SUPREME COURT

OF THE

STATE OF CONNECTICUT

SC 20607

MARJORIE GLOVER, *ET AL.*,

Plaintiffs-Appellants,

v.

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

Defendants-Appellees.

BRIEF FOR PLAINTIFFS-APPELLANTS

Hugh W. Cuthbertson
Glenn A. Duhl
ZANGARI COHN CUTHBERTSON
DUHL & GRELLO 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

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

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

TABLE OF CONTENTS

Page

TABLE OF CONTENTS
(continued)

Page

STATEMENT OF ISSUES

1. Whether a cause of action exists under the negligence or failure-to-warn provisions of the Connecticut Product Liability Act, Conn. Gen. Stat. §§ 52-572h, 52-572q, or elsewhere in Connecticut law, based on a manufacturer's alleged failure to report adverse events to a regulator like the FDA following approval of the device, or to comply with a regulator's post-approval requirements. Pp. 15-28.

2. Whether the Connecticut Product Liability Act's exclusivity provision, Conn. Gen. Stat. § 52-572n, bars a claim under the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. § 42-110a, *et seq.*, based on allegations that a manufacturer deceptively and aggressively marketed and promoted a product despite knowing that it presented a substantial risk of injury. Pp. 28-35.

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

STATUTES

REGULATIONS

INTRODUCTION AND SUMMARY OF ARGUMENT

This case arises out of serious, debilitating, and permanent injuries suffered by the plaintiff, Mrs. Marjorie Glover, caused by a defective product manufactured by the Defendants-Appellees (hereinafter collectively "Bausch"), called the Trulign Lens. Following cataract surgery in 2014 in which Trulign Lenses were implanted, Ms. Glover lost vision in both eyes. Since then, she has endured numerous painful surgeries, procedures and tests as her vision further deteriorated. She now faces a future of permanent and total loss of vision in both of her eyes.

The Trulign Lens was designed and marketed as a surgical correction for cataracts. Mrs. Glover had cataract surgery in both eyes in the fall of 2014, in which Trulign Lenses were implanted to replace the natural lenses that are removed as part of the surgery. Not only did the Trulign Lens not work, they ruined Mrs. Glover's eyes. She was diagnosed with Z Syndrome in both of her eyes, a post-operative complication unique to the Trulign Lens and its predecessor, in which part of the lens is pulled forward and the other stays in place or is pushed backward. This asymmetric vaulting of the lenses resembles the letter Z. Mrs. Glover has since endured *eight* surgeries, over *100* tests and procedures, and devastating deterioration of her vision. She now faces likely permanent and total loss of vision—complete blindness—in both of her eyes. Pieces of the broken lenses cannot be removed from her eyes.

This never should have happened. The U.S. Food & Drug Administration ("FDA"), the federal agency responsible for regulating medical devices under the Food, Drug, and Cosmetic Act ("FDCA"), knew the Trulign Lens was questionable even before it issued its approval of the device in 2013. Because of known safety issues with the lenses, the agency actually *conditioned* approval of the device on Bausch conducting a post-approval

study of the device and required Bausch to submit the study's protocol within 30 days of conditional approval. But Bausch delayed the start of the required safety study for *two years*, and then, making matters worse, failed to tell the FDA about myriad instances in which the Trulign Lens injured patients—both failures in direct violation of FDA requirements. Bausch's blatant disregard of the FDA's directives deprived Mrs. Glover and her doctor of crucial safety information that would have guided their choices and prevented her injuries.

Mrs. Glover and her husband sued Bausch under the Connecticut Product Liability Act, ("CPLA"), alleging that Bausch's failures to comply with its post-approval duties violated the law. In addition, following this Court's decision in *Soto v. Bushmaster Firearms Int'l, LLC*, 331 Conn. 53 (2019), which recognized, for the first time, a claim for damages for personal injuries caused by unlawful marketing under Connecticut's Unfair Trade Practices Act ("CUTPA"), Plaintiffs sought to amend their complaint to add a claim under CUTPA, alleging injuries stemming from Bausch's aggressive and unethical marketing of the Trulign Lens in which Bausch pushed a product to doctors across the United States despite knowing that the device could cause serious and permanent injuries.

The district court dismissed Plaintiffs' claims on the grounds that the claims were preempted by federal law, holding that Plaintiffs could not base their negligence or failure-to-warn claims on Bausch's failures to meet FDA requirements, even though Plaintiffs' claims were predicated on violations of state, not federal, law. The district court also denied Plaintiffs' motion for leave to amend their complaint to add a claim under CUTPA for Bausch's unlawful marketing of the Trulign Lens, even though the marketing involved

conduct entirely distinct from Bausch's failures to apprise the FDA (and, by association, prescribing physicians) of the device's dangers.

On appeal, the U.S. Court of Appeals for the Second Circuit deferred ruling, and instead certified two questions of state law to this Court: 1) whether a plaintiff may pursue claims under the CPLA when a manufacturer fails to report adverse events to a regulator or comply with a regulator's post-approval safety requirements, and 2) whether a plaintiff may pursue a claim under CUTPA for wrongful marketing where the marketer knows that the product presents a substantial risk of injury.

Together, these questions will allow this Court to decide whether remedies provided for in Connecticut's product liability and consumer protection statutes are truly available or whether they are illusory. In selling medical devices in this state, Bausch operates within a framework of federal laws and regulations; it discharges its duties under state law when it operates as a reasonably prudent manufacturer and complies with the responsibilities imposed on it by the FDCA and by the FDA as the regulator. But Bausch did not discharge its duties when it came to the Trulign Lens; instead, it brazenly violated them. In so doing, it breached duties long recognized by this state's courts and codified in the CPLA, which imposes on a product manufacturer a duty to warn of known safety issues so that the medical community knows of those risks and can protect patients like Mrs. Glover from dangerous products like the Trulign Lens. And it put Connecticut residents at risk of serious harm by depriving them and their doctors of important safety information.

Plaintiffs' CPLA claims fall squarely within a line of negligence-based claims that involve familiar negligence principles – a violation of standards set out by statute or regulation and a failure to warn of ongoing safety issues after a dangerous product is on

the market. Answering the Second Circuit's first question in the affirmative would break no new ground.

Similarly, this Court need only adhere to its prior holdings on the interplay between the CPLA and CUTPA to answer the Second Circuit's second question. This Court has previously explained that these two statutes cover distinct conduct, with the CPLA's exclusivity provision intended only to simplify pleadings and prevent needlessly repetitive separate causes of action, while leaving CUTPA claims intact. 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. This Court's decision in *Soto* reaffirmed that CPLA and CUPTA claims are separable and cover different conduct; Plaintiffs here have alleged conduct that makes out both claims, and should be able to pursue them together. Preventing them from doing so will allow manufacturers like Bausch to evade liability for exactly the type of unscrupulous trade practice that CUTPA was designed to address, thereby stripping Connecticut citizens and businesses of an important private enforcement mechanism—and threatening public health and safety.

The two certified questions ask this Court to determine whether medical device manufacturers like Bausch will be immune from the consequences of conduct that puts Connecticut citizens in harm's way in the marketing and sale of dangerous products. The deliberate withholding of safety information from regulators that the medical community relies on to make decisions about patient safety is a clear breach of a duty that this state – and states across the country – impose on medical device manufacturers. A holding that a

plaintiff has no claim under the CPLA under such circumstances would represent a startling and abrupt change in the law's direction. Likewise, a holding that a plaintiff is precluded from pursuing a claim under CUTPA arising out of allegations of unlawful and unethical marketing would similarly represent a restrictive change in the law unsupported by the statute itself or this Court's prior interpretations of it.

This Court should therefore follow its established precedent and (1) recognize a cause of action under the CPLA based on a manufacturer's alleged failure to report adverse events to a regulator like the FDA following approval of the device, or to comply with a regulator's post-approval requirements; and (2) hold that Plaintiffs have stated a claim under CUPTA based on Bausch's deceptive and aggressive marketing and promotion of the Trulign Lens despite knowing that it presented a substantial risk of injury.

STATEMENT OF FACTS

I. Federal Regulation of Class III Medical Devices

In 1976, Congress passed the Medical Device Amendments ("MDA") to the FDCA, which authorized federal regulation of medical devices. 21 U.S.C. § 360c *et seq*. The FDCA, as amended by the MDA, divides medical devices into three classes. As relevant here, Class III, the most stringently regulated class, encompasses devices for which lesser controls are not clearly sufficient to assure their safety and effectiveness, and which are "for a use in supporting or sustaining human life or . . . of substantial importance in preventing impairment of human health" or which "present[] a potential unreasonable risk of illness or injury." *Id*. § 360c(a)(1)(C)(i)-(ii).

Class III devices are subject to a pre-market approval ("PMA") process, in which the manufacturer must present to the FDA information about the device's safety and effectiveness, as well as proposed labeling for the device. *Id*. § 360e(c)(1). The FDA must

determine whether approval is appropriate, "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." *Id*. § 360c(a)(2)(C). The FDCA and its implementing regulations provide that the FDA may approve a Class III device subject to additional post-approval conditions. *See* 21 C.F.R. §§ 814.80, 814.82. If a manufacturer fails to comply with the FDA's regulations or any post-approval conditions, the agency may withdraw approval. *Id*. § 814.82(c). Once a device has been approved, the manufacturer must submit a supplemental application before making any change to the device that would "affect[] safety or effectiveness." 21 U.S.C. § 360e(d)(5)(A)(i).

All manufacturers of Class III medical devices must operate within FDCA's post-approval surveillance and reporting regime, a system designed to keep the public and treating physicians informed of any safety issues associated with a device, and which allows physicians to alter their practice or avoid devices altogether that are dangerous to their patients. After FDA approval, "the manufacturer is required to report any information that reasonably suggests that the device (1) '[m]ay have caused or contributed to a death or serious injury' or (2) '[h]as malfunctioned' and that any recurring malfunction 'would be likely to cause or contribute to a death or serious injury.'" *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1226-27 (9th Cir. 2013) (citing 21 C.F.R. § 803.50(a)). The FDCA requires medical device manufacturers to maintain and submit information as required by regulation, 21 U.S.C. § 360i, including the submission of "adverse event reports," 21 C.F.R. § 803.50 and § 803.52, and establishes internal procedures for reviewing complaints and such reports. 21 C.F.R. § 820.198(a); *see also Riegel v. Medtronic*, 552 U.S. 312, 319 (2008) (describing post-approval reporting requirements). This process is how the FDA, the

general public, and physicians are warned by manufacturers of dangers associated with their products.

II. Bausch's Failures to Comply With Its Post-Marketing Reporting Requirements.

At the top of conditional approval, the Trulign Lens was the latest in a line of lenses that are surgically implanted in the eyes to replace one's natural lens after the natural lens is removed during cataract surgery. A13-14. The Trulign Lens is classified as a Class III medical device under the MDA.

Bausch acquired the manufacturer of the Crystalens, the predecessor device to the Trulign Lens, in 2008. Even then, Bausch was aware that Z Syndrome was a complication unique to products like the predecessor device. A23. It was aware of, at least, several instances of Z Syndrome complications attributable to the device, but submitted only one report of this complication to the FDA. A24. Despite knowing of that unique risk, Bausch blanketed ophthalmologists' offices with marketing touting the Crystalens, omitting mention of Z Syndrome, A24-25, and reaped significant profits from the sale of the Lens. A33-34. By 2010, Bausch knew that Z Syndrome was serious and widespread enough to begin working with a cornea specialist "to create an instrument to help aid the surgical correction of Z Syndrome." A24. By the time Bausch presented the Trulign Lens to FDA for approval in 2013, Bausch was aware of numerous instances of Z Syndrome attributable to the predecessor Crystalens device, A24, but claimed in its presentation to the FDA that the Trulign Lenses "did not introduce new safety or effectiveness concerns," A25, downplayed known risks of asymmetric vaulting/Z syndrome, suggesting that doctors and patients were at fault when safety issues arose, and claimed that Z Syndrome could be successfully treated and the lenses could be easily removed, even citing the procedures that failed in Mrs. Glover's case. A25 (alleging violations of 21 U.S.C. § 352(q) and 21 C.F.R. § 801.6).

Members of the FDA Advisory Panel expressed concern about the quality of the data that Bausch submitted with its application for approval of the Trulign Lens, with one member stating, "The missing data issue was an important one because there's more missing data than there are vaulting events." A26. The FDA was sufficiently concerned so that as a condition of approval in 2013, the FDA required a post-market safety study of the Trulign Lens, specifically regarding vaulting/Z syndrome risk, dictating even the sample size and length of the study. A26-27. The FDA directed Bausch to submit a protocol for this study within 30 days after conditional approval, and to submit Post-Approval Study ("PAS") progress reports every six months during the first two years of the study and annually thereafter. *Id*. The FDA also required that the results be included in the labeling as the data became available. *Id.* The FDA's pre-market approval for the Trulign Lens, like the approval of the predecessor device, required Bausch to submit adverse event reports within 30 days after learning that its marketed devices may have caused injuries. A31.

Bausch violated all these requirements. It did not submit a protocol for a study within 30 days of conditional approval, as the FDA has ordered it to do. Nor did it submit the required progress reports every six months following the protocol. Instead, it waited more than *two years* – until 2015 – to even *begin* the post-market safety study that the agency required as a condition of approval. This was far too late for Mrs. Glover, who was implanted with Bausch's lenses in September 2014, six months before Bausch belatedly began the study. A27. It charged ahead with its nationwide marketing of the Trulign Lens as if the FDA had not imposed the condition that it immediately begin a safety study. Then, making matters worse, Bausch failed four times to timely provide its mandatory PAS Progress Reports to the FDA after finally beginning the study. *Id*. Notably, one of the

adverse events that Bausch should have reported was Mrs. Glover's own experience with the device, which Bausch withheld from the FDA. Bausch's repeated failures to timely file adverse event reports actually included Mrs. Glover's case; each of those failures violated 21 C.F.R. § 803.50(a). A31-32.

In 2016, well after Mrs. Glover's surgeries and again too late for her, Bausch finally added new and expanded warnings to the label for the Trulign Lens, including a specific warning about the risks of Z Syndrome. A30. The new warnings describe adverse events associated with the Trulign Lens, note that patients have experienced "higher order aberrations," and provide instructions for minimizing risk, recognizing symptoms, and treatment. A33.

III. Mrs. Glover's Injuries From the Trulign Lenses.

Bausch's conduct had devastating results for Mrs. Glover and others like her. Its violation of FDA's reporting requirements and delay in conducting the required safety study deprived ophthalmologists, including Mrs. Glover's, with complete and accurate information about the risks of the Trulign Lenses. Neither Mrs. Glover nor her ophthalmologist was made aware of the increased risk of vaulting or Z Syndrome and its serious complications, including the inability to take the broken device out of the globe of the eye.

In September of 2014, Mrs. Glover underwent two successive cataract surgeries during which her physician surgically implanted a Trulign Lens in each eye. *See* A17. A few weeks after the surgeries, Mrs. Glover began to experience significant loss in visual acuity, blurriness, hazing, halos, and significant eye pain. A18. Ultimately, Mrs. Glover was diagnosed with Z Syndrome in both of her eyes. A18.

Mrs. Glover's vision is permanently ruined. She has been forced to endure eight painful surgical, medical and other interventions, more than 40 visits to specialists, and

more than 100 tests and other procedures in an unsuccessful effort to correct her vision and remediate the considerable damage to her eyes. A18-19. These procedures have been intrusive and painful, requiring the insertion of large needles directly into her eyes while she was awake. The ophthalmologic surgeons who attempted repairs have been unable to get components of the lenses out of her eyes, so that Mrs. Glover must live with broken, twisted, and embedded fragments of the devices that have permanently impaired the vision in her eyes. A19. Mrs. Glover continues to suffer severe eye pain, light sensitivities, headaches, loss of balance, lack of depth perception, and other injuries, and is likely to completely lose her vision in both of her eyes in the near future. A19-20.

IV. Prior Proceedings

A. Plaintiffs' Claims

Plaintiffs initiated a lawsuit against Bausch first in California, where the company is based, alleging that Bausch's conduct violated California's consumer protection statutes and constituted negligence and other common law torts. After transfer to the District of Connecticut, Plaintiffs further alleged violations of the CPLA, which permits claims alleging failure to warn and negligence (*see* Conn. Gen. Stat. § 52-572m(b), § 52-572h, and § 52-572q), along with loss of consortium and other claims not at issue here. As the factual predicate for these claims, Plaintiffs alleged that Bausch failed to comply with its post-marketing surveillance requirements, both in delaying the post-approval safety study that the FDA required, and in failing to report adverse events to the FDA. Through this conduct, Bausch violated both federal law and parallel duties owed under Connecticut law.

Defendants moved to dismiss Plaintiffs' Second Amended Complaint, primarily arguing that Plaintiffs' claims were preempted by federal law.

B. This Court's Decision in *Soto v. Bushmaster Firearms Int'l*

While Bausch's motion to dismiss was pending, this Court issued its decision in *Soto v. Bushmaster Firearms Int'l, LLC*, 331 Conn. 53 (2019). *Soto* was brought by the estates of the victims in the Sandy Hook massacre against the manufacturer of the firearm used to kill 20 children and six educators at an elementary school in Newtown. This Court allowed the plaintiffs' claims under CUTPA to proceed, holding that the CPLA's exclusivity provision did not bar a CUTPA claim based on "unethical, oppressive, immoral, and unscrupulous" marketing. *Id.* at 107. *Soto* also held, for the first time, that a plaintiff may bring claims for personal injuries under CUTPA. *Id.* at 116. *Soto* thus made available a cause of action and category of damages that had not been previously available to Plaintiffs.

Recognizing the implications for cases involving allegations of improper marketing and a physically injured plaintiff, Plaintiffs moved for leave to amend their complaint to add a claim under CUTPA. The claim was based on conduct distinct from their failure-to-warn claim under the CPLA: specifically, allegations of the type of "unscrupulous" marketing *Soto* found to be sufficient to state a CUTPA claim. *See* A156-58 (Proposed Third Am. Compl. ¶¶ 260-71); *Soto*, 331 Conn. at 107. Among other allegations of particularly aggressive marketing, Plaintiffs alleged that Bausch employed paid physician promotors 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. A14.

C. The District Court's Ruling

On March 11, 2020, the district court granted Bausch's motion to dismiss and denied Plaintiffs' motion for leave to amend. The district court held, first, that Plaintiffs' failure-to-warn and negligence claims were preempted by federal law. The court observed that a

plaintiff must allege conduct that violates the FDCA, but not be suing only because the conduct violates the FDCA. "In other words, the plaintiff's state-law claim must 'parallel[ ] a federal-law duty under the MDA' but also exist 'independent[ly]' of the MDA." *A.F. By & Through Fogel v. Sorin Grp. USA, Inc.*, 346 F. Supp. 3d 534, 541 (S.D.N.Y. 2018) (quoting *Stengel*, 704 F.3d at 1226-27). Having so observed, the district court then reasoned that because Plaintiffs had not identified "any duty under Connecticut law that required the Defendants to warn or communicate adverse events to the FDA so as to give rise to a parallel claim under Connecticut law," A243, their claims were *impliedly* preempted.

The district court also held that Plaintiffs' failure-to-warn claim was *expressly* preempted by Section 360k(a) of the MDA, on the ground that Plaintiffs had not identified any duty on the part of Bausch to warn patients and physicians "separate and distinct from their disclosure obligations to the FDA or the use of FDA approved labels." A242.

The district court denied Plaintiffs' motion for leave to amend their complaint to add a CUTPA claim. It held—despite the allegations of the complaint showing that this claim is based on Bausch's *marketing* of the device, not its label—that the "primary allegation of the CUTPA claim appears to be that Defendants inadequately warned of the Trulign Lens' dangers." A247. In so ruling, the court failed even to acknowledge Plaintiffs' allegations of marketing misconduct separate and independent of Bausch's negligence and failure to warn. The district court then concluded that, because Plaintiffs do not allege that Defendants' warnings deviated from FDA-approved labeling for the Trulign Lens, they must be attacking the label itself as deficient. *Id.* Because such a claim would be expressly preempted, the district court found that the proposed CUTPA claim "would not survive dismissal pursuant to Rule 12(b)(6)." *Id.*

D. The Second Circuit's Certification of Issues to this Court

Plaintiffs appealed the district court's decision to the U.S. Court of Appeals for the Second Circuit. They argued that their negligence and failure-to-warn claims are not impliedly preempted because Connecticut law allows claims based on failure to warn a regulator, such as the FDA, of known safety risks and failure to comply with a regulator's post-approval safety requirements. Therefore, they contended, those claims proceed under traditional tort law and are not a veiled attempt to assert a private right of action not provided for by Congress. Plaintiffs further argued that their claims are not expressly preempted by the FDCA because they did not seek to impose requirements different from or in addition to those imposed by federal law. Instead, their claims are predicated on Bausch's failure to comply with the FDA's post-approval safety requirements—a failure, the Glovers argued, that violates Connecticut law.

Plaintiffs argued that amendment to add a CUTPA claim would not be futile because Connecticut law permits a CUTPA claim for wrongful marketing where a manufacturer "deceptively marketed and promoted" a product "despite possessing information that [the product] presented a substantial risk of causing" injury. A225. They also argued that their CUTPA claim is not barred by the exclusivity provision of the CPLA.

After full briefing and oral argument, the Second Circuit panel reserved decision on Plaintiffs' appeal and instead certified two questions to this Court regarding whether Plaintiffs' claims are cognizable under state law.

As to Plaintiffs' CPLA claims, the panel recognized that Plaintiffs' claims "can proceed, if at all, only if the CPLA provides a cause of action based on a manufacturer's failure to report adverse events to a regulator like the FDA, or to comply with post-approval requirements set by that regulator." *Glover v. Bausch & Lomb Inc.*, 6 F.4th 229, 239 (2d

Cir. 2021). The panel found no binding authority in Connecticut on this question, and noted divergent holdings among federal courts of appeal and state courts on whether the particular state law at issue allows for such claims. *See id.* at 240-41. It then asked this Court to decide "[w]hether a cause of action exists under the negligence or failure-to-warn provisions of the [CPLA], or elsewhere in Connecticut law, based on a manufacturer's alleged failure to report adverse events to a regulator like the FDA following approval of the device, or to comply with a regulator's post-approval requirements." *Id.* at 244.

As to Plaintiffs' CUTPA claim, the Second Circuit focused on whether the CPLA's exclusivity provision, which states that the CPLA is the exclusive remedy "for harm caused by a product," bars that claim. *Id.* at 242 (quoting Conn. Gen. Stat. § 52-572n). Acknowledging Plaintiffs' allegations that Bausch had engaged in wrongful marketing, *id.* at 233, the Court found that there was no binding interpretation of Connecticut law on the question of whether the CPLA preempts CUPTA claims like that brought by the Glovers. *Id.* at 243. The Second Circuit then asked this Court to decide a second certified question: "Whether the [CPLA] exclusivity 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." *Id.*

ARGUMENT

Standard of Review: Because both of the certified questions involve questions of law and statutory interpretation, this Court's review is *de novo*. *See Plan. & Zoning Comm'n of Town of Monroe v. Freedom of Info. Comm'n*, 316 Conn. 1, 9 (2015).

I. Connecticut Law Provides a Remedy for Warning-Based Claims.

This Court's answer to the Second Circuit's first question will determine whether Connecticut residents will have a remedy for serious injuries when a medical device

manufacturer fails to perform its most basic responsibilities as a seller of dangerous devices – to inform the medical community of potential safety issues with its devices. This Court should confirm that this state does recognize a cause of action for such a fundamental and basic breach of the duty of care. To hold otherwise would have stark consequences, rendering the CPLA toothless and leaving injured Connecticut residents without a remedy in the face of egregious misconduct.

Fortunately, nothing in the CPLA or in this Court's development of negligence principles compels such a result. To the contrary, the text of the CPLA, along with principles well developed before and since the CPLA's enactment, confirm the commonsense conclusion that Plaintiffs may pursue a claim when a medical device manufacturer fails to comply with its duties to report adverse events to the FDA or perform a safety study that could have prevented the injuries that Mrs. Glover suffered.

A. The Text and Legislative History of the CPLA Support the Glovers' Claims.

Plaintiffs maintain that Bausch's failure to report adverse events to the FDA and to conduct the safety study mandated by the FDA amount to a failure to warn cognizable under the CPLA. The statute provides 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*." Conn. Gen. Stat. § 52-572q(d) (emphasis added). Plaintiffs seek to prove at trial that if Bausch had done what the FDA required it to do, the agency would have taken steps that would have properly warned and informed Mrs. Glover's doctors. Her doctors cannot be properly warned if the FDA is kept in the dark. The question for this Court is whether this set of facts states a cognizable claim under Connecticut law. The answer should be yes.

1. The CPLA's Text Supports Plaintiffs' Claims.

The CPLA, enacted in 1979, "was intended to merge the various theories of common law theories of products liability into one cause of action." *Gajewski v. Pavelo*, 36 Conn. App. 601, 611 (1994), ***aff'd*** 236 Conn. 27 (1996) (footnote omitted). The statute was drafted broadly so that it could fulfill its "principal purpose," which is "to protect people from harm caused by defective and hazardous products." *Vitanza v. Upjohn Co.*, 257 Conn. 365, 381 (2001) (quotation and citation omitted). "[T]o meet this purpose, it is necessary that the statute be read to reach *all conduct* which affects the safety of a product prior to its entry into the stream of commerce." *Gajewski*, 36 Conn. App. at 614 (emphasis in original).

Any determination of the legislature's intent begins with the language of the statute. *See, e.g., Lynn v. Haybuster Mfg., Inc.*, 226 Conn. 282, 290 (1993) ("The legislature's intent is derived not in what it meant to say, but in what it did say.") (citation omitted); *see also* Conn. Gen. Stat. § 1-2z ("The meaning of a statute shall, in the first instance, be ascertained from the text of the statute itself and its relationship to other statutes."). The CPLA sets out "*generic categories of conduct which must be read broadly and in relationship to one another in order to accomplish the purposes of the statute.*" *Id.* (emphasis in original, quotation omitted). Under the CPLA, a plaintiff may bring a claim based on a failure to warn when the plaintiff "proves by a fair preponderance of the evidence that adequate warnings or instructions were not provided." Conn. Gen. Stat. § 52-572q(a). Finding that this duty includes a duty to warn the regulator, so that doctors can take appropriate precautions, is not only consistent with the statute's purpose, it is dictated by the statute's text and interpretation since its enactment.

Importantly, in codifying a claim for failure to warn, the legislature did not limit or specify to whom warnings must be given. Instead, it chose language that reflects the

reality that the person to whom warnings must be communicated can vary depending on the particular context. Thus, the statute provides 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*." *Id.* § 52-572q(d) (emphasis added).

In addition, the statute uses notably broad language to describe *non-exclusive* factors that the "trier of fact may consider" in determining whether warnings were adequate. *See* § 52-572q(b). It would cut against this broad language to find that the legislature did not intend for non-compliance to be a relevant factor in determining whether a manufacturer provided adequate warnings.

Here, Plaintiffs argue that Bausch should be held liable for its 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 which doctors rely on as the source of updated safety information.[1] Of course, this Court need not decide whether that's true as a matter of fact, because the question of who is "the person best able to take precaution against any potential harm associated with the use of the subject product" is a jury question. *See Gajewski*, 36 Conn. App. at 615 (citation omitted). All this Court need find is that the claim alleged here could fall within the plain language of the CPLA. It clearly does.

[1] As explained *infra* at § I(B), many courts have reached precisely that conclusion in recognizing state-law warning-based claims predicated on manufacturers' failures to notify the FDA of the risks of a drug or medical device.

Further, while the legislature could have narrowed the scope of warnings-based liability under the CPLA, it did not. This Court has recognized that such a decision is significant: "As we have stated, '[T]he legislature is capable of providing explicit limitations when that is its intent." *Vitanza*, 257 Conn. at 382 (quoting *Lynn*, 226 Conn. at 290). This Court has also emphasized that courts should tread lightly when asked to narrow the scope of liability and cut off a category of claims. "Interpreting 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." *Id.* at 381 (quoting *Ahern v. New Haven*, 190 Conn. 77, 82(1983)).

The CPLA is devoid of *any* indication, let alone a plain and unambiguous one, that the legislature intended to foreclose a warnings-based claim like the Glovers' here. To the contrary, the statute's broad wording indicates the opposite. That alone should be sufficient to answer the Second Circuit's first question in the affirmative.

2. <u>The CPLA Was Intended to Codify Existing Causes of Action—and Connecticut Law Has Long Recognized Failure-to-Warn Claims Like the Glovers' Claim</u>.

The legislative history of the CPLA supports this conclusion. Consistent with its text, there is nothing in the statute's history to suggest a legislative intent to prelude claims based on a failure to warn a regulator of safety issues or on a failure to comply with a regulator's conditions of approval. To the contrary, this Court summarized the legislative history of the act by explaining that "the legislature was merely recasting an existing cause of action and was not creating a wholly new right for claimants harmed by a product. The intent of the legislature was to eliminate the complex pleading provided at common law: breach of warranty, strict liability and negligence." *Lynn*, 226 Conn. at 292. Thus, while the CPLA established a single cause of action for plaintiffs harmed by defective products, it

was "not meant to alter the substance of a plaintiff's rights or the facts that a plaintiff must prove in order to prevail." *LaMontagne v. E.I. Du Pont De Nemours & Co.*, 41 F.3d 846, 855 (2d Cir. 1994); *Gerrity v. R.J. Reynolds Tobacco Co.*, 263 Conn. 120, 127-28 & n.8 (2003) (CPLA "was designed in part to codify the common law of product liability").

The question, then, is whether Plaintiffs' CPLA claim is consistent with causes of action that existed prior to the statute's passage and effectively codified by the CPLA. It is.

a. Connecticut Law Recognizes a Duty to Warn Third Parties of the Dangers of Hazardous Products.

For starters, Connecticut has long recognized a manufacturer's duty to warn of a product's known dangers. *See, e.g., Tomer v. Am. Home Prods. Corp.*, 170 Conn. 681, 689-90 (1976). The CPLA reflects the "established rule" that a "product may be defective because a manufacturer or seller failed to warn of the product's unreasonably dangerous propensities." *Sharp v. Wyatt, Inc.*, 31 Conn. App. 824, 833 (1993) (citing, *inter alia*, Conn. Gen. Stat. § 52–572q).

Here, Plaintiffs argue that Bausch's duty to warn the medical community of the dangers of the Trulign Lens included a duty to inform the FDA of adverse events associated with the device *and* to conduct the required safety study in a timely fashion. This formulation of the duty is consistent with the principle – settled in Connecticut – that a product manufacturer can satisfy its duty to warn of known safety defects through warnings made to third parties.

As noted above, the CPLA's provision establishing a claim for failure to warn itself does not specify that warnings must only be made to end users of a dangerous product, but instead refers to the "person best able to take or recommend precautions against the potential harm." Conn. Gen. Stat. § 52-572q(d). Indeed, this Court has explicitly

recognized that under certain circumstances, warnings must go to third parties, noting the statute's "pronouncement that there are times when warnings may be directed to someone other than the ultimate user." *Vitanza*, 257 Conn. at 384.

This case presents such a time. As a medical device manufacturer, Bausch discharges its duty to warn the medical profession of the dangers of its device by complying with its responsibility to inform the FDA of known safety issues. It is uniquely positioned to learn of safety issues and make that knowledge known to the medical community by complying with its obligations. To hold that a manufacturer's duty does not even encompass steps that the FDA otherwise requires a manufacturer to take would hollow out the duty and ignore the practical realities of how the medical community develops and refines its knowledge of dangers associated with these devices. Plaintiffs should be permitted to prove that by failing to comply with its reporting obligations to the FDA and to conduct the required safety study, Bausch failed to take the necessary steps to warn the medical community of the known dangers of the Trulign Lenses.

The learned intermediary doctrine is not to the contrary. Bausch argued in federal court (and will surely argue here) that Connecticut's adoption of the learned intermediary doctrine shields it from the Glovers' claims, because any warning was owed to Mrs. Glover's doctor, not the FDA. But the learned intermediary doctrine merely provides "that adequate warnings to prescribing physicians obviate the need for manufacturers of prescription products *to warn ultimate consumers directly*." *Vitanza*, 257 Conn. at 378 (emphasis added; quotation and citation omitted). As the foregoing quote makes clear, the doctrine *reaffirms* manufacturers' duty to provide "adequate warnings to *prescribing physicians*"—and here, Plaintiffs *are* arguing that Bausch violated its duty to warn

Mrs. Glover's prescribing physician: It did so by withholding crucial safety information from the FDA, information that would have led the agency to disseminate information about the device's dangers (via augmented warning labels, package inserts, "Dear Doctor" letters, or other agency guidance), and through the public availability of adverse event reports.

Put another way, neither *Vitanza* nor *Hurley v. Heart Physicians, P.C.*, 278 Conn. 305, 317 (2006) (which confirmed application of the learned intermediary doctrine to prescription medical devices), limited *how* manufacturers can satisfy their duty to warn to doctors. *Vitanza* merely held that *"adequate* warnings" to prescribing physicians may excuse manufacturers from warning consumers directly. 257 Conn. at 367 (emphasis added). The Court did not address whether an adequate warning included a duty to warn third parties like the FDA.

In fact, *the Vitanza* plaintiff conceded that the warnings provided to the physician *were* adequate, *id.* at 388-89—but here, Plaintiffs' argument is that Defendants' warnings were *not* adequate because key information was withheld from the FDA, and thus, from the doctor. The ultimate answer to that question must be supplied by the jury. *See* Conn. Gen. Stat. § 52-572q(b) (listing what "trier of fact" may consider in determining whether warnings "were adequate").

This case is entirely consistent with the learned intermediary doctrine. The question of *how* doctors may be "adequately" warned was left open by *Vitanza* and its progeny as a fact question that plaintiffs like the Glovers should be entitled to pursue.

b. <u>Connecticut Law Allows Negligence Claims Predicated on Violation of Federal Requirements.</u>

Plaintiffs' claims also fit neatly within Connecticut's long-standing recognition of tort claims predicated on violations of a statute or regulation. *See Gore v. People's Sav. Bank*,

235 Conn. 360, 375 (1995) ("[U]nder general principles of tort law, a requirement imposed by statute may establish the applicable standard of care to be applied in a particular action."). Connecticut has long held that "a requirement imposed by statute may establish a duty of care that could provide the underpinning for a tort claim." *K.E. v. GlaxoSmithKline LLC*, 2017 WL 440242, at *24 (D. Conn. Feb. 1, 2017), A382 (citing *Com. Union Ins. v. Frank Perrotti & Sons, Inc.*, 20 Conn. App. 253, 260 (1989)). This Court has held that failure to comply with federal regulations is evidence of negligence. *See, e.g., Wagner v. Clark Equip. Co. Inc.*, 243 Conn. 168, 191 (1997) (holding that compliance with OSHA regulations can be considered evidence of due care).

Thus, under established law of this state (as elsewhere), a manufacturer's violation of federal safety standards can form the basis for a negligence claim. Simply put, such a violation shows that the manufacturer did not behave in a reasonably prudent fashion. Bausch and other similarly situated manufacturers could easily satisfy their duties of care through compliance with federal regulations. To hold otherwise would upset and destabilize long-established negligence principles in Connecticut and put Connecticut citizens at increased risk of serious injuries like Mrs. Glover's.

c. <u>Connecticut Law Recognizes a Post-Sale Duty to Warn.</u>

Bausch's duty to report adverse events is also consistent with the post-sale duty to warn that has long been recognized under Connecticut law, dating as far back as this Court's 1957 decision in *Handler v. Remington Arms Co.*, 144 Conn. 316 (1957) (finding continuing duty to warn of defective ammunition cartridge); *see also Neuhaus v. DeCholnoky*, 280 Conn. 190, 203-204 (2006) (noting the Court's recognition of continuing duty to warn in product liability cases).

More recently, in *Densberger v. United Technologies Corp.*, 297 F.3d 66 (2d Cir. 2002), the Second Circuit affirmed a seller's post-sale duty to warn based on this Court's CPLA jurisprudence. The Court noted that the CPLA incorporates common law theories unless those theories "are expressly inconsistent with it." *Id.* at 70. It then held that because the CPLA "does not expressly prohibit post-sale liability for negligent failure to warn, the negligence-based common law duty survives and is cognizable under the statute." *Id.* at 71.[2] *Densberger* is also consistent with this Court's repeated recognition that "there may be instances in product liability situations where a continuing duty to warn may emanate from a defect, without proof that the manufacturer actually knew of the defect." *Martinelli v. Fusi*, 290 Conn. 347, 360 (2009).

In short, there is nothing new about the Glovers' negligence and failure-to-warn claims. Claims based on Bausch's failure to comply with its duty to report adverse events and to timely conduct a safety study fit squarely within well-established Connecticut authority. The Court should therefore answer the Second Circuit's first question in the affirmative.

B. Numerous Other States Recognize Claims Based on Failure to Report Adverse Events.

Any doubt about this should be dispelled by holdings in myriad other states allowing claims very similar to those asserted by Plaintiffs here. Connecticut is not alone in recognizing a duty to warn of known safety issues. Nor is it alone in recognizing that conduct similar to that issue here can constitute a claim for negligence or failure to warn.

[2] Federal courts in Connecticut have recognized that *Densberger*'s recognition of a post-sale duty to warn is consistent with a duty to report adverse events to the FDA. *See Simoneau v. Stryker Corp.*, 2014 WL 1289426, at *11 n.9 (D. Conn. Mar. 31, 2014), A440; *Nagel v. Smith & Nephew, Inc.*, 2016 WL 4098715, at *7 (D. Conn. July 28, 2016), A420.

Not surprisingly, federal and state courts across the country, when faced with the question that the Second Circuit certified to this Court, have held that plaintiffs may base failure-to-warn or negligence claims on a medical device manufacturer's failure to report adverse events or otherwise comply with FDCA regulations.

California: In *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 167 Cal. Rptr. 3d 300 (2014), the California Court of Appeals held that 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." *Id.* at 428. Likewise, a California district court, applying *Coleman* to a case involving the same injuries from the Trulign Lenses, held in *Michaljun v. Bausch & Lomb, Inc.*, 2015 WL 1119733 (S.D. Cal. Mar. 11, 2015), A410, that that California "requires medical-device manufacturers to warn of known or knowable risks, and they can do so by filing adverse event reports with the FDA if that is the only available method to warn doctors and consumers." *Id.* at *7 (alteration and citation omitted).

Hawaii: In *Beavers-Gabriel v. Medtronic, Inc.*, 2015 WL 143944 (D. Haw. Jan. 9, 2015), A349, the district court held that Hawaii (like Connecticut) "imposes a duty of reasonable care on product manufacturers, and recognizes a cause of action for failure to warn." *Id.* at *12. It further held that this duty includes the duty to report adverse events to the FDA as part of a manufacturer's duty to warn of "known dangers that the user of its product would not ordinarily discover." *Id*. (citation omitted)

Illinois: In *Laverty v. Smith & Nephew, Inc.*, 197 F. Supp. 3d 1026 (N.D. Ill. 2016), the district court held that the "longstanding state-imposed duty to warn" included a duty to report to the FDA. *Id.* at 1035. The duty to report to the FDA only "redefine[ed]" the way

that manufacturers satisfy their state law duty. *Id.* Just as the duty to warn in Connecticut is not limited to warning the "ultimate user," *Vitanza*, 257 Conn. at 384, the *Laverty* court noted that Illinois's "duty is not limited to providing warnings directly to end users." *Laverty*, 197 F. Supp. 3d at 1035.

Indiana: In *McAfee v. Medtronic, Inc.*, 2015 WL 3617755 (N.D. Ind. June 4, 2015), A404, the court held that a plaintiff's failure to warn claims premised on a medical device manufacturer's failure to file adverse event reports with the FDA stated a claim under Indiana's product liability statute that paralleled federal requirements. *Id.* at *5.

Kentucky: In *Waltenburg v. St. Jude Medical, Inc.*, 33 F. Supp. 3d 818 (W.D. Ky. 2014), the court's formulation of the plaintiff's claim mirrored that of the Glovers' here in allowing it to proceed. Noting the plaintiffs' argument that the manufacturers are required to report adverse events to the FDA "so that both medical professionals and the general public can obtain safety data on medical devices," *id.* at 838, the court found that "Plaintiffs are alleging a recognized state tort claim based on the underlying state-law duty to warn about the dangers or risks of a product. They seek to prove Defendants' breach of that duty by showing that Defendants violated the applicable federal reporting requirements." *Id.* at 840.

Louisiana: In *Gavin v. Medtronic, Inc.*, 2013 WL 3791612 (E.D. La. July 19, 2013), A362, the court held that a plaintiff's warnings claim premised on a failure to report adverse events to the FDA could proceed under Louisiana's product liability statute, pointing to the manufacturer's duty to warn even after the device has left its control, *id.* at *14, a requirement analogous to Connecticut's post-sale duty to warn. *See infra* § I(A)(2)(c).

Idaho: In *Richardson v. Bayer Healthcare Pharmaceuticals Inc.*, 2016 WL 4546369 (D. Idaho Aug. 30, 2016), A432, the court held that under Idaho law (as in Connecticut, as explained above in Section B(1)), a "'third party intermediary' may play a critical role in adequately warning users of a foreseeably dangerous product," and that "[i]n the context of Class III medical devices, that should be construed to include warnings and reports to the FDA." *Id.* at *8.

Maryland: In *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742 (D. Md. 2015), the court emphasized that under Maryland law (like Connecticut law, *see* § I(A)(2)(c)), a "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." *Id.* at 742.

Minnesota: In *Angeles v. Medtronic, Inc.*, 863 N.W.2d 404 (Ct. App. Minn. 2015), the Court held that a claim based on a medical device manufacturer's failure to report adverse events to the FDA was "based in traditional state tort law." *Id.* at 419.

Mississippi: In *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011), the Fifth Circuit applied Mississippi law to hold that federal medical device reporting requirements are designed to ensure that information is disseminated to the public, and that "a manufacturer's failure to provide this information a required by FDA regulations is a parallel violation of the state duty to provide reasonable and adequate information about a device's risks." *Id.* at 770-71.

Missouri: In *Williams v. Bayer Corp.*, 541 S.W.3d 594 (Mo. Ct. App. 2017), the court held that the plaintiff's allegations that the manufacturer failed to report adverse events

"properly invoke[d] a traditional state law tort cause of action; specifically, a strict liability failure to warn claim." *Id.* at 606 (citing Mo. Rev. Stat. § 537.760).

New York: In *A.F. v. Sorin Group USA, Inc.*, 346 F. Supp. 3d 534 (S.D.N.Y. 2018), the district court held that New York common law, "a manufacturer's duty to take steps that are reasonably necessary to warn the medical community" of a product's potential dangers "may include warning the FDA as required by the [Medical Device Amendments]." *Id.* at 544. Just as Connecticut recognizes that a requirement imposed by statute may establish the applicable standard of care, *see* § I(2)(b) above, the *A.F.* court went on to note that "New York courts have long recognized that the violation of a regulation mandating a standard of conduct is some evidence of negligence and probative of whether the conduct is reasonable and adequate under the circumstances." *Id.*

Washington: In *O'Neil v. St. Jude Med., Inc.*, 2013 WL 6173803 at *3 (W.D. Wash. Nov. 22, 2013), A428, the court held that Washington tort law allows a claim to be based on a duty of care established in a statute or regulation, and the plaintiff could proceed on a state law claim based on a failure to report adverse events to the FDA. *Id.* at *3.

Wisconsin: In *Garross v. Medtronic, Inc.*, 77 F. Supp. 3d 809 (E.D. Wis. 2015), the Court held that a plaintiff's claims based on a failure to report adverse events each "arise from an independent, well-recognized duty owed under [Wisconsin] law." *Id.* at 816.

These holdings are directly on point. In all these cases, the courts assessed claims based on closely analogous conduct – a medical device manufacturer's failure to report adverse events to the FDA – and found that their respective states' laws allowed such a claim. They adopted principles that, as Plaintiffs explained above, have long been applied in Connecticut, including the responsibility to warn third parties to discharge their duty to

warn, the predication of negligence claims on violation of federal duties, and recognition of duties to warn that post-date the sale of a defective product. The same result is appropriate here.

II. The Glovers' Proposed CUTPA Claim Is Not Barred by the CPLA.

Plaintiffs should also be allowed to pursue a claim under CUTPA based on Bausch's unethical and aggressive marketing of the Trulign Lens as safe and effective despite knowing full well that it posed serious risks. Importantly, this lawsuit involves two entirely *different* forms of wrongdoing: the first involves Bausch's negligent failure to warn of the dangers of the Trulign Lens; the second involves Bausch's unethical, deceptive, and aggressive marketing of the Trulign Lens with knowledge of the product's dangers. The CPLA claim addresses the first form of wrongdoing; the CUTPA claim addresses the second. The Glovers intend to show that there are distinct harms stemming from Defendants' distinct forms of wrongdoing – injuries from the product itself, and injuries caused by Defendants' deceptive actions in the marketplace.

The second certified question is whether the CPLA's exclusivity provision bars a claim under CUTPA when a plaintiff has made allegations like the ones Plaintiffs have here. This Court should answer this question in the negative—and it can do so simply by adhering to prior holdings on the CPLA's exclusivity provision. As this Court has held, while the CPLA may preempt common law claims aimed at recompense for injuries caused by a product, it does not preempt CUTPA claims that are based on the broad range of conduct that CUTPA is intended to address, including wrongful and unethical marketing.

CUTPA is a powerful tool that allows plaintiffs to recover attorneys' fees and costs in certain cases—remedies that are not permitted under the CPLA. It was designed to target precisely the kind of unfair and deceptive marketing conduct at issue here. That tool

should be made available to the Glovers and other citizens who are injured by the unethical and deceptive marketing of a dangerous product that a manufacturer *knows* poses serious risks yet pushes on the public as safe and effective. Any other result would deprive Connecticut citizens of an important safeguard that the legislature intended should be available in precisely this circumstance.

1. The Text of the CPLA's Exclusivity Provision Does Not Cover CUTPA Claims Based on Deceptive or Aggressive Marketing.

The language of the CPLA's exclusivity provision is again the starting point. The relevant language is as follows: "(a) A product liability claim as provided in sections 52-240a, 52-240b, 52-572m to 52-572q, inclusive, and 52-577a 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." Conn. Gen. Stat. § 52-572n(a).

Claims based on unfair trade practices – a distinct theory of liability – are conspicuously not on that list. As this Court has previously explained, this is no accident. In *Gerrity*, this Court examined the scope and purpose of the CPLA's exclusivity provision, including a detailed review of the CPLA's legislative history. From the record, this Court highlighted the statement that CPLA's exclusivity provision was merely intended to "cut down on the number of counts in a complaint for injuries caused by a product. *It is not intended to affect other state statutory schemes such as anti-trust acts or the state unfair trade practice act*." 263 Conn. at 128-29 (emphasis in *Gerrity*). *Gerrity* held while the CPLA was not intended to eliminate "other claims, such as one under CUTPA, which fall *outside* the scope of the product liability act…." *Id.* at 128. 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 or product, or if the party is not pursuing a claim for personal injury, death or property damage." *Id.* (citation omitted).

Plaintiffs' proposed CUTPA claim here does not fall within the specifically delineated list of product liability claims within the CPLA's exclusivity provision, and thus should be deemed cognizable.

2. CUTPA Covers Conduct Distinct From Plaintiffs' Claims for Negligence and Failure to Warn.

As CPLA and CUTPA cover different conduct, a plaintiff need not choose between two different statutory schemes. This Court explicitly held in *Gerrity* that a CUTPA claim "may be asserted in conjunction with the product liability act claim." *Id.* at 126-27. This is entirely consistent with the distinct text and purposes of the two statutes. While the CPLA provides remedies for injuries attributable to defective products themselves, *see Hurley*, 278 Conn. at 326, CUTPA applies more broadly to commercial activity; its purpose "is to protect the public from unfair practices in the conduct of any trade or commerce." *Willow Springs Condo. Ass'n., Inc. v. Seventh BRT Devel. Corp.*, 245 Conn. 1, 42 (1998). A plaintiff bringing a CUTPA claim must prove elements that are distinct from those that she must prove to assert a CPLA claim, *see Associated Inv. Co. P'ship v. Williams Assocs. IV*, 230 Conn. 148, 156 (1994), and "has access to a remedy far more comprehensive than the simple damages recoverable under common law." *Id.* at 160 (citation omitted). In fact, this Court has emphasized that unlike the CPLA, which codified common law doctrines of negligence and other theories of liability, "the action established by CUTPA provides a remedy for a wider range of business conduct than does the common law, and CUTPA exists wholly independent of any common law claim." *Id.* at 161.

Moreover, there is a broad spectrum of conduct covered by CUTPA that falls outside of the CPLA because CUTPA itself is written expansively. "CUTPA, by its own terms, applies to a broad spectrum of commercial activity." *Willow Springs*, 245 Conn. at 42. CUTPA encompasses a broad prohibition against unfair conduct in the marketplace, prohibiting "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Conn. Gen. Stat. § 42-110b(a). In adopting this sweeping language, the legislature "deliberately chose not to define the scope of unfair or deceptive acts proscribed by CUTPA so that courts might develop a body of law responsive to the marketplace practices that actually generate such complaints." *Sportsmen's Boating Corp. v. Hensley*, 192 Conn. 747, 755 (1984). Moreover, "[b]ecause CUTPA is a self-avowed 'remedial' measure, Conn. Gen. Stat. § 42-110b(d), it is construed liberally in an effort to effectuate its public policy goals. . . . Indeed, there is no . . . unfair method of competition, or unfair [or] deceptive act or practice that cannot be reached [under CUTPA]." *Assoc. Inv.*, 230 Conn. at 157-58 (citations omitted).

Here, Plaintiffs intend to proceed precisely as this Court has contemplated, with distinct claims, based on distinct conduct, pursuing distinct categories of damages. The Glovers' wrongful marketing claim, brought under CUTPA, will focus on Bausch's activities in aggressively and unethically promoting the Trulign Lens as a fully approved medical device, when in fact, its approval was subject to a condition that Defendants brazenly disregarded—the requirement that it conduct a safety study within 30 days of the device's approval—and despite *knowing* that the product could actually cause blindness. It is a claim based on Defendants' "acts or practices in the conduct of … trade and commerce," just as CUTPA contemplates. Conn. Gen. Stat. § 42-110(a). Plaintiffs' CPLA claim, in

contrast, focuses on the defective nature of the Trulign Lenses themselves. Both statutory schemes should be available to address Defendants' distinct misconduct and the distinct harms they caused.

3. That This Case Involves a Defective Product Does Not Render CUTPA Inapplicable.

Plaintiffs' CUTPA claim, based on allegations of unethical and aggressive marketing of an inherently dangerous product, is fully consistent with the CUTPA claim endorsed by this Court in *Soto.* Plaintiffs' proposed amended complaint echoed the language of *Soto* in alleging that Bausch "unethically, oppressively, immorally, and unscrupulously marketed and promoted these Lenses for use." A158; *see Soto*, 331 Conn. at 106-07. Just as in *Soto*, Plaintiffs' allegations of aggressive marketing tactics are separate and distinct from the conduct that form the basis for Plaintiffs' negligence and warnings-based claims. *See Soto*, 331 Conn. at 116 ("[W]e conclude that, at least with respect to wrongful advertising claims, personal injuries alleged to have resulted directly from such advertisements are cognizable under CUTPA."); *id.* at 110 ("CUTPA permits recovery for personal injuries that result directly from wrongful advertising practices.").

Here, Plaintiffs allege that Defendants deceptively marketed and promoted the Trulign Lens as perfectly safe and effective despite *knowing* that Trulign Lens presented a substantial risk of causing Z Syndrome complications unique to the product and its predecessor, Crystalens.[3] This conduct is entirely distinct from the conduct at the heart of Plaintiffs' CPLA claims: namely, Defendants' failure to comply with their obligations to report adverse events to the FDA and perform the required safety study. For their CUTPA

[3] Because this case has yet to move beyond the pleadings, Plaintiffs have not begun formal discovery and instead are relying on the marketing allegations in their complaint.

claim, Plaintiffs will only seek to recover damages attributable to Defendants' marketing conduct. *Soto* drew a clear line between allegations that would state a CUTPA claim and those that would state a claim under the CPLA. Trial courts, including the district court when this case is returned to it, can continue to draw that line as Plaintiffs pursue compensation for their injuries here.

Notably, *Soto* did not reach the question of whether a CUTPA claim based on the allegation that a product is inherently unreasonable and dangerous would be barred by the CPLA's exclusivity provision. *See* 331 Conn. at 106-07. The Court did say, in *dicta*, that one of the reasons the plaintiffs should be allowed to bring their wrongful marketing claim under CUTPA is because "[t]here is no allegation in the present case . . . that the marketing for the XM15-E2S contained inadequate warnings that made the weapon unreasonably dangerous." *Id.* at 107. Citing that dicta, Bausch argued in the Second Circuit that because Plaintiffs here allege that the Trulign Lens is defective, and that Bausch failed to warn of these defects, they cannot state a claim under CUTPA. But *Soto*'s actual holding does not dictate that result, and its logic is to the contrary: *Soto* recognized that it makes sense to allow a plaintiff to bring a distinct claim under CUTPA where the defendant has aggressively marketed a product it *knows* to be dangerous, thereby lulling its consumers into a false sense of security. That's *Soto*; it's also this case.

The fact that the product at issue happens to be defective should not make a difference where, as here, the manufacturer *also* engages in deceptive marketing practices of an inherently dangerous product that go beyond the conduct underlying the CPLA claims for negligence and failure to warn. Where that is true, allowing Plaintiffs to bring both CUTPA and CPLA claims makes sense as a policy matter, because the two statutes

protect the public from distinct harms, some of which might go unaddressed if the availability of one claim were deemed a bar to the other essentially in all cases in which a sale of a product is involved. That would be contrary to the broad reach and remedial purposes of CUTPA and a bad outcome from the perspective of public policy. For example, a prevailing plaintiff brining a CUTPA claim may recover, among other damages, attorneys' fees and costs. *See Assoc. Inv.*, 230 Conn. at 160-61. It makes little sense to cut off a plaintiff who can show harms from unethical and aggressive marketing from those remedies simply because her case involved the sale of a product.

And such a result is not compelled by the case law. Notably, the principal case relied on by Bausch in the Second Circuit – *Appiah v. Home Depot U.S.A, Inc*., 2020 WL 6263544 (D. Conn. Oct. 23, 2020), A344 – did not involve the type of distinct marketing misconduct alleged in this case – and in *Soto*. Instead, the only allegation in *Home Depot* was that the product at issue – floor tiles – were defective because they were too slippery to be used as flooring. The court held that the claims were not cognizable under CUTPA because the case *solely* involved a defective product; unlike here, the plaintiffs did not make separate allegations of "outrageous or immoral" marketing, but instead based their claims on the same conduct. *Id*. at *5. This case, in contrast, is not just about a defective product. Rather, like *Soto*—and unlike *Home Depot*— it also involves a deceptive marketing campaign.[4]

[4] Other cases previously relied on by Bausch as support for its anti-CUTPA argument are distinguishable on similar grounds. For example, *Hurley*, 278 Conn. 305, did not involve widespread, let alone aggressive or immoral marketing, but instead involved the question of whether a device manufacturer's representative had made statements to the plaintiff's physician that nullified the otherwise adequate warnings provided. *See id.* at 324.

But where, as here, and as in *Soto*, the marketing misconduct is distinct from the misconduct that provide the basis for the CPLA claims (a failure to do what the FDA directed it to do), the marketing claims should be cognizable under CUTPA because they concern Defendants' alleged "unfair practices in the conduct of any trade or commerce . . . ." *Willow Springs*, 245 Conn. at 42. That is consistent with *Soto* and with how this Court and courts in this state have interpreted CUTPA and the CPLA. *See, e.g., Haynes v. Yale-New Haven Hosp.*, 243 Conn. 17, 38 (1997) (holding that the "touchstone for a legally sufficient CUTPA claim against a health care provider is an allegation that an entrepreneurial or business aspect of the provision of services is implicated"); *Gallinari v. Kloth*, 148 F. Supp. 3d 202, 215–17 (D. Conn. 2015) (allowing CUTPA and CPLA claims to proceed together where plaintiff pled distinct conduct for each).

This Court has recognized that allegations of aggressive and immoral marketing of a dangerous product stand apart from cases appropriately subsumed within the CPLA. The Court should confirm that plaintiffs who have alleged such commercial misconduct can continue to rely on CUTPA to seek relief for injuries caused by such misconduct.

CONCLUSION

For the foregoing reasons, this Court should answer the first certified question in the affirmative and the second in the negative.

Dated: September 17, 2021

Respectfully submitted,

By: /s/ Hugh W. Cuthbertson

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

By: /s/ Wendy R. Fleishman

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 17th day of September, 2021, the following:

1. On September 17, 2021, I caused a copy of the foregoing Brief of the Plaintiffs-Appellants ("Brief") and Appendix to be served on the following counsel of record for Defendants by email and the Brief and Appendix to be filed with the appellate clerk:

Toby S. Soli, Esq.
Robert J. Kirshenberg, 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

3. The Brief and Appendix being filed with the appellate clerk are true copies of the brief and appendix that were submitted electronically pursuant to Rule of Appellate Procedure § 67-2(g).

4. The Brief and Appendix do not contain any names or other personal identifying information that is prohibited from disclosure by rule, state, court order, or case law.

5. The Brief and Appendix comply with the format requirements of Rule of Appellate Procedure § 67-2.

Dated: September 17, 2021

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

Attorneys for Plaintiffs-Appellants