

SUPREME COURT  
OF THE  
STATE OF CONNECTICUT

---

SC 20607

---

MARJORIE GLOVER, *ET AL.*,

*Plaintiffs-Appellants,*

v.

BAUSCH & LOMB INC., *ET AL.*,

*Defendants-Appellees.*

---

REPLY BRIEF FOR PLAINTIFFS-APPELLANTS

---

Hugh W. Cuthbertson  
Glenn A. Duhl  
ZANGARI COHN CUTHBERTSON  
DUHL & GRELO P.C.  
59 ELM STREET, SUITE 400  
NEW HAVEN, CONNECTICUT 06510  
TEL.: (203) 789-0001  
FAX: (203) 782-2766  
hcuthbertson@zcclawfirm.com  
gduhl@zcclawfirm.com

Wendy R. Fleishman (to argue)  
Daniel E. Seltz  
LIEFF CABRASER HEIMANN  
& BERNSTEIN, LLP  
250 HUDSON STREET,  
8<sup>TH</sup> FLOOR  
NEW YORK, NEW YORK 10013  
TEL.: (212) 355-9500  
FAX: (212) 355-9592  
wfleishman@lchb.com  
dseltz@lchb.com

Leslie A. Brueckner  
PUBLIC JUSTICE  
475 14<sup>TH</sup> STREET, SUITE 610  
OAKLAND, CALIFORNIA 94612  
TEL.: (510) 622-8205  
lbrueckner@publicjustice.net

## TABLE OF CONTENTS

	<b>Page</b>
INTRODUCTION .....	1
ARGUMENT .....	3
I. Connecticut Recognizes a Claim Based on a Failure to Report Adverse Events to a Regulator or Comply With a Regulator’s Conditions of Approval.....	3
A. B&L Breached Its Duty to Warn By Failing to Report Safety Issues and Perform the Required Safety Study.....	3
B. The Glovers Seek Compensation for Their Injuries, Not to Enforce the FDCA. ....	9
II. Plaintiffs’ CUTPA Claim Is Cognizable.....	13
CONCLUSION.....	15

## TABLE OF AUTHORITIES

Page

### CASES

<i>Basko v. Sterling Drug, Inc.</i> , 416 F.2d 417 (2d Cir. 1969).....	7, 12
<i>Bausch v. Stryker</i> , 630 F.3d 546 (7th Cir. 2010).....	5, 12
<i>Buckman v. Plaintiffs’ Legal Committee</i> , 531 U.S. 341 (2001).....	10, 11, 12
<i>Caplinger v. Medtronic, Inc.</i> , 784 F.3d 1335 (10th Cir. 2015).....	3
<i>Desiano [v. Warner-Lambert &amp; Co.]</i> , 467 F.3d 85 (2006).....	9
<i>Gerrity v. R.J. Reynolds Tobacco Co.</i> , 263 Conn. 120, 818 A.2d 769 (2003).....	14
<i>Glover v. Bausch &amp; Lomb Inc.</i> , 6 F.4th 229 n.9 (2d Cir. 2021).....	9, 10
<i>Hurley v. Heart Physicians, P.C.</i> , 278 Conn. 305, 898 A.2d 777 (2006).....	4
<i>In re Allergan Biocell Textured Breast Implant Prods. Liab. Litig.</i> , No. 2:19-MD-2921-BRM-ESK, 2021 WL 1050910 (D.N.J. Mar. 19, 2021).....	7
<i>In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.</i> , 623 F.3d 1200 (8th Cir. 2010).....	8
<i>Lohr v. Medtronic</i> , 518 U.S. 470 (1996).....	10, 11
<i>McConologue v. Smith &amp; Nephew, Inc.</i> , 8 F. Supp. 3d 93, 101 (D. Conn. 2014).....	3
<i>Mendez v. Shah</i> , 28 F. Supp. 3d 282 (D.N.J. 2014).....	12
<i>Nagel v. Smith &amp; Nephew</i> , 15-cv-00927-JAM, 2016 WL 4098715 (D. Conn. July 28, 2016).....	3, 11
<i>Prokolkin v. General Motors Corp.</i> , 170 Conn. 289, 365 A.2d 1180 (1976).....	7
<i>Richardson v. Bayer Healthcare Pharms. Inc.</i> , No. 4:15-CV-00443-BLW, 2016 WL 4546369 (D. Idaho Aug. 30, 2016)	6

**TABLE OF AUTHORITIES**  
**(continued)**

	<b>Page</b>
<i>Riegel v. Medtronic, Inc.</i> , 552 U.S. 312 (2008).....	10
<i>Riley v. Cordis Corp.</i> , 625 F. Supp. 2d 769 (D. Minn. 2009).....	3
<i>Silver v. Medtronic, Inc.</i> , 236 F. Supp. 3d 889 (M.D. Pa. 2017) .....	6
<i>Soto v. Bushmaster Firearms Int'l, LLC</i> , 331 Conn. 53, 202 A.3d 262 (2019).....	13
<i>Vitanza v. Upjohn Co.</i> , 257 Conn. 365, 778 A.2d 829 (2001).....	4
<i>Ward v. Greene</i> , 267 Conn. 539 (2004) .....	12

**STATUTES**

21 U.S.C. § 360k(a)(1) .....	10
Conn. Gen. Stat. § 52-572n(a) .....	13
Conn. Gen. Stat. § 52-572q.....	6
Conn. Gen. Stat. § 52-572q(b) .....	7
Restatement (Second) of Torts § 388.....	5, 6

## INTRODUCTION

This case involves an attempt by a manufacturer to completely avoid liability for knowingly selling a dangerous medical device that can cause blindness. As explained in their opening brief, Defendants (collectively “B&L”) failed to report known post-market safety problems involving the Trulign Lens to the Food and Drug Administration (“FDA”)—problems that have nearly blinded Plaintiff Marjorie Glover. B&L also violated the FDA’s unusual condition that it commence a safety study of the device within 30 days of its conditional approval. B&L delayed the required study for over *two years*, no doubt because it knew that the study would reveal the dangers it sought to conceal. B&L’s actions deprived Mrs. Glover, her doctors, and the medical community of safety information that could have guided their choices and prevented Mrs. Glover’s injuries.

Indeed, it was only after it conducted the required study, but too late for Mrs. Glover, that B&L updated the warnings on the Trulign Lens to include “Z Syndrome,” the harmful adverse effect that Mrs. Glover experienced. Because of B&L’s failures to warn the FDA of the device’s defects, Mrs. Glover is almost blind, and likely will become completely blind. None of this would have happened if B&L fulfilled its duty to warn the FDA of the dangers of its device.

In their opening brief, Plaintiffs explained how these allegations unquestionably state a cause of action under Connecticut’s Product Liability Act (“CPLA”) under both negligence and failure to warn theories, applying established principles of Connecticut law. They argued, in a nutshell, that the same actions that violated the FDA’s requirements *also* violated Connecticut law: by failing to inform the FDA of known safety issues, B&L breached its duty to warn Mrs. Glover, through her doctor, of the risks of the Trulign Lens.

In its brief, B&L asks this Court to allow it to shirk those duties by finding these claims non-cognizable under the CPLA. It asks this Court to do something radical: to hold, as a matter of law, that there can and should be *no* consequences when a medical device manufacturer sells a dangerous device to a Connecticut resident while withholding from the regulator – the entity best positioned to convey up-to-date safety information to Connecticut doctors – information that could prevent injury. B&L disclaims any responsibility to patients like Mrs. Glover in carrying out its responsibilities with respect to the FDA, even as it concedes that the duty to warn includes warnings owed to third parties and that its duty to warn extends post-sale. B&L’s position, if adopted by this Court, would directly threaten the health and safety of Connecticut citizens. It should be rejected.

Plaintiffs’ opening brief also explained why this Court should answer the Second Circuit’s second question – whether the CPLA’s exclusivity provision bars a claim based on allegations that a manufacturer deceptively and aggressively marketed and promoted a product despite knowing that it presented a substantial risk of injury – in the negative. This Court has previously held that the CPLA’s exclusivity provision preempts only common law claims, and not claims alleging injury from unfair trade practices. Plaintiffs here have alleged distinct conduct about B&L’s marketing of the Trulign Lens, and should be permitted to pursue their CUTPA claim in conjunction with their CPLA claims.

## ARGUMENT

### I. Connecticut Recognizes a Claim Based on a Failure to Report Adverse Events to a Regulator or Comply With a Regulator's Conditions of Approval

#### A. B&L Breached Its Duty to Warn By Failing to Report Safety Issues and Perform the Required Safety Study.

B&L's primary argument for avoiding any potential liability for Mrs. Glover's injuries is that its duty to warn runs only to Mrs. Glover through her physician. See Br. at 12 (arguing that Connecticut does not recognize "a post-regulatory approval duty to warn of known dangers to a federal regulator."). B&L's formulation is an evasion. The question is not whether B&L owes the FDA a duty to warn, as if the FDA were in danger of being injured by B&L's products. It is whether, by failing to report adverse events to the FDA and otherwise comply with conditions of the Trulign Lens' approval, B&L breached its duties to Mrs. Glover under Connecticut law and failed to warn Mrs. Glover and her doctors. As previously explained (Pls' Br. at 15-28), Connecticut law is clear that such allegations state a claim under the CPLA. Each of the arguments B&L makes in trying to evade liability for the breach of its duties runs afoul of principles that this Court and other Connecticut courts have long recognized, including the duty to warn third parties where necessary and Connecticut's post-sale duty to warn.<sup>1</sup>

---

<sup>1</sup> The first set of cases that B&L relies on (at 11) do not shed light on the question at hand, or they support Plaintiffs. The non-Connecticut cases cited on that page merely describe preemption jurisprudence, including a plaintiff's obligation to assert state law claims that parallel federal law. See *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1339 (10th Cir. 2015). Other cases are factually inapposite. In *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769 (D. Minn. 2009), for example, alleged failures to report adverse events were not a factor, because the plaintiff's device was implanted only a week after FDA approval. *Id.* at 789-90. Two of the Connecticut district court cases, *Nagel v. Smith & Nephew*, 2016 WL 4098715, at \*7 (D. Conn. July 28, 2016); *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 101, 109 (D. Conn. 2014), indicate that allegations of a device manufacturer's failure to report adverse events, if properly and sufficiently pled, would state a claim under the CPLA—as the Glovers argue here.

1. Importantly, B&L does not dispute that it owes a duty to warn of the known dangers of the Trulign Lens. However, B&L seeks to shrink that duty to a vanishing point through a misguided reliance on the learned intermediary doctrine. B&L leans heavily on this Court's two decisions adopting that doctrine, *Vitanza v. Upjohn Co.*, 257 Conn. 365 (2001), and *Hurley v. Heart Physicians, P.C.*, 278 Conn. 305 (2006), which hold that a manufacturer may discharge its duty to warn by warning a patient's doctor. Citing these cases, B&L says that it has no cognizable state-law duty to tell the FDA about known safety defects in its products, no matter how big a danger they pose to public safety and regardless of whether the FDA itself requires such information. But therein lies the rub, because the primary source of information for updated and developing information about medical devices for doctors is the FDA.

Thus, as Plaintiffs explained in their opening brief (at 19-21), there is nothing inconsistent in recognizing the Glovers' CPLA claims as pled and the learned intermediary doctrine. Under that doctrine, B&L must ensure that physicians are properly warned. Mrs. Glover has alleged that by failing to comply with its obligations to the FDA, B&L effectively failed to warn her doctors of the Trulign Lens' dangers. Those obligations – reporting known safety issues to the FDA and conducting a study that the FDA required as a condition of approval – are precisely how doctors and their patients are warned; they make up a bare minimum of what B&L must do to discharge its duties. B&L's argument to the contrary ignores the reality that doctors get their information from the FDA and are a key part of B&L's duty to act as a reasonably prudent manufacturer.

2. In addition, as Plaintiffs set out in their opening brief (at 21-22), a defendant's violation of a statute or regulation has long been an accepted form of proof

of negligence. B&L's request that courts turn a blind eye to allegations that it violated the law is contrary to both logic and Connecticut law, particularly in a case involving Class III medical devices, which pose unique dangers to patients. As the Seventh Circuit held in another case involving a Class III medical device, federal standards are "tied directly to the duty of manufacturers to avoid foreseeable dangers with their products by complying with federal law." *Bausch v. Stryker*, 630 F.3d 546, 557 (7th Cir. 2010). Evidence of a violation of federal law "goes a long way toward showing that the manufacturer breached a duty under state law toward the patient." *Id.*

So too here. B&L's *multiple* post-approval violations of the FDA's requirements are directly relevant to showing that B&L failed to exercise due care in designing and warning about the Trulign Lens. While B&L attempts to separate its failure to report adverse events from its outrageous refusal to timely begin the required safety study, devoting a separate section of its brief to it (at 18-19), the two failures are related, as the Second Circuit's certified question reflects. Both constitute straightforward violations of regulations that Connecticut has long held can be offered as evidence of negligence.

**3.** B&L also invokes the Second Restatement of Torts, including Section 388, in an attempt to absolve it of any responsibility to provide full and accurate information to the FDA as part of its warnings to Mrs. Glover and her doctors. See Br. at 13-14. Section 388, however, supports Plaintiffs here. Section 388 mirrors the CPLA: it provides that a supplier of property known to be dangerous is liable for injuries caused by the chattel if the supplier "fails to exercise reasonable care" to warn of the chattel's dangerous condition. Restatement (Second) of Torts § 388(c); see Conn. Gen. Stat. §

52-572q (providing for cause of action where “adequate warnings or instructions were not provided”).

That standard fits here. Plaintiffs allege that B&L “fail[ed] to exercise reasonable care” by failing to inform the FDA of known safety issues with the Trulign Lens. The accompanying comments explicitly acknowledge that the “party supplying the chattel”—here, B&L—may sometimes have to inform a “third party”—here, the FDA—of the chattel’s dangerous condition. See Restatement (Second) of Torts § 388 cmt. n (“the question may arise as to whether the person supplying the chattel is exercising that reasonable care, which he owes to those who are to use it, by informing the third person through whom the chattel is supplied of its actual character.”). The Restatement does not support B&L’s attempt to disclaim any duty to warn the FDA of the dangers of the Trulign Lens; it does the opposite.

In fact, multiple other states have explicitly rejected attempts like B&L’s to rely on Section 388 to avoid liability in similar cases. For example, in *Richardson v. Bayer Healthcare Pharms. Inc.*, 2016 WL 4546369 (D. Idaho Aug. 30, 2016), the court pointed to Idaho’s adoption of Section 388 as *support* for its holding that where a “third party intermediary may play a critical role in adequately warning users of a foreseeably dangerous product,” a manufacturer’s duty to warn, in the context of Class III medical devices, “should be construed to include warnings and reports to the FDA.” *Id.* at \*8 (citation omitted). Similarly, in *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889 (M.D. Pa. 2017), the court pointed to Pennsylvania’s adoption of Section 388 to conclude that a duty to provide “information about the product’s dangerous propensities” is parallel to FDA reporting requirements. *Id.* at 900. See also *In re Allergan Biocell Textured Breast*

*Implant Prods. Liab. Litig.*, 2021 WL 1050910, at \*11 (D.N.J. Mar. 19, 2021) (Section 388 “may establish a device manufacturer's traditional state law duty to warn by reporting adverse safety events to the FDA”).

In short, the Restatement affirmatively supports Plaintiffs’ argument that the duty to warn in Connecticut includes the duty to provide information to relevant third parties, whether doctors (as recognized by the learned intermediary doctrine), or regulators who play a key role in disseminating what the manufacturer knows about safety issues.<sup>2</sup>

4. As previously argued (Br. at 19-21), Plaintiffs’ CPLA claim is also consistent with Connecticut’s well-established post-sale duty to warn. B&L’s statements about that post-sale duty to warn are as misplaced as those about the Restatement: it acknowledges that duty, but suggests it somehow may not apply to medical device manufacturers. See Br. at 14 n.7. B&L does not say why this would be, and concedes that the case it relies on, *Prokolkin v. General Motors Corp.*, 170 Conn. 289 (1976) (a case involving the application of the statute of limitations), involved strict liability, not negligence. It cites no case that calls into question a post-sale duty to warn in negligence actions, and indeed, that duty has long been recognized in Connecticut, including in the context of FDA-approved drugs. See *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 426 (2d Cir. 1969) (“When the risk became apparent, however, a duty to warn attached.”).

---

<sup>2</sup> While B&L asserts that it has no duty to provide warnings to third parties with “no relationship with the plaintiff” (Br. at 14), there is nothing in the CPLA that so limits a manufacturer’s duties. To the contrary, the CPLA uses broad language to describe the non-exclusive factors a jury “may consider” in determining whether proper warnings were provided. See Conn. Gen. Stat. § 52-572q(b).

B&L does not grapple with these principles long applied specifically in Connecticut. Instead, it provides a string citation of cases (at 16-17) from other jurisdictions to claim that the “overwhelming majority that have confronted the question” (Br. at 16) have found no state law claim based on a failure to report adverse events to the FDA. But it ignores the long list of states provided by Plaintiffs whose courts have done just that, see Pls.’ Br. at 24-27, and makes no attempt to show that the laws of the states whose decisions it cites look anything like the CPLA, that the allegations in those cases mirrored the Glovers’ allegations, or that the decisions even involved the determination that this Court has agreed to make: whether state law recognizes a cause of action based on a failure to report adverse events or comply with a regulator’s conditions of approval.<sup>3</sup>

Nor does B&L acknowledge the startling implications of the holding that it seeks from this Court. B&L asks this Court to weaken the CPLA to the point that the duties that this state has long recognized as necessary to protect Connecticut consumers’ health and safety would be rendered illusory. If B&L had its way, it would be free to violate all of its obligations as a medical device manufacturer and escape liability for otherwise avoidable injuries. If B&L’s failure to warn FDA about the serious dangers of its product were not cognizable under Connecticut law, there would be no way to protect Connecticut residents from dangerous medical devices. Fortunately, that outcome is neither compelled nor supported by the CPLA or Connecticut law.

---

<sup>3</sup> Certain courts have addressed failure-to-report claims not by determining whether state law recognizes such a claim, but instead disposed of the claims by holding that they were attempts to enforce the FDCA. See, e.g., *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1203 (8th Cir. 2010).

**B. The Glovers Seek Compensation for Their Injuries, Not to Enforce the FDCA.**

Perhaps recognizing that the Glovers' cause of action is cognizable under a direct application of Connecticut law, B&L attempts to shift this Court's focus away from the first certified question and onto federal preemption issues not before the Court. B&L repeatedly argues that the Glovers seek to "enforce the FDCA" and that allowing the Glovers' claims to proceed would "interfere with the federal regulatory framework" constructed for medical devices. Br. at 19. Those issues are not before the Court, and even if they were, B&L misstates the potential implications of a ruling that Connecticut (like numerous other states) would allow claims based on a failure to report adverse events or comply with a regulator's conditions of approval. It also mischaracterizes federal law as effectively banning damages actions involving medical devices, and mischaracterizes the Glovers' claims as an attempt to "enforce the FDCA." Br. at 21.

First, contrary to B&L's assertions, neither the Glovers nor the Second Circuit has invited this Court to "re-write federal law." Br. at 21. The Second Circuit explicitly limited the scope of the questions that it certified to this Court, emphasizing that "[b]ecause preemption is a question of federal law, *see Desiano [v. Warner-Lambert & Co.]*, 467 F.3d 85, 91 (2006)], we certify only the question of whether Connecticut law recognizes such a cause of action, *and not whether that cause of action would be preempted under the FDCA.*" *Glover v. Bausch & Lomb Inc.*, 6 F.4th 229, 241 n.9 (2d Cir. 2021) (emphasis added).

The Second Circuit will take this Court's definitive answers about the scope of the CPLA and then apply that answer within the preemption framework that it set out. *See id.* at 236-39, 241 (noting that answer to question of state law is "potentially

dispositive of this appeal”). B&L asks this Court to short-circuit the analysis: rather than declare state law, which will guide a preemption analysis, B&L asks this Court to apply federal law and declare that no plaintiff can bring a claim like the Glovers’ claim here.

In ranging well beyond the first certified question, B&L also paints a distorted picture of the preemption landscape in which virtually no state damages actions are permitted. However, notwithstanding B&L’s lengthy discussion of the FDA’s “exclusive authority to enforce the FDCA” and those enforcement tools (Br. at 19-20), the United States Supreme Court has repeatedly rejected attempts to foreclose state damages actions for defective medical devices. See *Lohr v. Medtronic*, 518 U.S. 470, 491 (1996) (“§ 360k simply was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions.”); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (“§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.”) (quoting 21 U.S.C. § 360k(a)(1)). In *Buckman v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001), the Court held that a plaintiff cannot step into the shoes of the FDA to police “fraud-on-the-FDA,” as such a claim is impliedly preempted, but distinguished such a claim from one based on “traditional state tort law principles of the duty of care.” *Id.* at 351-52.

As the Second Circuit explained, these decisions opened a “narrow gap” for state law damages claims involving defective medical devices. “The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).” *Glover*, 6 F. 4th at 237

(quotation and citation omitted). B&L, in seeking a categorical ruling that the Glovers' damages claim is an attempt to enforce the FDA simply because the Glovers have identified violations of federal law, seeks to erase that gap entirely so that any invocation of FDCA regulations renders a claim preempted. That is not the law. The Glovers have identified conduct that violates the FDCA and also violates parallel state duties.

Further, the compensatory damages that the Glovers seek do not constitute "enforcement" of the FDCA. Their case has nothing to do with the set of enforcement tools that B&L lists as exclusive to the FDA – fraud investigations, criminal prosecutions, withdrawal of pre-market approval (Br. at 20) – indeed, such tools are "of little use to injured plaintiffs." *Lohr*, 518 U.S. at 487 n.7. Those tools belong to the FDA; the Glovers seek only compensation permitted under Connecticut law. The Glovers' invocation of the CPLA to seek such damages cannot remotely be called an attempt to "usurp FDA's exclusive authority," in B&L's overheated characterization. Br. at 20.

It is also far from a case like *Buckman*, in which the plaintiffs based their claims not from an "alleged failure to use reasonable care in the production of the product," but "solely from the violation of FDCA requirements." 531 U.S. at 352-53. The Glovers' claims here are not an attempt to hijack any agency process; they seek compensation caused by B&L's negligent conduct under the CPLA.<sup>4</sup> See *Mendez v. Shah*, 28 F.

---

<sup>4</sup> In the cases cited by B&L (all but one of them from outside Connecticut), applying *Buckman*, courts determined that the plaintiffs' claims existed solely by virtue of FDCA violations. See Br. at 19. The sole Connecticut case cited, *Nagel*, 2016 WL 4098715, did not find that Connecticut did not recognize plaintiff's failure to warn claim, only that the plaintiff had failed to allege facts sufficient "to indicate the defendant failed to comply with FDA requirements regarding reporting adverse events *that would provide the basis for a parallel claim*" (emphasis added).

Supp. 3d 282, 291 (D.N.J. 2014) (noting that *Buckman* “is often limited to ‘fraud-on-the-agency’ claims and not extended to claims based on state law tort principles (citing *Bausch*, 630 F.3d at 557).

Damages actions for federally regulated defective drugs existed in this state (and many others) long before Congress passed the Medical Device Amendments (“MDA”) in 1976. See *Basko*, 416 F.2d 417 (applying Connecticut law). B&L points to nothing in the CPLA’s legislative history or passage that indicates the legislature intended to cut off claims involving medical devices in light of the passage of the MDA, or that allowing Connecticut juries to find facts in cases involving dangerous medical devices would interfere with FDA enforcement or upset the balance of state and federal power, as B&L warns of here. See Br. at 19-20. B&L’s attempt to equate the Glovers’ CPLA claims with agency enforcement of the FDCA (which this Court need not consider at all) should be rejected.

Given the state of the law relevant to medical devices, B&L is left to make a strained analogy to *Ward v. Greene*, a wrongful death action brought by the mother of a child who died in the custody of a day care facility, brought against an organization that had contracted with the facility. 267 Conn. 539, 541-42 (2004). The plaintiff alleged that this tragedy would have been avoided had the organization reported suspected abuse of other children. This Court concluded that the defendant agency did not owe a duty of care to the mother, but only to identifiable victims of abuse. *Id.* at 560. This case does not help B&L. Unlike in *Ward*, where the defendant had merely failed to report prior abuse, B&L is *both* the wrongdoer *and* the defendant failing to follow federal law in reporting adverse events. And where *Ward* turned on whether the defendant

owed a duty of care to the plaintiff, B&L does not deny such a duty here. It only seeks to cut Plaintiffs off from showing the ways in which it did not discharge its duty.

## **II. Plaintiffs' CUTPA Claim Is Cognizable.**

As previously argued, this Court need only adhere to its prior holdings to conclude that Plaintiff's unfair trade practices claim is cognizable under CUTPA. This Court has previously held that these two statutes cover distinct conduct, and that the CPLA's exclusivity provision—which merely covers “actions of negligence, strict liability, and warranty,” Conn. Gen. Stat. § 52-572n(a) —was merely intended to simplify pleadings and prevent needlessly repetitive separate causes of action, while leaving CUTPA claims intact. See Pls.' Br. at 28-29. Although the CPLA sometimes preempts common law claims based on injuries from defective products, this Court has been clear that a plaintiff may concurrently bring CUTPA claims that allege injuries attributable to aggressive and unethical marketing of an inherently dangerous product. See *Soto v. Bushmaster Firearms Int'l, LLC*, 331 Conn. 53, 116 (2019). Plaintiffs here have alleged conduct that makes out both claims, and should be able to pursue them together.

B&L nonetheless insists that allowing Plaintiffs' claim under CUTPA would render the CPLA's exclusivity provision “useless,” because the CPLA is the exclusive remedy for “actions of *negligence*, strict liability and warranty, for harm caused by a product.” Br. at 28. (citing Conn. Gen. Stat. § 52-572n(a); emphasis added). B&L argues that because Plaintiffs' failure-to-warn claim is negligence-based, allowing Plaintiffs to sue under CUTPA would render the exclusivity provision's reference to “actions of negligence” superfluous.

B&L is wrong on two counts. First, Plaintiffs' CUTPA claim is not a negligence claim; to the contrary, it is based on B&L's unfair trade practices: specifically, B&L's

unlawful and aggressive marketing of its device as safe and effective. This is exactly the type of unscrupulous trade practice that CUTPA was designed to address. It is also a claim that was conspicuously *omitted* from § 52-572n(a), which merely provides that the CPLA is the exclusive remedy for “actions of negligence, strict liability and warranty...”. As this Court explained in *Gerrity v. R.J. Reynolds Tobacco Co.*, 263 Conn. 120, 128–29 (2003), CUTPA’s legislative history reveals that the exclusivity provision was merely “intended to cut down on the number of counts in a complaint for injuries caused by a product. It [was] not intended to affect other state statutory schemes such as anti-trust acts *or the state unfair trade practice act.*” (Emphasis altered from original). If anyone’s interpretation runs afoul of the CPLA’s exclusivity provision, it is B&L’s, not the Glovers’.

Second, B&L’s argument that excluding unfair trade practices claims from the CPLA’s exclusivity provision would render that provision “useless” ignores that, under Plaintiffs’ reading, the provision will still make the CPLA the exclusive remedy for all the claims listed therein—including negligent failure-to-warn claims, strict liability claims, and warranty claims. The only type of claim that would *not* be included under the Glovers’ reading of that provision are marketing claims that are *distinct* from failure-to-warn claims. Excluding that type of claim from the CPLA does no violence to the statute’s text; is consistent with its legislative history; and ensures that CUTPA’s powerful remedies remain available to address unethical marketing practices designed to trick consumers into using dangerous products.

B&L is also wrong as a factual matter. B&L argues (at 28-29) that because Plaintiffs’ CUTPA claim is based on the same conduct as their CPLA claim, the CUTPA

claim is necessarily covered by the CLPA exclusivity provision's reference to "negligence" claims. This argument is solely based on selected excerpts from Plaintiffs' Third Amended Complaint, which B&L says show that Plaintiffs' marketing claim rests on the same conduct as their failure-to-warn claim. Br. at 29. But as Plaintiffs pointed out in their opening brief, "[a]mong other allegations of particularly aggressive marketing, Plaintiffs alleged that Bausch employed paid physician promoters to persuade doctors to use devices that Bausch knew posed serious risks of injury and that its representatives were physically present during Mrs. Glover's surgery." Pls.' Br. at 11 (citing A14). Allegations of aggressive marketing – particularly of a product whose conditions of approval B&L 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. Plaintiffs should be permitted to pursue damages related to such marketing in conjunction with damages caused by B&L's negligence and failure to warn of the Trulign Lens' defects.

B&L's argument also ignores that this case went up on appeal following the district court's ruling on a motion to dismiss, prior to any formal discovery. Plaintiffs should be permitted to take discovery of B&L's representatives and agents to further demonstrate that their CUTPA claim rests on marketing allegations distinct from any alleged defect in the device at issue here.

### **CONCLUSION**

The Court should affirm that Connecticut recognizes a cause of action based on the Glovers' allegations, and that the CPLA does not preempt their CUTPA claim.

Dated: October 7, 2021

Respectfully submitted,

By: /s/ Hugh W. Cuthbertson

By: /s/ Wendy R. Fleishman

Hugh W. Cuthbertson  
hcuthbertson@zcclawfirm.com  
Glenn A. Duhl  
gduhl@zcclawfirm.com  
ZANGARI COHN CUTHBERTSON  
DUHL & GRELO P.C.  
59 Elm Street, Suite 400  
New Haven, CT 06510  
Telephone: (203) 789-0001  
Facsimile: (203) 782-2766

Wendy R. Fleishman  
wfleishman@lchb.com  
Daniel E. Seltz  
dseltz@lchb.com  
LIEFF CABRASER HEIMANN  
& BERNSTEIN, LLP  
250 Hudson Street, 8th Floor  
New York, NY 10013-1413  
Telephone: (212) 355-9500  
Facsimile: (212) 355-9592

Leslie A. Brueckner  
lbrueckner@publicjustice.net  
PUBLIC JUSTICE  
475 14th Street, Suite 610  
Oakland, CA 94612  
Telephone: (510) 622-8205

*Attorneys for Plaintiffs-Appellants*

## CERTIFICATIONS

I, hereby certify, on this 7<sup>th</sup> day of October, 2021, the following:

1. On October 7, 2021, I caused a copy of the foregoing Reply Brief of the Plaintiffs-Appellants (“Reply Brief”) to be served on the following counsel of record for Defendants by email and to be filed with the appellate clerk:

Toby S. Soli, Esq.  
Robert J. Kirshenbergr, Esq.  
Greenberg Traurig, LLP  
MetLife Building  
200 Park Avenue  
New York, NY 10166  
(212) 801-9200  
solit@gtlaw.com  
kirshenbergr@gtlaw.com

Lori G. Cohen, Esq.  
Greenberg Traurig, LLP, Terminus 200  
3333 Piedmont Rd., NE,  
Suite 2500, Atlanta, GA 30305  
(678) 553-2385  
lcohen@gtlaw.com

Jeffrey R. Babbin  
Wiggin and Dana LLP  
265 Church Street  
P.O. Box 1832  
New Haven, CT 06508-1832  
(203) 498-4366  
jbabbin@wiggin.com

Adam C. Martin, Esq.  
Thomas Henry Balestracci, Esq.  
Cetrulo LLP  
Two Seaport Lane  
10th Floor  
Boston, MA 02210  
(617) 217-5500  
amartin@cetllp.com  
tbalestracci@cetllp.com

2. The Reply Brief being filed with the appellate clerk are true copies of the brief which was submitted electronically pursuant to Rule of Appellate Procedure § 67-2(g).

3. The Reply Brief does not contain any names or other personal identifying information that is prohibited from disclosure by rule, statute, court order, or case law.

4. The Reply Brief complies with the format requirements of Rule of Appellate Procedure § 67-2.

Dated: October 7, 2021

By: /s/ Wendy R. Fleishman  
Wendy R. Fleishman

Attorneys for Plaintiffs-Appellants