and unambiguously reflects such an intent" (internal quotation marks omitted)); see also *LaMontagne* v. *E.I. Du Pont De Nemours & Co.*, 41 F.3d 846, 856 (2d Cir. 1994) ("[because] the CPLA was not meant to eliminate common-law substantive rights but does not itself spell out the elements of the types of claims it consolidates . . . the [D]istrict [C]ourt was correct to assess [the] plaintiffs' theories of recovery in light of the Connecticut common-law requirements"). "We have stated that the test for the existence of a legal duty of care entails (1) a determination of whether an ordinary person in the defendant's position, knowing what the defendant knew or should have known, would anticipate that harm of the general nature of that suffered was likely to result, and (2) a determination, on the basis of a public policy analysis, of whether the

defendant's responsibility for its negligent conduct should extend to the particular consequences or particular plaintiff in the case. . . . Additionally, [a] duty to use care may arise from a contract, from a statute, or from circumstances under which a reasonable person, knowing what he knew or should have known, would anticipate that harm of the general nature of that suffered was likely to result from his act or failure to act." (Citation omitted; internal quotation marks omitted.) *Grenier* v. *Commissioner of Transportation*, 306 Conn. 523, 539, 51 A.3d 367 (2012).

"Our law makes clear, however, that [a] simple conclusion that the harm to the plaintiff was foreseeable . . . cannot by itself mandate a determination that a legal duty exists. Many harms are quite literally foreseeable, yet for pragmatic reasons, no recovery is allowed. . . . The final step in the duty inquiry, then, is to make a determination of the fundamental policy of the law, as to whether the defendant's responsibility should extend to such results. . . . As we have explained, in making that determination, our courts consider the following four factors: (1) the normal expectations of the participants in the activity under review; (2) the public policy of encouraging participation in the activity, while weighing the safety of the participants; (3) the avoidance of increased litigation; and (4) the decisions of other jurisdictions. . . . [This] totality of the circumstances rule . . . is most consistent with the public policy goals of our legal system, as well as the general tenor of our [tort] jurisprudence." (Citation omitted; internal quotation marks omitted.) *Raspberry Junction Holding, LLC* v. *Southeastern Connecticut Water Authority*, 340 Conn. 200, 215, 263 A.3d 796 (2021).

In the present case, the plaintiff contends that these principles governing the scope of the CPLA and the existence of a duty to use care demonstrate that the defendants "should be held liable for [their] failure to communicate the potential harm of the Trulign Lens to the FDA via adverse event reports and the required safety study. Common sense dictates that, when it comes to a medical device, the person best able to take or recommend precautions against the potential harm includes the federal agency that regulates the device and [that] doctors rely on as the source of updated safety information." (Internal quotation marks omitted.) The plaintiff points out that this court recognized in *Vitanza* v. *Upjohn Co.*, supra, 257 Conn. 384, that "there are times when warnings may be directed to someone other than the ultimate user." Accordingly, the plaintiff contends that identifying "the person best able to take or recommend precautions" is a question of fact that must be determined on a case-by-case basis, taking into account all of the relevant circumstances, including any practical or legal limitations on a manufacturer's obligations to provide warnings to a specific class of persons who otherwise would be in the best

position to take or recommend precautions. Because the state law requirement that the defendants provide warnings about the Trulign Lens to healthcare providers or users is preempted by federal law; see *Riegel* v. *Medtronic, Inc.*, supra, 552 U.S. 321–23 (MDA expressly preempts state law claims that impose requirements with respect to medical device that are different from, or in addition to, federal requirements); the plaintiff contends that the defendants had a duty to prevent foreseeable harm to her by complying with federal law requiring them to report adverse events to the FDA, which, under these particular circumstances, is the entity in the best position to take or recommend precautions against harm to users.[12] The plaintiff contends that, "[i]f [the defendants'] failure to warn the FDA about the serious dangers of [their] product were not cognizable under Connecticut law, there would be no way to protect Connecticut residents from dangerous medical devices."[13]

The defendants contend, to the contrary, that, under the learned intermediary doctrine, the duty to warn about the known dangers of medical devices is limited *only* to physicians and other healthcare providers. In support of this contention, the defendants rely on this court's statement in *Vitanza* v. *Upjohn Co.*, supra, 257 Conn. 365, that § 52-572q (d) "defines to whom the duty of providing an adequate warning runs, namely, to the appropriate party, which in the case of a prescription drug would be the prescribing physician." Id., 383; see id., 384 ("as a matter of law, the prescribing physician of a prescription drug is the person best able to take or recommend precautions against the harm"); see also *Hurley* v. *Heart Physicians, P.C.*, supra, 278 Conn. 317 (extending learned intermediary doctrine to warnings about medical devices). The defendants also rely on numerous federal and sister state decisions construing the product liability laws of other states[14] and two decisions of the United States District Court for the District of Connecticut concluding that the law of this state imposes no duty on manufacturers of medical devices to report adverse events to the FDA. See *Pratt* v. *Bayer Corp.*, Docket No. 3:19cv1310 (MPS), 2020 WL 5749956, *8 (D. Conn. September 25, 2020); *Norman* v. *Bayer Corp.*, supra, 2016 WL 4007547, *4. The defendants further contend that this court "cannot newly [extend this duty to warn to include warnings to the FDA] because doing so would interfere with the FDA's exclusive authority—granted by Congress—to enforce the FDCA."

Thus, the primary dispute between the parties is whether, under the circumstances of the present case, § 52-572q (d) requires manufacturers to provide warnings to the FDA, rather than a physician, as the "person"[15] in the best position to take or recommend precautions against harm to the ultimate user. We agree with the plaintiff that the defendants had a duty under the

CPLA to comply with federal laws requiring them to report adverse events associated with the Trulign Lens to the FDA in order to prevent harm to users such as the plaintiff.

First, nothing in the CPLA or our case law construing that statute suggests that, as a matter of law, *only* healthcare providers can be found to be in the best position to prevent harm to users of medical devices. Section 52-572q (d) provides generally 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*." (Emphasis added.) It is true that, under the common-law learned intermediary doctrine this court adopted in *Vitanza* v. *Upjohn Co.*, supra, 257 Conn. 376, and expanded to include warnings about medical devices in *Hurley* v. *Heart Physicians, P.C.*, supra, 278 Conn. 317, healthcare providers are identified as the persons best able to take or recommend precautions with respect to harms caused by medical devices. See *Vitanza* v. *Upjohn Co.*, supra, 384 (under learned intermediary doctrine, "as a matter of law, the prescribing physician of a prescription drug is the person best able to take or recommend precautions against the harm"). But nothing in the language of § 52-572q (d) or the principles animating the learned intermediary doctrine leads us to conclude that the immediate healthcare provider is the only person who can qualify as occupying the best position to take or recommend precautions. It stands to reason that the healthcare provider typically will be that person *if* there are no upstream obstructions to the flow of information about the known dangers of the product. If such obstructions exist, we cannot perceive why the legislature would have wanted to bar juries from looking elsewhere to identify other persons or entities that, as a factual matter, are in the best position to take or recommend precautions; any other construction would allow manufacturers to evade their duty to prevent foreseeable harm to users by withholding the necessary information from those persons or entities in a position to ensure that it reaches the end user. See *Gajewski* v. *Pavelo*, supra, 36 Conn. App. 612–13 ("Section 52-572q leaves many issues to the trier of fact. These issues include whether there is a duty to warn, *whether the manufacturer or the seller is in a better position to directly warn the ultimate user*, whether the warnings were adequate, and the consideration to be given to the sophisticated user doctrine." (Emphasis added; footnote omitted.)). Although manufacturers may invoke the learned intermediary doctrine as a shield against claims that they failed to provide adequate warnings to users as long as they provided such warnings to healthcare providers; see *Vitanza* v. *Upjohn Co.*, supra, 367 ("adequate warnings to a prescribing physician obviate the need for a manufacturer of a prescrip-

tion drug to warn ultimate consumers"); we see nothing in the CPLA or our case law that would indicate that the doctrine was intended to provide a shield against liability for foreseeable injuries caused by the *withholding* of information about inherently dangerous medical devices.

Second, and relatedly, the CPLA must be read broadly to accomplish its remedial purpose of preventing injury from defective products, including products such as medical devices that are inherently dangerous and that, therefore, must be accompanied by adequate warnings. See *Gajewski* v. *Pavelo*, supra, 36 Conn. App. 614. Under the defendants' construction of the statute, users who are injured by an inherently dangerous medical device because the manufacturer failed to comply with federal law requiring it to report adverse events to the FDA would have no remedy at all against the manufacturer or anyone else.[16]

Third, our conclusion in this respect is fortified by the principles that animate our legal doctrine regarding the imposition of a duty of care more generally. This court has recognized that "[a] duty to use care may arise from a contract, from a statute, or from circumstances under which a reasonable person, knowing what he knew or should have known, would anticipate that harm of the general nature of that suffered was likely to result from his act or failure to act." (Internal quotation marks omitted.) *Grenier* v. *Commissioner of Transportation*, supra, 306 Conn. 539. The plaintiff has alleged that (1) the defendants knew of numerous cases of Z syndrome caused by the Trulign Lens before she had her surgery, (2) they failed to report all of these adverse events to the FDA in a timely manner, as required by federal law, (3) they failed to conduct the required postmarket safety study related to the occurrence of Z syndrome until after her surgery, (4) if she and her physician had known about the true frequency of Z syndrome, they would not have selected the Trulign Lens, and (5) after the defendants reported the adverse events to the FDA, the labeling of the Trulign Lens was changed to include accurate information about the frequency of Z syndrome and instructions for minimizing risk and for treatment. As we have indicated, at this stage of the proceedings, we must assume the truth of these allegations and read them in the light most favorable to the plaintiff, giving them the benefit of all reasonable inferences.[17] See, e.g., *Burton* v. *Dominion Nuclear Connecticut, Inc.*, supra, 300 Conn. 550. These allegations are sufficient to raise the inference that the defendants knew or should have known that harm of the general nature that was suffered by the plaintiff was likely to result from their failure to provide information about the adverse effects of the Trulign Lens to the FDA in a timely manner, as required by federal law.

Although "[a] simple conclusion that the harm to the

plaintiff was foreseeable . . . cannot by itself mandate a determination that a legal duty exists," the other four factors that this court considers when making that determination, namely, "(1) the normal expectations of the participants in the activity under review; (2) the public policy of encouraging participation in the activity, while weighing the safety of the participants; (3) the avoidance of increased litigation; and (4) the decisions of other jurisdictions," also weigh in the plaintiff's favor. (Internal quotation marks omitted.) *Raspberry Junction Holding, LLC v. Southeastern Connecticut Water Authority*, supra, 340 Conn. 215. With respect to the first factor, both users and manufacturers in this state would normally expect that the manufacturers would be required to take all reasonable steps to provide warnings about the known dangers of a product to the person or entity in the best position to take or recommend precautions, as expressly provided by § 52-572q. With respect to the second factor, public policy favors encouraging individuals to seek necessary medical treatment by ensuring that they can be confident that their healthcare providers have accurate, current and complete information about the risks of the medical devices that they are recommending to their patients and that, if manufacturers withhold information about inherently dangerous medical devices, patients can be compensated for foreseeable and preventable injuries caused by them. With respect to the third factor, litigation arising from a manufacturer's failure to warn users about the inherent dangers of its products is already a familiar feature of the Connecticut legal landscape. We cannot conclude that public policy mandates or counsels an *exception* for medical devices.[18]

Finally, we conclude that the fourth factor—the decisions of other jurisdictions—weighs in favor of the plaintiff. Although the courts of other jurisdictions are split on this point, we find the cases cited by the plaintiff, in which federal and state courts have construed the product liability laws of our sister states as creating a duty to comply with federal law requiring manufacturers to report adverse events associated with inherently dangerous medical devices to the FDA, to be more persuasive than the cases cited by the defendants. See *A.F. ex rel. Fogel* v. *Sorin Group USA, Inc.*, 346 F. Supp. 3d 534, 542–43 (S.D.N.Y. 2018) (claim that defendant had failed to timely and properly report information to FDA concerning adverse effects of product in violation of FDA requirements was cognizable under New York law providing that, "[t]o state a claim for a manufacturer's failure to warn, a plaintiff must demonstrate that the warning was inadequate and that the failure to adequately warn of the dangers . . . was a proximate cause of his or her injuries" (internal quotation marks omitted));[19] *Richardson* v. *Bayer Healthcare Pharmaceuticals, Inc.*, Docket No. 4:15-cv-00443-BLW, 2016 WL 4546369, *8 (D. Idaho August 30, 2016) ("Idaho law

contemplates that a [third-party] intermediary may play a critical role in adequately warning users of a foreseeably dangerous product. . . . Therefore, under Idaho law, a manufacturer of a product may have a duty to forewarn a user of the product, regardless [of] whether the user is the direct purchaser of the product . . . . In the context of Class III medical devices, that should be construed to include warnings and reports to the FDA." (Citations omitted; internal quotation marks omitted.)); *Laverty* v. *Smith & Nephew*, *Inc.*, 197 F. Supp. 3d 1026, 1035 (N.D. Ill. 2016) ("Illinois does recognize a claim for failure to warn predicated on a product manufacturer's failure to disclose known defects. . . . This duty is not limited to providing warnings directly to end users, but rather depends on whether [the defendant] and [the plaintiff] stood in such a relationship to each other that the law imposed [on the defendant] an obligation of reasonable conduct for the benefit of [the plaintiff]. . . . The MDA sets standards for what, when, how, and to whom a manufacturer must report; it does not eviscerate the [long-standing state imposed] duty to warn simply by redefining the way medical device manufacturers satisfy that obligation." (Citations omitted; internal quotation marks omitted.));[20] *Williams* v. *Smith & Nephew*, *Inc.*, 123 F. Supp. 3d 733, 742 (D. Md. 2015) ("Maryland tort law recognizes that a duty to warn can undergird a negligence case in . . . a product liability action. . . . Moreover, this duty to warn extends beyond the time of sale, and requires the manufacturer to make reasonable efforts to convey an effective warning. . . . And reasonable efforts would, in some circumstances, entail a warning to a third party such as the FDA." (Citations omitted; footnote omitted; internal quotation marks omitted.)); *McAfee* v. *Medtronic*, *Inc.*, Docket No. 1:12-CV-417 RLM, 2015 WL 3617755, *5 (N.D. Ind. June 4, 2015) (under Indiana statute providing that, in action based on alleged failure to provide adequate warnings or instructions regarding use of product, party making claim must establish that manufacturer or seller failed to exercise reasonable care under circumstances in providing warnings or instructions, "[the plaintiff] stated plausible claims for relief . . . based on an alleged failure to warn the FDA" that were sufficient to survive motion to dismiss); *Garross* v. *Medtronic*, *Inc.*, 77 F. Supp. 3d 809, 815 (E.D. Wis. 2015) (plaintiff could rely on allegations that defendant failed to report adverse events to FDA, as required by federal regulations, "as evidence that [the defendant] violated a state [common-law] duty [under Wisconsin law] to warn patients of the risks"); *Beavers-Gabriel* v. *Medtronic*, *Inc.*, Docket No. 13-00686 JMS-RLP, 2015 WL 143944, *12 (D. Haw. January 9, 2015) ("Hawaii law impose[s] liability through the entire chain of distribution and manufacture under strict liability law . . . and Hawaii courts have a recognized public policy of providing the maximum possible protection that the law can muster against dangerous defects in products. . . .

Thus, this duty of care supplies a basis for [the plaintiff's] strict liability and negligence claims that arises independently of [the plaintiff's] duty to warn the FDA under federal law." (Citations omitted; internal quotation marks omitted.)); *Waltenburg* v. *St. Jude Medical, Inc.*, 33 F. Supp. 3d 818, 838–40 (W.D. Ky. 2014) (under Kentucky law imposing general duty on manufacturers to warn of dangers known to them but not known to persons whose use of product can reasonably be anticipated, plaintiffs' claim that defendants violated federal law governing reporting of complaints to FDA was recognized state tort claim);[21] *O'Neil* v. *St. Jude Medical, Inc.*, Docket No. C13-0661RSL, 2013 WL 6173803, *3 (W.D. Wn. November 22, 2013) (when plaintiffs alleged that defendants had breached their duty of care under the Washington Product Liability Act and that scope and nature of duty is established by FDA regulations, and Washington tort law provided that claim may be based on duty of care established by statute or regulation, claim that defendants breached their duty of care when they failed to alert FDA of risks was cognizable state law tort claim); *Gavin* v. *Medtronic, Inc.*, Docket No. 12-0851, 2013 WL 3791612, *5, *12, *14 (E.D. La. July 19, 2013) (Louisiana statute providing that "[a] product is unreasonably dangerous because an adequate warning about the product has not been provided if . . . the manufacturer failed to use reasonable care to provide an adequate warning . . . to users and handlers of the product" and requiring manufacturers to provide warning about dangers that come to light after product has left their control applied to plaintiff's claim that defendant violated federal regulations requiring it to report adverse events to FDA (internal quotation marks omitted));[22] *Coleman* v. *Medtronic, Inc.*, 223 Cal. App. 4th 413, 428–29, 167 Cal. Rptr. 3d 300 (under California law providing that medical device manufacturer "can be found liable if it did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution," "the duty to warn should not be so narrowly defined as to exclude a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers" (internal quotation marks omitted)), review dismissed, 331 P.3d 178, 175 Cal. Rptr. 3d 809 (2014); *Angeles* v. *Medtronic, Inc.*, 863 N.W.2d 404, 419 (Minn. App. 2015) ("Under Minnesota law, [when] the manufacturer or the seller of a product has actual or constructive knowledge of danger to users, the seller or manufacturer has a duty to give warning of such dangers. . . . Because [the plaintiffs'] claim that [the defendant] failed to warn the FDA of adverse events is based in traditional state tort law, we conclude that this claim is not expressly or impliedly preempted by federal law to the extent that [the plaintiffs] allege that [the defendant] failed to report adverse events to the FDA." (Citation omitted;

internal quotation marks omitted.));[23] *Williams* v. *Bayer Corp.*, 541 S.W.3d 594, 606 (Mo. App. 2017) (under statute defining products liability claim to include claim that product was unreasonably dangerous when put to reasonably anticipated use without knowledge of its characteristics, claim that defendant had failed to comply with postmarket approval reporting requirements listed in MDA constituted "a traditional state law tort cause of action"), transfer denied, Missouri Supreme Court, Docket No. SC96969 (April 3, 2018).[24] We acknowledge that, in some of these cases, the court's analysis was somewhat cursory. Nevertheless, we find the cases persuasive because their reasoning is generally consistent with ours and because the failure to warn provision of the CPLA is at least as broad as any of the analogous provisions reviewed therein.

In contrast, we find the cases cited by the defendants to be unpersuasive. The two cases from our local United States District Court that the defendants cite for the proposition that "there is no general or background duty under Connecticut law to report risks to a regulatory body"; (internal quotation marks omitted) *Pratt* v. *Bayer Corp.*, supra, 2020 WL 5749956, *8; accord *Norman* v. *Bayer Corp.*, supra, 2016 WL 4007547, *4; did not engage in a full analysis of the CPLA or this court's cases construing that statute. Nor did they engage in any analysis of this state's jurisprudence governing the existence of a duty to use care. Rather, they relied primarily on the decisions of other federal courts construing the product liability laws of other states—also without fully analyzing those laws. Moreover, the courts in *Pratt* and *Norman* intertwined their abbreviated analyses of Connecticut law with their analyses of the issue of federal preemption—an issue that is distinct and, as we have explained; see footnote 9 of this opinion; is not before us in the present case. See *Pratt* v. *Bayer Corp.*, supra, *8 (citing *Doe* v. *Bausch & Lomb, Inc.*, supra, 443 F. Supp. 3d 273, for proposition that plaintiff's claim that defendants failed to comply with FDA reporting requirements was impliedly preempted because "it is wholly derivative of the FDCA" (internal quotation marks omitted)); *Norman* v. *Bayer Corp.*, supra, *4 ("To avoid preemption, a claim must be premised on the type of conduct that would traditionally give rise to liability under state law—and that would give rise to liability under state law even if the FDCA had never been enacted. . . . The failure-to-warn claim arises solely from the MDA's reporting requirements, and therefore is subject to implied preemption." (Citation omitted; internal quotation marks omitted.)).[25] Although it is obviously true that Connecticut law would not impose a duty on a manufacturer of a medical device to report adverse events associated with the device *to the FDA* in the absence of federal law requiring such reports and preempting the state law requirement to warn healthcare providers, that does not mean that,

given the existence of such federal law, no state law duty to report adverse events to the FDA exists.[26]

We also do not find persuasive the other cases cited by the defendants addressing the existence of a state law duty to report an adverse event associated with a medical device to the FDA. Many of those cases held more or less conclusorily that the learned intermediary doctrine requires manufacturers to provide warnings *only* to healthcare providers, not to the FDA. See *Brooks* v. *Mentor Worldwide, LLC*, 985 F.3d 1272, 1278 n.1, 1281 (10th Cir.) (applying Missouri law), cert. denied, U.S. , 142 S. Ct. 477, 211 L. Ed. 2d 289 (2021); *Plourde* v. *Sorin Group USA, Inc.*, 517 F. Supp. 3d 76, 91 (D. Mass. 2021) (applying Massachusetts law); *Hill* v. *Bayer Corp.*, 485 F. Supp. 3d 843, 854 (E.D. Mich. 2020) (applying Michigan law); *Noel* v. *Bayer Corp.*, 481 F. Supp. 3d 1111, 1121 (D. Mont. 2020) (applying Montana law); *English* v. *Bayer Corp.*, 468 F. Supp. 3d 573, 580 (W.D.N.Y. 2020) (applying New York law); *Conklin* v. *Medtronic, Inc.*, 245 Ariz. 501, 507–508, 431 P.3d 571 (2018) (applying Arizona law). Similarly, a number of courts have held that the state product liability law under review required only that manufacturers warn *consumers* of the known dangers of their products. See *McNeil-Williams* v. *DePuy Orthopaedics, Inc.*, 384 F. Supp. 3d 570, 576 (E.D.N.C. 2019) (applying North Carolina law); *Kubicki ex rel. Kubicki* v. *Medtronic, Inc.*, 293 F. Supp. 3d 129, 183–84 (D.D.C. 2018) (applying District of Columbia law); *Pinsonneault* v. *St. Jude Medical, Inc.*, 953 F. Supp. 2d 1006, 1015 (D. Minn. 2013) (applying Minnesota law). In none of these cases, however, did the court confront a state product liability law imposing a "duty . . . to provide suitable warnings to the person best able to take or recommend precautions against the potential harm." (Internal quotation marks omitted.) *Vitanza* v. *Upjohn Co.*, supra, 257 Conn. 382. Accordingly, regardless of whether the cases were correctly decided under the relevant state's law, for the reasons that we have already explained, we do not read the CPLA so narrowly. We conclude, therefore, that the defendants had a duty under the CPLA to comply with federal statutes and regulations requiring them to report adverse events associated with the Trulign Lens and its predecessor products to the FDA and to comply with the FDA's postapproval requirements in a timely manner.

The defendants contend that the law of this state does not impose such a duty because the submission of an adverse event report to the FDA does not constitute a "warning" for purposes of the CPLA. According to the defendants, this is so because the FDA is not *required* to publish adverse event reports. See, e.g., *Aaron* v. *Medtronic, Inc.*, 209 F. Supp. 3d 994, 1005 (S.D. Ohio 2016) ("[Adverse event] reports are not warnings. Although the FDA *may* disclose [adverse event] reports, it is not required to do so. 21 C.F.R. § 803.9 (a) [2016]

. . . . Thus, [adverse event] reports, unlike the warnings on a device label, are not automatically made public." (Emphasis in original; internal quotation marks omitted.)), appeal dismissed, United States Court of Appeals, Docket No. 16-4211 (6th Cir. June 29, 2017), and appeal dismissed sub nom. *Atwood* v. *Medtronic, Inc.*, United State Court of Appeals, Docket Nos. 16-4206, 16-4210, 16-4216 and 16-4223 (6th Cir. June 29, 2017); *Conklin* v. *Medtronic, Inc.*, supra, 245 Ariz. 508 ("[A] manufacturer . . . cannot have a reasonable assurance that the information in adverse event reports will reach end users (or end users' [healthcare] providers) . . . because the FDA is not required to publicly release such reports [under] 21 C.F.R. § 803.9 (a) [which provides] that the FDA *may* disclose to the public any [adverse event] report . . . . [R]elatedly, when the FDA exercises its discretion to release adverse event reports publicly, it does so only passively by uploading the reports to a database. . . . An end user (or an end user's health care provider) must then affirmatively access the database and search for adverse event reports." (Citations omitted; emphasis in original; internal quotation marks omitted.)). The defendants further contend that adverse event reports to the FDA are not warnings under the CPLA because they are inherently unreliable. See *DeLuca ex rel. DeLuca* v. *Merrell Dow Pharmaceuticals, Inc.*, 791 F. Supp. 1042, 1050 (D.N.J. 1992) (adverse drug reaction reports "have inherent biases as they are second-or-third hand reports, are affected by medical or mass media attention, and are subject to other distortions"), aff'd, 6 F.3d 778 (3d Cir. 1993), cert. denied, 510 U.S. 1044, 114 S. Ct. 691, 126 L. Ed. 2d 658 (1994); see also *Goldstein* v. *Centocor*, Docket No. 05-21515 CIV Cooke, 2007 WL 7428597, *3 (S.D. Fla. May 14, 2007) ("[the] [d]efendant cannot be considered to have manifested an adoption or belief in the truth of the reports to the extent that it may have forwarded them to [the] FDA under a legal duty to do so"), aff'd, 310 Fed. Appx. 331 (11th Cir. 2009).

We are not persuaded. As we explained, the plaintiff has alleged that, if the defendants had complied with their obligations under federal law to report adverse events to the FDA and to conduct the postmarket safety study in a timely manner, the labeling of the Trulign Lens would have been altered to include warnings about Z syndrome and instructions for minimizing risk and for treatment before the plaintiff's surgery. The plaintiff further alleged that, if the labeling had been changed before the surgery, she and her physician would not have used the Trulign Lens. Although the CPLA does not define "warning," it is implicit in § 52-572q (d) that the term is broad enough to include information that, if provided to "the person best able to take or recommend precautions against the potential harm," would ultimately be used to prevent harm to the user. It is also reasonable to conclude that the entire purpose of the

federal laws and regulations requiring manufacturers to report adverse events associated with medical devices to the FDA is to prevent injuries to users by ensuring that reliable and significant information about the inherent dangers of a medical device will be made available, at some point and in some form, to healthcare providers. We conclude, therefore, that whether the adverse event reports received by the manufacturer were sufficiently reliable and significant that the manufacturer knew or should have known that it was required to report the adverse events to the FDA, and whether the FDA would have required a change to the labeling of the device or otherwise made the substance of the information available to healthcare providers if it had received the reports, are factual considerations to be taken into account by the jury when determining whether the plaintiff's injury was foreseeable and caused by the defendants' conduct. This determination is not significantly different from the factual determination that a jury is ordinarily required to make in a failure to warn case as to whether a manufacturer had reliable knowledge of significant adverse events associated with its product such that the manufacturer knew or should have known that user warnings were required to reduce the risk of injury. See *Giglio* v. *Connecticut Light & Power Co.*, 180 Conn. 230, 235–36, 429 A.2d 486 (1980) ("[t]here is no dispute that the seller is under a duty to give adequate warning of *unreasonable* dangers involved in the use of which *he knows, or should know*" (emphasis added; internal quotation marks omitted)); see also General Statutes § 52-572q (c) ("the claimant shall prove by a fair preponderance of the evidence that if adequate warnings or instructions had been provided, the claimant would not have suffered the harm"); *Moss* v. *Wyeth, Inc.*, 872 F. Supp. 2d 162, 173 (D. Conn. 2012) (under CPLA, "there is only a duty to warn of those dangers that are known, or that are reasonably foreseeable, to the defendant"); *Battistoni* v. *Weatherking Products, Inc.*, 41 Conn. App. 555, 563, 676 A.2d 890 (1996) (For purposes of § 52-572q (c), "[q]uestions regarding the existence of a causal link . . . are reserved for determination by the trier of fact. . . . Proximate cause becomes a question of law only when the mind of a fair and reasonable person could reach only one conclusion . . . . The question should be submitted to the trier of fact if there is room for a reasonable disagreement." (Citations omitted; internal quotation marks omitted.)); *Gajewski* v. *Pavelo*, supra, 36 Conn. App. 612–13 ("Section 52-572q leaves many issues to the trier of fact. These issues include whether there is a duty to warn, whether the manufacturer or the seller is in a better position to directly warn the ultimate user, whether the warnings were adequate, and the consideration to be given to the sophisticated user doctrine." (Footnote omitted.)). We conclude, therefore, that the plaintiff in the present case can prevail at trial if she establishes that it is more likely than not that, if the

defendants had complied in a timely manner with the federal laws requiring them to report adverse events to the FDA and to perform a postmarket safety study, the FDA would have required the defendants to change the labeling of the Trulign Lens or otherwise made the substance of the reports available to healthcare providers before the plaintiff's surgery and that, as a result, she and her physician would not have chosen that device.[27]

For the foregoing reasons, we conclude that the answer to the first certified question of law is "yes."

II

We next address the second certified question: "Whether the [CPLA's] exclusivity provision . . . § 52-572n, bars a claim under [CUTPA] based on allegations that a manufacturer deceptively and aggressively marketed and promoted a product despite knowing that it presented a substantial risk of injury." *Glover* v. *Bausch & Lomb, Inc.*, supra, 6 F.4th 244. We conclude that the answer to this question is "yes."

The following additional procedural history is relevant to our resolution of this issue. While the defendants' motion to dismiss was pending in the United States District Court, this court issued its decision in *Soto* v. *Bushmaster Firearms International, LLC*, 331 Conn. 53, 202 A.3d 262, cert. denied sub nom. *Remington Arms Co., LLC* v. *Soto*, U.S. , 140 S. Ct. 513, 205 L. Ed. 2d 317 (2019), holding that (1) the CPLA's exclusivity provision does not bar CUTPA claims based on the "unethical, oppressive, immoral, and unscrupulous" marketing of products that are not defective; id., 107; and (2) a claim for personal injuries is cognizable under CUTPA, at least with respect to wrongful advertising claims. See id., 116. Believing that *Soto* had "made available a cause of action and category of damages that had not been previously available" to her, the plaintiff filed a motion for leave to amend her complaint to add a CUTPA claim based on the defendants' alleged unscrupulous marketing of the Trulign Lens. The plaintiff alleged in the proposed amended complaint that, among other things, the "[d]efendants knew, or should have known, that the [Trulign Lens], when used in the intended manner, would be likely to inflict serious injuries and harm. Despite this knowledge, the defendants unethically, oppressively, immorally, and unscrupulously marketed and promoted these lenses for use." She further alleged that this conduct "was a substantial factor resulting in [her] injuries, suffering, and damages . . . ." As we already explained, the District Court did not reach the issue of whether the plaintiff's proposed CUTPA claim is barred by the CPLA's exclusivity provision because it concluded that the claim was indistinguishable from a claim that the FDA approved labeling of the Trulign Lens was deficient under state law and, therefore, that amending the complaint would be futile insofar as the claim would be expressly preempted by

federal law. Accordingly, the court denied the motion for leave to amend the complaint.

Whether the exclusivity provision of the CPLA bars the plaintiff's CUTPA claim is a question of statutory interpretation. See, e.g., *Gerrity* v. *R.J. Reynolds Tobacco Co.*, 263 Conn. 120, 124, 818 A.2d 769 (2003). The principles that guide our statutory analysis are set forth in part I of this opinion.

We begin with the language of the relevant statutory provision. Section 52-572n (a) provides that "[a] product liability claim as provided [under the CPLA] may be asserted and shall be in lieu of all other claims against product sellers, including actions of negligence, strict liability and warranty, for harm caused by a product." Section 52-572m (b) defines "product liability claim" in relevant part to include "all claims or actions brought for personal injury, death or property damage caused by the manufacture, construction, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging or labeling of any product. . . ." Thus, "the language of the exclusivity provision makes clear that the [CPLA] was intended to serve as the exclusive remedy for a party who seeks recompense for [personal injury, death or property damage] caused by a product defect"; *Gerrity* v. *R.J. Reynolds Tobacco Co.*, supra, 263 Conn. 128; including damages caused by the marketing of a defective product. See General Statutes § 52-572m (b) (" '[p]roduct liability claim' includes all claims or actions brought for personal injury, death or property damage caused by the . . . marketing . . . of any product").

This court has recognized, however, that not all actions arising from the sale of products that cause injury are barred by the CPLA's exclusivity provision. In *Gerrity*, the plaintiff brought a wrongful death action, alleging that the defendants had violated the CPLA by selling defective cigarettes that were "unreasonably dangerous because they are addictive and cause lung cancer." *Gerrity* v. *R.J. Reynolds Tobacco Co.*, supra, 263 Conn. 123. In addition, the plaintiff alleged that the defendants had violated CUTPA when they "issued false public statements [regarding the safety of cigarettes], failed to disclose evidence of the addictive nature of cigarettes . . . neutralized warnings of smoking related health hazards, and targeted minors in advertising their products." Id., 124. As the result of these deceptive practices, the plaintiff "alleged that the decedent was forced to pay a higher price for the defendants' cigarettes than she would have had to pay in the absence of the" deceptive conduct. Id., 130. This court concluded that, because the plaintiff's CUTPA claim "[did] not seek a remedy for personal injury, death or property damage," which is a required element of a claim under the CPLA, the exclusivity provision of the CPLA did not bar the CUTPA claim. Id., 129.

More recently, in *Soto* v. *Bushmaster Firearms International, LLC*, supra, 331 Conn. 53, we considered whether the CPLA's exclusivity provision barred a CUTPA claim alleging that the defendants had "wrongfully marketed the [Bushmaster XM15-E2S semiautomatic rifle that was used during the mass shooting at Sandy Hook Elementary School in Newtown] by promoting the gun's use for illegal purposes—offensive, military style assault missions . . . ." Id., 107. The plaintiffs in *Soto* made no claim that the gun at issue was defective in any manner but did claim that the defendants' wrongful marketing had caused the death of the shooting victims. See id., 109. This court concluded that the CPLA's exclusivity provision did not bar the CUTPA claim because the plaintiffs had made no claim that the injuries were caused by a defective product. See id.; see also id., 107 n.33 ("it is well established that the exclusivity provision of the [CPLA] applies only to those claims seeking to recover damages caused by a *defective* product" (emphasis in original)). This court also concluded for the first time that damages for personal injuries may be sought under CUTPA, at least with respect to wrongful advertising claims. Id., 116.

Thus, standing together, *Gerrity* and *Soto* stand for the proposition that the CPLA's exclusivity provision permits a CUTPA claim based on the sale of product when (1) the plaintiff does not seek a remedy for *personal injury, death or property damage* that was caused by a defective product,[28] or (2) the plaintiff seeks a remedy for personal injury, death or property damage that was caused by the unscrupulous advertising of a product *that was not defective*. In the present case, the plaintiff's CUTPA claim seeks damages for a *personal injury* that was caused by unscrupulous advertising of the allegedly *defective* Trulign Lens.[29] It is clear, therefore, that the CUTPA claim does not fall within *Gerrity*—because it seeks damages for personal injury—or *Soto*—because it seeks damages caused by an allegedly defective product. See *Hunte* v. *Abbott Laboratories, Inc.*, 556 F. Supp. 3d 70, 94–95 (D. Conn. 2021) (*Soto* did not apply to CUTPA claim seeking damages for decedent's personal injuries and death allegedly caused by defective infant formula because plaintiff claimed product was defective under CPLA, and *Gerrity* did not apply because plaintiff sought damages for wrongful death); *Appiah* v. *Home Depot U.S.A., Inc.*, Docket No. 3:20-cv-00489 (VLB), 2020 WL 6263544, *5 (D. Conn. October 23, 2020) ("*Soto* made clear that the exclusivity provision of the [CPLA] applies to those claims seeking to recover damages caused by a *defective product*" (emphasis in original)).

Although the plaintiff's claim clearly does not come within the scope of either *Gerrity* or *Soto*, we acknowledge that this court has never directly addressed the

issue of whether a CUTPA claim seeking damages for personal injury caused by a defective product is barred by the exclusivity provision.[30] We further acknowledge, as the amici, the Connecticut Trial Lawyers Association and the American Association for Justice, point out, that the CPLA's exclusivity provision does not *expressly* bar CUTPA claims and that the legislative history of the CPLA indicates that it was "not intended to affect other state statutory schemes such as [antitrust] acts or the state unfair trade practice[s] act." (Emphasis omitted; internal quotation marks omitted.) *Gerrity* v. *R.J. Reynolds Tobacco Co.*, supra, 263 Conn. 128–29. Nothing in *Gerrity* or *Soto*, however, suggests that a CUTPA claim can survive if it subsumes all of the elements of a claim pursuant to the CPLA. To the contrary, we expressly stated in *Gerrity*, albeit in dictum, that "the language of the exclusivity provision makes clear that the [CPLA] was intended to serve as the exclusive remedy for a party who seeks recompense for [personal injury, death or property damage] caused by a product defect," and we concluded that the plaintiffs' CUTPA claim survived *only* because they did not seek damages for personal injury, death or property damage. Id., 128. Similarly, we made it clear in *Soto* that the plaintiffs' CUTPA claim survived *only* because they made no claim that the gun at issue was defective. See *Soto* v. *Bushmaster Firearms International, LLC*, supra, 331 Conn. 107 n.33 ("the exclusivity provision of the [CPLA] applies . . . to those claims seeking to recover damages caused by a *defective* product" (emphasis in original)). We therefore reject the invitation of the plaintiff and the amici to recognize an exception to the CPLA's exclusivity provision for CUTPA claims, like the plaintiff's, seeking damages for personal injury caused by a defective product.

The plaintiff contends that "[a]llegations of aggressive marketing—particularly of a product [the] conditions of approval [of which the defendants] had violated and ignored—are separate and distinct from those that go solely to a failure to warn of a product's defect, and would be cognizable under CUTPA absent allegations of a product defect. The plaintiffs should be permitted to pursue damages related to such marketing in conjunction with damages caused by [the defendants'] negligence and failure to warn of the Trulign Lens' defects." We are not persuaded. Although a claim alleging that a defendant *unscrupulously advertised* a defective or inherently dangerous product is arguably distinguishable from a run-of-the-mill failure to warn claim alleging that the defendant had *marketed* a defective or inherently dangerous product, the difference is a matter of degree rather than a matter of kind and does not warrant different treatment for purposes of the CPLA exclusivity provision. Accordingly, we conclude that the answer to the second certified question is "yes."

The answer to the first certified question, namely,

whether a cause of action exists under the negligence or failure-to-warn provisions of the CPLA, § 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 postapproval requirements is: Yes.

The answer to the second certified question, namely, whether the CPLA's exclusivity provision, § 52-572n, bars a claim under CUTPA based on allegations that a manufacturer deceptively and aggressively marketed and promoted a product despite knowing that it presented a substantial risk of injury is: Yes.

No costs shall be taxed in this court to either party.

In this opinion McDONALD, D'AURIA, MULLINS, KAHN and KELLER, Js., concurred.

[1] General Statutes § 51-199b (d) provides: "The Supreme Court may answer a question of law certified to it by a court of the United States or by the highest court of another state or of a tribe, 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."

[2] Marjorie Glover's husband, Charles Glover, is also a plaintiff. Because all of his claims are derivative of Marjorie Glover's claims, we refer to Marjorie Glover as the plaintiff for convenience.

[3] The plaintiff alleged in the operative complaint that she is "ignorant of the true names and capacities of the defendants sued by fictitious names, who are described throughout as [DOE 1 thorough DOE 50], and such names are fictitious."

[4] The original question certified by the Second Circuit refers to General Statutes § 52-572h, which governs the apportionment of liability in negligence actions. It is unclear to us how this statute relates to the issues before the court. Because the parties have briefed only the issue of whether a cause of action based on a failure to report adverse events to the FDA exists pursuant to § 52-572q, which governs product liability claims based on a failure to provide adequate warnings, we limit our analysis to that statute.

[5] Although § 51-199b (g) directs that, "[i]f the parties cannot agree upon a statement of facts, then the certifying court shall determine the relevant facts and shall state them as a part of its certification order," given the procedural posture of this case, no facts have yet been found.

[6] Specifically, the plaintiff alleged in the operative complaint that the defendants had violated title 21 of the 2021 edition of the Code of Federal Regulations, § 803.50, which provides: "(a) If you are a manufacturer, you must report to [the FDA] the information required by § 803.52 in accordance with the requirements of § 803.12 (a), no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market:

"(1) May have caused or contributed to a death or serious injury or

"(2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

"(b) What information does FDA consider 'reasonably known' to me?

"(1) You must submit all information required in this subpart E that is reasonably known to you. [The FDA] consider[s] the following information to be reasonably known to you:

"(i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter;

"(ii) Any information in your possession; or

"(iii) Any information that you can obtain by analysis, testing, or other evaluation of the device.

"(2) You are responsible for obtaining and submitting to [the FDA] information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters.

"(3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete

information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under § 803.56 in accordance with the requirements of § 803.12 (a)."

The plaintiff also alleged in the operative complaint that the FDA's initial premarket approval for a product known as the Crystalens, which was the predecessor model of the Trulign Lens, required the defendants to provide the FDA with "[a]dverse [r]eaction [r]eports" within ten days of receiving or acquiring knowledge or information about "[a]ny . . . injury . . . that is attributable to the device and (a) has not been addressed by the device's labeling; or (b) has been addressed by the device's [labeling] but is occurring with unexpected severity or frequency." (Internal quotation marks omitted.) The plaintiff further alleged that the FDA's supplemental premarket approval for the Trulign Lens required the defendants to submit adverse event reports within thirty days of receiving or becoming "aware of information, from any source, that reasonably suggests that one of their marketed devices: (a) may have caused or contributed to a death or serious injury; or (b) has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur." (Internal quotation marks omitted.)

[7] The Second Circuit noted that the plaintiff had expressly limited her CPLA claim to allegations that the defendants had failed to comply with the FDA's postapproval requirements to report adverse events and did not challenge the FDA approved labeling of the Trulign Lens. See *Glover* v. *Bausch & Lomb, Inc.*, supra, 6 F.4th 236.

[8] After accepting the certified questions of law, we granted permission to the Connecticut Trial Lawyers Association and the American Association for Justice to file an amici curiae brief in support of the plaintiff's claim that the District Court improperly denied her request for leave to amend the complaint to include a CUTPA claim. We also granted permission to the Product Liability Advisory Council, Inc., to file an amicus brief in support of the defendants' position that the District Court properly dismissed the plaintiff's failure to warn claim.

[9] "The question of preemption is one of federal law, arising under the supremacy clause of the United States constitution." (Internal quotation marks omitted.) *Murphy* v. *Darien*, 332 Conn. 244, 249, 210 A.3d 56 (2019), cert. denied sub nom. *Metro-North Commuter Railroad Co.* v. *Murphy*, U.S. , 140 S. Ct. 847, 205 L. Ed. 2d 468 (2020). As such, the question of whether federal law preempts the defendants' state law duty to report adverse events associated with the Trulign Lens to the FDA is not within the scope of the first certified question of law.

[10] The plaintiffs in *Buckman Co.* claimed that the defendant, a consulting company that assisted the manufacturer of certain orthopedic bone screws in obtaining regulatory approval for the screws, "made fraudulent representations to the [FDA] in the course of obtaining approval to market the screws. [The] [p]laintiffs further claim[ed] that such representations were at least a 'but for' cause of injuries that [the] plaintiffs sustained from the implantation of these devices: Had the representations not been made, the FDA would not have approved the devices, and [the] plaintiffs would not have been injured. [The] [p]laintiffs sought damages from [the consultant] under state tort law." *Buckman Co.* v. *Plaintiffs' Legal Committee*, supra, 531 U.S. 343.

[11] In other words, it is reasonable to conclude that, if the courts would have determined that a duty to warn existed under the common law before the enactment of the CPLA, the legislature intended that § 52-572q (d) would embody that duty.

[12] The plaintiff also cites numerous state and federal cases construing the product liability laws of several of our sister states in support of her claim that the defendants had a state law duty to comply with federal reporting requirements. We discuss these cases subsequently in this opinion.

[13] The plaintiff also suggests that the defendants' "duty to report adverse events is also consistent with the [postsale] duty to warn that has long been recognized under Connecticut law . . . ." The amicus, the Product Liability Advisory Council, Inc., contends that, to the contrary, this court never has held that a manufacturer of medical devices has a postsale duty to warn. Insofar as the plaintiff does not appear to claim that the defendants breached a continuing duty to warn *after* the sale of the Trulign Lens, we find this line of cases to be uninstructive and decline to address this issue.

[14] See *Brooks* v. *Mentor Worldwide, LLC*, 985 F.3d 1272, 1281 (10th Cir.) (plaintiffs failed to identify any duty under Missouri law to comply with federal requirements to report dangers to FDA), cert. denied, U.S. , 142 S. Ct. 477, 211 L. Ed. 2d 289 (2021); *Mink* v. *Smith & Nephew, Inc.*, 860 F.3d 1319, 1330 (11th Cir. 2017) (claim under Florida common law that defendant violated duty to warn of dangers of medical device by failing to report dangers to FDA was impliedly preempted under *Buckman Co.*); *Morris* v. *PLIVA, Inc.*, 713 F.3d 774, 778 (5th Cir. 2013) (although generic drug manufacturers might have duty under federal law to alert FDA of need to strengthen warnings and labels, Louisiana tort law imposed no such duty); *In re Medtronic, Inc., Sprint Fidelis Leads Product Liability Litigation*, supra, 623 F.3d 1205–1206 (claims in multidistrict litigation that defendant did not timely file adverse event reports with FDA, as required by federal regulations, were "simply an attempt by private parties to enforce the MDA" and were preempted under *Buckman Co.*); *Green* v. *Bayer Corp.*, 522 F. Supp. 3d 492, 502–503 (E.D. Ark. 2021) (claim that defendant violated duty under Arkansas law to warn consumers and healthcare providers about dangers of medical device was expressly preempted because federal law imposes no such duty); *Plourde* v. *Sorin Group USA, Inc.*, 517 F. Supp. 3d 76, 91–92 (D. Mass. 2021) (duty to warn doctors of dangers of medical device under Massachusetts learned intermediary doctrine does not include duty to report dangers to FDA); *Hill* v. *Bayer Corp.*, 485 F. Supp. 3d 843, 854 (E.D. Mich. 2020) (Michigan common law providing that manufacturer has duty to provide adequate warning of dangers of medical devices to physicians and surgeons, but not to their patients, did not include duty to report dangers to FDA); *Noel* v. *Bayer Corp.*, 481 F. Supp. 3d 1111, 1121 (D. Mont. 2020) (Montana law requiring manufacturers to warn users and healthcare professionals about dangers of product did not create duty to warn FDA); *McNeil-Williams* v. *DePuy Orthopaedics, Inc.*, 384 F. Supp. 3d 570, 575–76 (E.D.N.C. 2019) (North Carolina statute providing cause of action for "failure to provide adequate warning or instruction" when, "[a]fter the product left the control of the manufacturer or seller, the manufacturer or seller became aware of or in the exercise of ordinary care should have known that the product posed a substantial risk of harm to a reasonably foreseeable user or consumer" did not create duty to inform FDA of adverse events (internal quotation marks omitted)); *Kubicki ex rel. Kubicki* v. *Medtronic, Inc.*, 293 F. Supp. 3d 129, 184 (D.D.C. 2018) (violation of District of Columbia common law requiring manufacturers to warn consumers about new adverse information "is not, in fact, the functional equivalent of a manufacturer's failure to report adverse incidents to the FDA in violation of federal law"); *Hafer* v. *Medtronic, Inc.*, 99 F. Supp. 3d 844, 860 (W.D. Tenn. 2015) ("to the extent that [the] [p]laintiffs seek recourse for [the] [d]efendants' failure to file adverse event reports with the FDA, the [c]ourt finds such claim [to be] impliedly preempted under *Buckman* [*Co.*]"); *Dawson* v. *Medtronic, Inc.*, Docket No. 3:13-cv-663-JFA, 2013 WL 4048850, *7 (D.S.C. August 9, 2013) (under California law, claim that defendant had violated federal regulations requiring it to provide information to FDA was impliedly preempted); *Conklin* v. *Medtronic, Inc.*, 245 Ariz. 501, 507, 431 P.3d 571 (2018) (Arizona common law providing that manufacturer may satisfy its duty to warn consumers of foreseeable risks by warning third party under learned intermediary doctrine does not require warning to "any and all third parties" but extends only to "prescribing and other [healthcare] providers" (internal quotation marks omitted)); *Cornett* v. *Johnson & Johnson*, 211 N.J. 362, 387–89, 48 A.3d 1041 (2012) (under New Jersey statute providing that manufacturer will not be liable for failure to warn if it "communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used," claim that defendant submitted fraudulent representations to or withheld material information from FDA was impliedly preempted under *Buckman Co.* (internal quotation marks omitted)).

[15] General Statutes § 1-1 (k) provides in relevant part: "The [word] 'person' . . . may extend and be applied to communities, companies, corporations, public or private, limited liability companies, societies and associations." The defendants make no claim that the FDA is not a "person" for purposes of § 52-572q (d).

[16] As we discuss more fully subsequently in this opinion, whether the manufacturer's failure to comply with federal law requiring it to report the adverse events associated with a medical device to the FDA had a causal relationship to a plaintiff's injury is a question of fact for the jury.

[17] For example, we may reasonably infer at this stage of the proceedings that the plaintiff intends to establish that the reason that the FDA changed the labeling for the Trulign Lens after the plaintiff's surgery was that the defendants provided new and more accurate information to the FDA about adverse events and that the defendants knew or should have known that there was a risk that, as the result of their failure to report all cases of Z syndrome to the FDA in a timely manner, healthcare providers would ultimately receive less than complete and accurate information about the dangers of the Trulign Lens.

[18] The defendants cite *Ward* v. *Greene*, 267 Conn. 539, 839 A.2d 1259 (2004), in support of their claim that public policy militates against imposing a state law duty to provide information to the FDA about the adverse effects of the medical devices for the benefit of users. The plaintiff in *Ward* brought a wrongful death action, alleging that the defendant, a private, nonprofit organization that contracted with individuals to provide daycare for children in need, had violated its duty under General Statutes (Rev. to 1997) § 17a-101 to report past incidents of child abuse committed by one of the individuals with whom it contracted. See id., 541–43. The trial court rendered summary judgment for the defendant on the ground that the defendant owed no duty to the plaintiff to report the abuse of children other than the plaintiff's decedent. See id., 544. On appeal, this court agreed, concluding that the class of persons that General Statutes (Rev. to 1997) § 17a-101 is intended to protect "is limited to those children who have been abused or neglected and are, or should have been, the subject of a mandated report," and does not include other children who are exposed to the alleged abuser. Id., 560.

The defendants contend that *Ward* supports their claim that their duty to warn about the adverse effects of medical devices under state law is limited to a particular class, namely, healthcare providers and users, and does not include a duty to report to the FDA. The short answer to the defendants' argument is that *Ward* provides little guidance for purposes of the present case because the CPLA is different from the mandated reporter statute, implicates different public policies, and imposes different duties. As we already explained, those duties include the manufacturer's duty to provide warnings about the inherent dangers of medical devices to the person best able to take or recommend precautions against the potential harm. We also note that our decision in *Ward* did not leave the plaintiff without *any* remedy for the decedent's death; presumably, she had a valid claim against the individual who caused the death.

With respect to the defendants' argument that recognizing a state law duty to provide information about adverse events to the FDA would interfere with "the regulatory framework [that] Congress has carefully constructed and imposed on medical device manufacturers," and would improperly allow "Connecticut juries to enforce the FDCA," those arguments go more properly to the issue of federal preemption, which is not before us, than to the existence of a state law duty. See footnote 9 of this opinion. We note, however, that we find it difficult to understand how recognizing a state law duty *to comply with federal law* could interfere with federal law. We recognize that the court in *Buckman Co.* v. *Plaintiffs' Legal Committee*, supra, 531 U.S. 341, stated that the conflict between "[state law] fraud-on-the-FDA claims" and federal law "stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the [a]dministration, and that this authority is used by the [a]dministration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the [a]dministration can be skewed by allowing fraud-on-the-FDA claims under state tort law." Id., 348; see id., 351 (concluding that state law fraud-on-FDA claims would dramatically increase burdens facing applicants by subjecting them to unpredictable civil liability and would increase burden on FDA by causing "applicants to fear that their disclosures to the FDA, although deemed appropriate by the [FDA], will later be judged insufficient in state court thereby prompting them to" submit "a deluge of information that the [FDA] neither wants nor needs"). The court in *Buckman Co.* also stated, however, that fraud-on-the-FDA claims are "*in contrast* to situations implicating . . . the historic primacy of state regulation of matters of health and safety . . . ." (Citation omitted; emphasis added; internal quotation marks omitted.) Id., 348; see *O'Neil* v. *St. Jude Medical, Inc.*, supra, 2013 WL 6173803, *3 ("[s]tates have traditionally exercised their police powers to protect the health and safety of their citizens, and Congress has not clearly signaled its intent to deprive [s]tates of any role in protecting consumers from the dangers inherent in many medical devices" (internal quotation marks omitted)). Thus, an argument can be made that fraud-on-the-FDA

claims are distinguishable from state law product liability claims under *Buckman Co.* for purposes of preemption. We further note that, *to the extent that disclosures to the FDA that are deemed compliant under federal law are deemed insufficient under state law*, federal law would preempt the application of state law.

[19] But see *English* v. *Bayer Corp.*, 468 F. Supp. 3d 573, 580 (W.D.N.Y. 2020) ("as a [stand-alone] claim, failure to report adverse events to the FDA is not a cognizable cause of action under New York law" (internal quotation marks omitted)); *Pearsall* v. *Medtronics, Inc.*, 147 F. Supp. 3d 188, 201 (E.D.N.Y. 2015) (New York law providing that "a drug manufacturer's duty is not to warn the patient, but to warn the medical profession of dangers inherent in its biological drugs [that], in the exercise of reasonable care, it knew or should have known to exist" is preempted because it "impose[d] obligations that are different from, or in addition to, the federal requirements" (internal quotation marks omitted)). It is not entirely clear to us whether the court's decision in *Pearsall*, on which the court in *English* relied; see *English* v. *Bayer Corp.*, supra, 580; concluded that the plaintiffs' claim was expressly preempted because the plaintiffs sought to impose a duty that federal law did not impose, namely, a duty to report dangers to the medical profession, or, instead, that the claim was impliedly preempted because New York law does not impose a duty to report medical dangers to the FDA, or that it was both expressly and impliedly preempted.

[20] But see *Norabuena* v. *Medtronic, Inc.*, 86 N.E.3d 1198, 1207 (Ill. App. 2017) ("[a]lthough 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" (citation omitted)), appeal dismissed, 111 N.E.3d 959 (Ill. 2018).

[21] But see *Cales* v. *Medtronic, Inc.*, Docket No. 14-CI-1774, 2014 WL 6600018 (Ky. Cir. November 21, 2014), modified on other grounds, 2015 WL 4081908 (Ky. Cir. July 1, 2015). The court in *Cales* observed in its initial decision that "[c]ourts have held that failure-to-warn claims based on failure to report adverse events to the FDA escape . . . both express and implied preemption. . . . The problem with [the] [p]laintiffs' claims is that although they have alleged that [the defendant] failed to warn the FDA about adverse events, they have not alleged how that failure to warn caused or contributed to their damages or injuries." (Citations omitted; internal quotation marks omitted.) Id., *14. The court granted permission to the plaintiffs to amend their complaint to remedy this defect. Id. Thus, the court suggested that, if the plaintiffs *could* allege causation, their failure to warn the FDA claim would survive. The court then stated that the plaintiffs had not offered "any persuasive reason why th[e] [c]ourt should permit them to pursue a failure-to-warn claim premised on [the defendant's] alleged failure to submit (unidentified) [adverse event] reports to the FDA" when any such claim would exist solely because of the FDCA disclosure requirement and, therefore, be preempted. Id. The court later addressed this apparent inconsistency and concluded that the "[p]laintiffs' failure-to-warn claim was in fact preempted, which would render any amendment of the claim futile." *Cales* v. *Medtronic, Inc.*, Docket No. 14-CI-1774, 2015 WL 4081908, *2 (Ky. Cir. July 1, 2015).

[22] The defendants contend that this holding is inconsistent with the court's holding in *Morris* v. *PLIVA, Inc.*, 713 F.3d 774 (5th Cir. 2013). *Morris* involved the labeling of generic drugs, which, under federal law, must bear the same labels as brand-name drugs. See id., 776. The court concluded that, although generic drug manufacturers might have a duty under federal law to alert the FDA of the need to strengthen warnings and labels, Louisiana tort law imposed no such duty. See id., 778.

[23] The defendants contend that this holding is inconsistent with the court's holding in *Flynn* v. *American Home Products Corp.*, 627 N.W.2d 342, 349 (Minn. App. 2001), that "common-law tort and statutory consumer fraud claims [related to drugs] are preempted by federal law and are not actionable in Minnesota." This portion of the court's analysis in *Flynn*, however, focused exclusively on the issue of preemption, which, as we explained, is not before us in this case. See footnote 9 of this opinion. With respect to the issue of whether Minnesota law would recognize claims for fraudulent misrepresentation or negligent misrepresentation, or a claim pursuant to Minnesota's consumer fraud statutes, the court in *Flynn* concluded that the plaintiff had failed to establish a genuine issue of material fact as to the elements of each of those torts. See id., 349–51. The plaintiffs in *Flynn* did not assert a product liability claim based on a failure to warn.

The defendants also cite to *Pinsonneault* v. *St. Jude Medical, Inc.*, 953 F. Supp. 2d 1006, 1015 (D. Minn. 2013), for the proposition that Minnesota law does not recognize a duty to warn the FDA of the dangers of medical devices as the basis of a failure to warn claim. See id. (duty under Minnesota law to warn users of safety hazards does not include duty to warn FDA). The later decision of the Minnesota Court of Appeals in *Angeles* v. *Medtronic, Inc.*, supra, 863 N.W.2d 404, is more authoritative than the decision of the United States District Court for the District of Minnesota on this issue of state law.

[24] The plaintiff also contends that the court in *Hughes* v. *Boston Scientific Corp.*, 631 F.3d 762, 769–71 (5th Cir. 2011), held that a claim that a manufacturer failed to comply with FDCA reporting requirements for adverse events is cognizable under Mississippi product liabilitylaw, as construed by Mississippi courts. The court in *Hughes*, however, appears to have merely *assumed* that that was the case for purposes of conducting its preemption analysis. See id., 769 ("[a]ssuming that a failure to warn claim may be pursued under Mississippi law . . . it is clear that such a claim is preempted only to the extent that it purports to impose liability despite . . . compliance with FDA regulations"). We also note that the United States District Court for the Southern District of Mississippi later observed that the Mississippi Supreme Court held after the *Hughes* decision that, in light of certain amendments to Mississippi statutes governing product liability law in 2014, Mississippi law provided the exclusive remedy for failure to warn claims. See *Knoth* v. *Apollo Endosurgery US, Inc.*, 425 F. Supp. 3d 678, 694–95 (S.D. Miss. 2019). The court in *Knoth* also observed that the court in *Hughes* had held only that the plaintiff had a cognizable claim "under a theory of negligence"; id., 694; despite the fact that the court in *Hughes* expressly cited the Mississippi product liability law. See *Hughes* v. *Boston Scientific Corp.*, supra, 769. The court in *Knoth* concluded that an allegation that the defendant had not provided timely adverse event reports to the FDA, as required by its regulations, did not constitute a claim that the "product was defective because it failed to contain adequate warnings or instructions," as provided by Mississippi product liability law. (Internal quotation marks omitted.) *Knoth* v. *Apollo Endosurgery US, Inc.*, supra, 695. Because we find the reasoning and conclusions of both *Hughes* and *Knoth* to be somewhat unclear, we do not find either case persuasive.

[25] Several of the other cases that the defendants cite in support of their claim that there is no state law duty to report adverse events to the FDA also concluded that any state law duty to report adverse effects of a medical device to the FDA would be the equivalent of the fraud-on-the-FDA claim that the court in *Buckman Co.* v. *Plaintiffs' Legal Committee*, supra, 531 U.S. 353, determined to be impliedly preempted, without determining whether a state law duty existed in the first instance. See *Mink* v. *Smith & Nephew, Inc.*, 860 F.3d 1319, 1330 (11th Cir. 2017) (claim under Florida common law that defendant violated duty to warn of dangers of medical device by failing to report dangers to FDA was impliedly preempted under *Buckman Co.*); *In re Medtronic, Inc., Sprint Fidelis Leads Product Liability Litigation*, supra, 623 F.3d 1205–1206 (claims in multidistrict litigation that defendant did not timely file adverse event reports with FDA, as required by federal regulations, were "simply an attempt by private parties to enforce the MDA" and were preempted under *Buckman Co.*); *Green* v. *Bayer Corp.*, 522 F. Supp. 3d 492, 502–503 (E.D. Ark. 2021) (because, unlike Arkansas law, federal law does not require manufacturers to provide warnings to healthcare providers and consumers, plaintiff's failure to warn claim was expressly preempted); *Hafer* v. *Medtronic, Inc.*, 99 F. Supp. 3d 844, 860 (W.D. Tenn. 2015) ("to the extent that [the] [p]laintiffs seek recourse for [the] [d]efendants' failure to file adverse event reports with the FDA, the [c]ourt finds such claim [to be] impliedly preempted under *Buckman* [*Co.*]"); *Dawson* v. *Medtronic, Inc.*, Docket No. 3:13-cv-663-JFA, 2013 WL 4048850, *7 (D.S.C. August 9, 2013) (applying California law and concluding that any state claim related to violation of federal regulations requiring manufacturer to provide information to FDA would be impliedly preempted); *Cornett* v. *Johnson & Johnson*, 211 N.J. 362, 387–89, 48 A.3d 1041 (2012) (under New Jersey statute providing that manufacturer will not be liable for failure to warn if it "communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used," claim that defendant submitted fraudulent representations to or withheld material information from FDA was impliedly preempted under *Buckman Co.* (internal quotation marks omitted)).

[26] Because the issue of federal preemption is for the United States Court of Appeals for the Second Circuit to decide; see footnote 9 of this opinion; we do not address the defendants' claim that federal laws and regulations preempt any state law duty to report the adverse effects of a medical device to the FDA that did not "preexist" the enactment of those laws and regulations. We note, however, that the duty that we recognize in this opinion is based on well established state law principles governing the statutory and common-law duty to provide warnings about a product to the person in the best position to take or recommend precautions and the general duty to use care.

[27] This assumes, of course, that the Second Circuit determines that the plaintiff's claim under the CPLA is not preempted by federal law.

At least one court has held to the contrary. In *Kubicki ex rel. Kubicki* v. *Medtronic, Inc.*, supra, 293 F. Supp. 3d 129, the court concluded that the plaintiffs' failure to warn claims "ultimately relie[d] on sheer speculation: [The] [p]laintiffs contend that, *if* [the defendant] had complied with the federal requirement to report adverse events to the FDA, and *if* the FDA had directed [the defendant] to update the label of the [medical device at issue] based on these reported events, then [the defendant] would have had the duty to provide adequate warnings to consumers, as [District of Columbia] common law requires. But it is by no means certain that the FDA would have directed [the defendant] to give consumers different or additional information about the [medical device] if the agency had been made aware of other incidents that predated [the] . . . injury. And unless such label changes would *necessarily* have occurred as a result of [the defendant's] failure to notify the FDA, [the] [p]laintiffs' contention that [the defendant's] failure to notify the agency is the functional equivalent of failing to warn consumers in violation of state law cannot be sustained." (Emphasis in original.) Id., 184. We fail to see why, at least under Connecticut law, a plaintiff making a claim based on a defendant's failure to comply with federal law requiring it to report adverse events to the FDA must establish that it is "certain" that reporting the events would "*necessarily*" have resulted in a label change for the claim to survive a motion to dismiss. As we explained, the plaintiff need only make a showing that a reasonable fact finder could conclude that it is more likely than not that, if the defendant had complied with the reporting requirements, the substance of the reports would have been made available in some form to the plaintiff's healthcare providers and the plaintiff's injuries would not have occurred.

[28] In *Soto*, this court characterized *Gerrity* as concluding that the plaintiff's "claim that [the] tobacco companies violated CUTPA by targeting minors with their cigarette advertising did not allege [a] product defect and, therefore, was not precluded by [the CPLA] . . . ." *Soto* v. *Bushmaster Firearms International, LLC*, supra, 331 Conn. 109. This characterization was based on the statement in *Gerrity* that "[t]he language of the exclusivity provision . . . suggests that it was not designed to serve as a bar to additional claims, including one brought under CUTPA, either *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 . . . ." (Emphasis added; internal quotation marks omitted.) *Gerrity* v. *R.J. Reynolds Tobacco Co.*, supra, 263 Conn. 128. The emphasized portion of this statement was dictum because the plaintiff in that case did claim that the cigarettes that caused the decedent's death were defective. See id., 123.

[29] As we have explained, an inherently dangerous medical device is deemed to be defective if it is not accompanied by adequate warnings. See, e.g., *Hurley* v. *Heart Physicians, P.C.*, supra, 278 Conn. 315 ("[a] product may be defective due to a flaw in the manufacturing process, a design defect or because of inadequate warnings or instructions" (internal quotation marks omitted)).

[30] As we explained, the plaintiff in *Gerrity* did not seek damages for personal injury, death or property damage in his CUTPA claim, and the plaintiffs in *Soto* did not allege that the product was defective. Thus, in neither case did the CUTPA claim subsume a CPLA claim.