No. _____

IN THE

Supreme Court of the United States

TARGET CORPORATION AND
TEVA PHARMACEUTICALS USA, INC.,
Petitioners,

v.

NICOLE GUVENOZ,
Respondent.

On Petition for a Writ of Certiorari to the Illinois Appellate Court

PETITION FOR A WRIT OF CERTIORARI

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February 25, 2016

QUESTION PRESENTED

Whether the decision of the Illinois Appellate Court, which permits personal-injury plaintiffs in Illinois to proceed with the very "stop-selling" theory of liability this Court rejected as "incompatible with our pre-emption jurisprudence" in *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013), should be summarily reversed.

PARTIES TO THE PROCEEDING

Petitioners, the Defendants-Appellants below, are Target Corporation ("Target") and Teva Pharmaceuticals USA, Inc. ("Teva").

Respondent, the Plaintiff-Appellee below, is Nicole Guvenoz, who sued both individually and as the representative of the Estate of Lewis Guvenoz.

RULE 29.6 DISCLOSURE

Target Corporation is a publicly traded company that has no parent company. No publicly traded company owns 10% or more of its stock.

Teva Pharmaceuticals USA, Inc. is directly owned by (i) Orvet UK (Majority Shareholder), which in turn is directly owned by Teva Pharmaceuticals Europe B.V., which in turn is directly owned by Teva Pharmaceutical Industries Ltd.; and (ii) Teva Pharmaceutical Holdings Coöperatieve U.A. (Minority Shareholder), which in turn is directly owned by IVAX LLC, a direct subsidiary of Teva Pharmaceuticals USA, Inc. Teva Pharmaceutical Industries Ltd. is the only publicly traded direct or indirect parent company of Teva Pharmaceuticals USA, Inc., and no other publicly traded company owns more than 10% of Teva Pharmaceuticals USA, Inc.'s stock.

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Petitioners respectfully request a writ of certiorari to summarily reverse the judgment of the Appellate Court of Illinois, First District, Fifth Division.

OPINION BELOW

The decision of the Illinois Appellate Court is reported at 30 N.E.3d 404 and is included in the Appendix ("App.") at 1a-44a.

JURISDICTION

The Illinois Appellate Court issued its decision on March 27, 2015. The Supreme Court of Illinois denied a petition for leave to appeal the decision on September 30, 2015. The Supreme Court of Illinois denied a motion for leave to file a motion for reconsideration on November 16, 2015. On December 21, 2015, Justice Kagan granted Petitioners' motion to extend the date for filing a Petition for a Writ of Certiorari to February 25, 2016. This Court has jurisdiction under 28 U.S.C. § 1257(a).

PROVISIONS INVOLVED

The Supremacy Clause of the U.S. Constitution, art. VI, cl. 2, provides:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

STATEMENT OF THE CASE

A. Introduction

As this Court has recognized, "generic drug manufacturers have an ongoing federal duty of 'sameness'" that requires generic drug products to have the same active ingredient and labeling as the brand-name version of the same drug. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2575 (2011); *see also Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013). Thus, if state tort law requires a generic manufacturer to alter the active ingredient or labeling of its product, that law is preempted because it conflicts with the sameness requirements of federal law. *Mensing*, 131 S. Ct. at 2577-78.

In *Bartlett*, this Court held that a court cannot avoid this conflict between state and federal law by holding that a generic manufacturer should have ceased selling its product altogether. The Court "reject[ed] this 'stop-selling' rationale as incompatible with our pre-emption jurisprudence" because "an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." *Id.* at 2477.

Since *Bartlett*, the federal appellate courts have been unanimous in recognizing that federal law "preempts a state-law claim against a generic manufacturer if … that claim would require the manufacturer to redesign its drug, change its labeling, or exit the market in order to avoid liability." *Houston v. United States*, No. 15-2411, 2016 WL 403310, at *4 (7th Cir. Feb. 3, 2016); *see also Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1141 (8th Cir. 2014) (holding

that because the generic defendant could not "avoid liability under Missouri law for the alleged design defects without changing its product, changing its labeling, or leaving the market, [the] design defect claims—whether sounding in strict liability or negligence—'are preempted by impossibility'"); *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 476 (4th Cir. 2014) (holding that because "a generic may not unilaterally change its labeling or change its design or formulation, and cannot be required to exit the market or accept state tort liability …. if a generic drug manufacturer cannot satisfy a state law duty except by taking one of these four actions, that law is preempted"); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, 751 F.3d 150, 165 (3d Cir. 2014) ("*Mensing* and *Bartlett* recognize that manufacturers have no control over the design or labeling of generic drugs. Short of exiting the market—which *Bartlett* rejects—the Appellants have failed to identify anything the Generic Defendants can do to reconcile their conflicting duties under state and federal law."); *Johnson v. Teva Pharm. USA, Inc.*, 758 F.3d 605, 613 (5th Cir. 2014); *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 391 (6th Cir. 2013); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1290 (10th Cir. 2013).

In this case, however, the Illinois Appellate Court departed from that consensus and adopted the "stop-selling" theory that this Court squarely rejected in *Bartlett*. According to the appellate court, this case supposedly is not controlled by *Bartlett* because Respondent here is not claiming that Petitioners should have altered their product design or product labeling but instead should have stopped selling their prod-

uct altogether. *See* App. 27a ("Since plaintiffs do not suggest that there was an improved design or label that could have cured the problem, there was no 'direct and positive conflict' with the generic manufacturer's federal duty to use the same design and label as the lead manufacturer. The only remedy was to withdraw the product.") (internal citations omitted). But that is the precise claim raised by the plaintiff in *Bartlett* and rejected by this Court. As in that case, Respondent here brought claims for defective design and argued that the generic manufacturer should have withdrawn its generic drug product from the market.[1] Yet, when faced with the same claim as that considered in *Bartlett*, the Illinois Appellate Court reached the opposite result.

The decision of the Illinois Appellate Court directly contradicts this Court's decision in *Bartlett*. Whether that result was based on willful defiance or a fundamental misunderstanding of this Court's precedent, it requires summary reversal because the issue "has already been settled clearly by past decisions of this Court." *California v. Beheler*, 463 U.S. 1121, 1121-22 (1983).

B. Regulatory Background

In 1984, Congress amended the federal Food, Drug, and Cosmetic Act ("FDCA") in order to expand access to affordable generic drugs by reducing barri-

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[1] *Compare* App. 27a ("In the case at bar, plaintiff alleged that the drug was simply unsafe and should not have been sold at all."), *with* Brief for Respondent at 10, *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013) (No. 12-142), 2013 WL 602909 (arguing that "sulindac is 'unreasonably dangerous' to the public as a whole and thus 'shouldn't be on the market'").

ers to generic market entry. 21 U.S.C. § 355 *et seq*. Those amendments—commonly known as the Hatch-Waxman Act—allowed the modern generic drug industry to develop and thereby reduced pharmaceutical expenditures by trillions of dollars over the past three decades. *See Mensing*, 131 S. Ct. at 2582 ("[I]t is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public.").

Before the Hatch-Waxman Act, most companies were required to file a New Drug Application ("NDA") to receive FDA approval to market a drug. NDA applicants must conduct extensive and costly clinical trials to prove the safety and efficacy of a proposed new drug. Following Hatch-Waxman, federal law distinguishes between branded and generic drug applicants. While a brand company must still submit a full NDA for each new drug, *id*. at 2574 (citing 21 U.S.C. § 355(b)(1), (d)), a generic drug company seeking to market a copy of a previously approved drug may file an Abbreviated New Drug Application ("ANDA") that demonstrates the product's chemical and biological equivalence to a previously approved drug product, *id.* (citing 21 U.S.C. § 355(j)(2)(A)).

Accordingly, the Hatch-Waxman Act requires ANDA applicants to show that a generic drug is identical to the branded equivalent in all material respects. ANDA applicants must demonstrate that the proposed generic drug contains "the same" active ingredient or ingredients, employs "the same" route of administration (e.g. oral or injected), utilizes "the

same" dosage form (e.g. tablet or capsule), and exhibits "the same" strength (e.g. 20mg or 40mg) as the brand-name drug—all in order to ensure that the two drugs will "have the same therapeutic effect." 21 U.S.C. § 355(j)(2)(A)(i)-(iv); *see also Mensing*, 131 S. Ct. at 2583 (noting that a generic manufacturer must show "its product has the same active ingredients as an approved brand-name drug; that 'the route of administration, the dosage form, and the strength of the new drug are the same' as the brand-name drug; and that its product is 'bioequivalent' to the brand-name drug").

In short, the design of a generic drug must be identical to that of its brand-name counterpart. Because the products must be identical, a "generic drug application must also 'show that the [safety and efficacy] labeling proposed ... is the same as the labeling approved for the [brand-name] drug.'" *Id.* at 2574 (quoting 21 U.S.C. § 355(j)(2)(A)(v) and citing 21 U.S.C. § 355(j)(4)(G)) (alterations in original). The FDA requires an "ongoing federal duty of 'sameness'" pursuant to which "the warning labels of a brand-name drug and its generic copy must always be the same." *Id.* at 2574-75; *see also* Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17950, 17961 (Apr. 28, 1992) ("[T]he ANDA product's labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for ANDA approval.").

C. Regulatory History of Propoxyphene

This case involves state-law tort claims alleging injuries arising from the use of the generic drug propoxyphene. Propoxyphene is an opioid analgesic

prescription medication indicated for the treatment of mild to moderate pain. App. 4a. The FDA first approved propoxyphene in 1957, and it has been marketed in various forms by over a dozen companies at various times over the last fifty years—both under the brand name Darvon® (or, when combined with acetaminophen, Darvocet®) and as a generic. *Id.*; *see also In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 923 (6th Cir. 2014).

In February 2006, the advocacy group Public Citizen filed a petition with the FDA requesting that propoxyphene be removed from the market.[2] In response—and against the backdrop of ongoing regulatory action on propoxyphene in the European Union—the FDA's Anesthetic and Life Support Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee held a January 2009 meeting to discuss propoxyphene. FDA Response at 4; *see also* App. 5a. The committees heard presentations from Public Citizen, Xanodyne Pharmaceuticals (which held the NDA for the drug), and FDA personnel. FDA Response at 4-5. The advisory committees "voted by a narrow margin (14 to 12) against the continued marketing of propoxyphene products." *Id.* at 6; App. 5a.

"Those committees recommended withdrawing propoxyphene from the market, but the FDA did not follow the advisory committee's recommendation, determining that available data did not warrant mar-

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[2] *See* FDA, Citizen Petition Response at 4, Docket No. FDA-2006-P-0270, http://1.usa.gov/1Pi0P0i [hereinafter FDA Response].

ket withdrawal." *Darvocet*, 756 F.3d at 924. The FDA concluded instead that "the withdrawal of propoxyphene products in the United States is not appropriate at this time" because "the overall risk-benefit profile for propoxyphene products remain[s] favorable in properly selected patients." FDA Response at 7.

The FDA did, however, require Xanodyne Pharmaceuticals to undertake a Risk Evaluation and Mitigation Strategy, which included revising the drug label and sponsoring a clinical trial to assess safety risks. *Id.* at 2, 7-8, 27-28. The FDA decided that "these safety measures will address the safety concerns" that Public Citizen raised in its petition, and the agency announced that it would "keep closely attuned to the safety information provided to us about propoxyphene products, including the development and results of the clinical trial that we are requiring" and would take further action "[s]hould we later discover that additional measures are necessary." *Id.* at 28.

Following its review of the new data collected during the Xanodyne study—a study to which the various generic manufacturers lacked access until it was publicly released—the FDA announced on November 19, 2010 that Xanodyne agreed voluntarily to withdraw propoxyphene from the market.[3] The

[3] *See Darvocet*, 756 F.3d at 930 ("Plaintiffs submit as 'new information' that the initial data from the Xanodyne study confirmed the safety risks of propoxyphene, resulting in the FDA's conclusion that the safety risks of the drug outweighed its benefit. But the Generic Manufacturers did not have access to, and thus had no ability to evaluate, that study.").

FDA requested that generic manufacturers do the same, "and the manufacturers complied." *Darvocet*, 756 F.3d at 924; App. 6a.

D. Proceedings Below

Respondent's First Amended Complaint alleges that between January 8, 2010 and May 13, 2010, her spouse Lewis Guvenoz was prescribed and ingested generic propoxyphene that was manufactured or distributed by Petitioners. Respondent alleges that Mr. Guvenoz's ingestion of the recommended doses of propoxyphene led to his cardiac arrest and resultant anoxic encephalopathy on May 13, 2010. App. 6a.

Respondent asserted various state-law theories related to the product's safety as labeled and designed, including negligence, strict product liability and design defect, fraudulent misrepresentation, fraudulent concealment, and consumer fraud. App. 4a. According to Respondent, Petitioners' generic propoxyphene product was "unreasonably dangerous," contained "dangerous design and manufacturing defects," and was "unsafe for normal, or reasonably anticipated, handling and use." App. 50a. Despite precedent from this Court holding that the FDCA preempts state-law tort claims based on the allegedly inadequate design or labeling of generic drugs, Respondent sought to hold Petitioners liable for breaching a state-law duty "to exercise reasonable care in the design, manufacture, testing, distribution, promotion, and sale of" generic propoxyphene. App. 51a.

Petitioners moved to dismiss the First Amended Complaint on federal preemption grounds. App. 8a.

On September 11, 2013, the trial court denied Petitioners' motions in a one-page handwritten order without analysis. App. 9a. The trial court then certified its order for appellate review, and the Illinois Appellate Court granted leave to appeal a series of questions which asked whether federal law preempts Respondent's state-law claims. App. 9a-13a.

On March 27, 2015, the Illinois Appellate Court issued its opinion holding that none of Respondent's claims were preempted. App. 28a-44a. Specifically, the court held that Respondent's claims did not concern the design or labeling of propoxyphene—which would clearly be foreclosed under *Bartlett* and *Mensing*—but instead were premised on the stop-selling theory of liability, asserting that propoxyphene was so unreasonably dangerous it should never have been sold at all. The Illinois Appellate Court held that this stop-selling claim was not preempted by federal law. *See* App. 27a ("Since plaintiffs do not suggest that there was an improved design or label that could have cured the problem, there was no 'direct and positive conflict' with the generic manufacturer's federal duty to use the same design and label as the lead manufacturer.").

Though this Court explicitly rejected the stop-selling theory in *Bartlett*, the Illinois Appellate Court nevertheless concluded that *Bartlett* "assumes that there exists a warning that would cure the problem of an otherwise unreasonable risk of harm." App. 26a. The court stated that *Bartlett*'s "logic has no application to plaintiff's claims, which are that this drug is not effective and that its risks do not outweigh its benefits for the public at large." App.

27a. The court concluded that "the logic of *Bartlett* and *Mensing* does not apply to plaintiff's claims, and their holdings do not preempt the state-law claims in this case." App. 28a.

Petitioners timely filed a petition for leave to appeal the decision to the Illinois Supreme Court. The Illinois Supreme Court denied that petition with a summary order on September 30, 2015. Petitioners sought reconsideration of that denial, but the Illinois Supreme Court denied their motion for leave to file a motion for reconsideration on November 16, 2015.

REASONS FOR GRANTING THE PETITION

The Illinois Appellate Court made clear that it was rendering a result-oriented opinion—in defiance of this Court's controlling precedent—when it identified "the 'potential injustice' created by recent Supreme Court law" and noted "the hope that state courts would address this unfairness through the interpretation of their own states' tort laws." App. 20a. Its opinion therefore refuses to apply the application of this Court's decisions in *Bartlett* and *Mensing* to state-law claims that are indistinguishable from the claims this Court held preempted in those cases. Rather than limiting the scope of those cases in some principled way, the Illinois Appellate Court created a direct conflict with this Court's preemption precedents—and with those circuits and state courts that have faithfully applied those precedents—that justifies a summary reversal by this Court.

The hostility of the Illinois Appellate Court to this Court's precedents was manifest in its opinion. The court characterized Petitioners' federal constitu-

tional claims, dismissively and unfairly, by writing that "what defendants are arguing … is that they should be able to market a drug, even assuming that they know that it is dangerous and useless, until the Federal [sic] Drug Administration (FDA) officially stops them, and then bear no financial responsibility for the consequences." App. 3a.[4]

This Court has acknowledged that federal regulation of generic drugs—when combined with the supremacy of federal law—sometimes leaves plaintiffs without a remedy under state law. *See Mensing*, 131 S. Ct. at 2581 ("We acknowledge the unfortunate hand that federal drug regulation has dealt [plaintiffs] and others similarly situated."); *Bartlett*, 133 S. Ct. at 2480 ("Respondent's situation is tragic and evokes deep sympathy, but a straightforward application of pre-emption law requires that the judgment below be reversed."). That result follows from decisions by Congress to provide for comprehensive regulation of generic drugs at the federal level. *Mensing*, 131 S. Ct. at 2582 ("It is beyond dispute that the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers."); *Bartlett*, 133 S. Ct. at 2480 (noting "Congress' decision to regulate the manufacture and sale of generic drugs in a way that reduces their cost to patients but leaves generic drug manufacturers inca-

[4] *See also* App. 8a ("[D]efendants are trying to shield themselves from liability simply because the drug that Lewis ingested happened to be a generic brand and that, if the court accepts this theory, then Illinois residents will have no recourse simply because they chose to purchase a less expensive product.").

pable of modifying either the drugs' compositions or their warnings").

The sympathy of the Illinois Appellate Court for Respondent's circumstances does not justify a judicial decision that undermines the federal regulatory scheme and that defies this Court's interpretation of federal law. As this Court has said, "sympathy for respondent does not relieve us of the responsibility of following the law." *Id.* at 2478.

Other courts—including every federal appellate court to address the issue—have followed this Court's precedents despite tragic circumstances.[5] Here, the Illinois Appellate Court refused to apply those precedents in a plainly result-oriented opinion that makes Illinois an outlier among jurisdictions. To resolve that conflict, this Court need only summarily reverse and direct that the Illinois Appellate Court follow this Court's decision in *Bartlett*.

I. THE DECISION BELOW CONFLICTS WITH *BARTLETT*.

In *Bartlett*, this Court rejected the "'stop-selling' rationale as incompatible with our pre-emption jurisprudence" because "[o]ur pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease

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[5] *See, e.g.*, *Fosamax*, 751 F.3d at 165 n.31 ("The Appellants argue that the Hatch-Waxman Act 'did not give generic drugmakers a free pass in remaining ignorant of drugs' risks (or concealing those risks).' Regardless of the appeal such policy arguments may have, they are unavailing because, as the Supreme Court stated in *Bartlett*, 'sympathy for [a plaintiff] does not relieve us of the responsibility of following the law.'") (internal citations omitted).

acting altogether in order to avoid liability." *Bartlett*, 133 S. Ct. at 2477. In this case, however, the Illinois Appellate Court adopted the stop-selling rationale and held that Petitioners were required to cease selling propoxyphene in order to avoid liability for design defect under state law. That holding directly contradicts *Bartlett*. The Illinois Appellate Court asserted that "the logic of *Bartlett* and *Mensing* does not apply to plaintiff's claims," App. 28a, but the court identified nothing about Respondent's claims or circumstances that would distinguish this case from *Bartlett*.

A. Respondent's Stop-Selling Claim Is Indistinguishable From The Stop-Selling Claim This Court Rejected In *Bartlett*.

The Illinois Appellate Court concluded that Respondent's design-defect claim was distinguishable from the design-defect claim this Court held preempted in *Bartlett* on the ostensible ground that Respondent "alleged that the drug was simply unsafe and should not have been sold at all, and there was no warning that could have cured the problem." App. 27a. This, in the appellate court's view, distinguished her claim from that in *Bartlett*, which alleged "a warning that would cure the problem of an otherwise unreasonable risk of harm." App. 26a.

That is wrong. The plaintiff in *Bartlett* similarly asserted that the generic drug product in that case was so unreasonably dangerous that it should not have been sold at all. *See* Brief for Respondent at 10, *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013) (No. 12-142), 2013 WL 602909 (arguing based on ex-

pert testimony that "sulindac is 'unreasonably dangerous' to the public as a whole and thus 'shouldn't be on the market'"); *id.* (relying on evidence, including FDA adverse event reports, "demonstrating that sulindac's risks outweigh its benefits"); *id.* at 39 (arguing that "[i]f a State's strict-liability law imposes a tort duty on a manufacturer to withdraw an unreasonably dangerous drug from the market, nothing in federal law preempts that decision").

The design-defect claim in *Bartlett* did not focus specifically on the adequacy of the warnings. Rather, the plaintiff in *Bartlett* asserted a traditional strict-liability design-defect claim "as set forth in Section 402A of the Restatement (Second) of Torts," which has been adopted into New Hampshire law. *Bartlett*, 133 S. Ct. at 2473. The Illinois law under which Respondent brings her claim has also "adopted the strict liability doctrine set forth in section 402A of the Second Restatement of Torts." *Calles v. Scripto-Tokai Corp.*, 864 N.E.2d 249, 254 (Ill. 2007). Just as New Hampshire follows the Restatement standards for determining whether a product is "unreasonably dangerous," *Bartlett*, 133 S. Ct. at 2473, Illinois follows the same Restatement standards for determining whether a product is "unreasonably dangerous," *Calles*, 864 N.E.2d at 254. Thus, when Respondent asserts a count of "Strict Product Liability/Design Defect" in her First Amended Complaint, and therein alleges that Petitioners' product was "unreasonably dangerous," App. 57a-58a, she is asserting exactly the same claim—with exactly the same elements—as the plaintiff in *Bartlett*.

If Respondent were somehow asserting a differ-

ent claim from the *Bartlett* plaintiff, then she would fail to state a claim under Illinois law because Illinois recognizes the same cause of action for strict product liability as that considered in *Bartlett*. *Compare Bartlett*, 133 S. Ct. at 2474 ("[T]he New Hampshire Supreme Court employs a 'risk-utility approach' under which 'a product is defective as designed if the magnitude of the danger outweighs the utility of the product.'"), *with Calles*, 864 N.E.2d at 257 ("Under the risk-utility test, a plaintiff may prevail in a strict liability design-defect case if he or she demonstrates that the magnitude of the danger outweighs the utility of the product, as designed."). The legal standards are the same in New Hampshire and Illinois.

The Illinois Appellate Court refused to recognize the similarity between Respondent's design-defect claim and the preempted design-defect claim in *Bartlett* based on its insistence that the *Bartlett* claim was specifically about the warnings accompanying the product rather than the allegedly "unreasonably dangerous" design of the product itself. But that is false. The warnings became relevant in *Bartlett* only because it was clear that the manufacturer was legally unable to change the design, and for that reason the only way to alter the allegedly "unreasonably dangerous" design was to enhance the warnings. *See Bartlett*, 133 S. Ct. at 2475 ("Given the impossibility of redesigning sulindac, the only way for Mutual to ameliorate the drug's 'risk-utility' profile—and thus to escape liability—was to strengthen 'the presence and efficacy of [sulindac's] warning' in such a way that the warning 'avoid[ed] an unreasonable risk of

harm from hidden dangers or from foreseeable uses.'").

Exactly the same conclusion follows under Illinois law. Under Illinois law, "strict liability may be imposed based on proof of injury proximately caused by an unreasonably dangerous condition of a product and that such a condition may consist of a manufacturing defect, a design defect, or *inadequate warnings*." *Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 339 (Ill. 2008) (emphasis added). Thus, this case presents the same circumstance as *Bartlett*: where there is no manufacturing defect, and the manufacturer is unable to alter the design, a strict-liability claim related to an unreasonably dangerous product becomes focused on the adequacy of the warnings. This is equally true under the New Hampshire law considered in *Bartlett* and the Illinois law applicable to this case.

If the Illinois Appellate Court were correct that Respondent had not alleged that the warnings were inadequate,[6] that would simply mean Respondent had failed to allege one possible ground of her strict-liability claim. It would not mean that she was somehow asserting a *different claim* than the *Bartlett* plaintiff—who, again, also alleged that the generic drug in that case was too dangerous to be sold at all.

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[6] In fact, Respondent's complaint *does* allege that the warning label for propoxyphene was inadequate because it asserts that Petitioners failed to exercise reasonable care in the "promotion" of propoxyphene and made misleading statements "in the act of promoting and selling Propoxyphene." App. 51a-52a.

There is no avoiding the conclusion that Respondent has asserted the identical claim that this Court held preempted in *Bartlett*. A plaintiff asserting such a claim against a generic drug manufacturer would fail to state a claim before this Court—or before the Third, Fourth, Fifth, Sixth, Seventh, Eighth, and Tenth Circuits, which have all followed this Court's holding in *Bartlett*.[7] Yet in Illinois state court, the same claim is now allowed to proceed despite the conflict with federal law that this Court has identified. To achieve the uniform application of federal law, summary reversal in this case is warranted.

B. Respondent's State-Law Claim Conflicts With Federal Law.

The Illinois Appellate Court nonetheless held that Respondent's claim survived Petitioner's preemption defense because it occasioned "no 'direct and positive conflict' with the generic manufacturer's federal duty to use the same design and label as the lead manufacturer" given that "[t]he only remedy was to withdraw the product." App. 27a. But again, that assertion runs headlong into *Bartlett*: Saying that a generic manufacturer can continue "to use the same design and label as the lead manufacturer" so long as it "withdraw[s] the product" from the market conflicts directly with this Court's recognition that "[o]ur pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." *Bartlett*, 133 S. Ct. at 2477.

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[7] *See* cases cited *supra* at pages 2-3.

Nor is this a case where *both* federal *and* state law would require the manufacturer to withdraw its product from the market. In *Bartlett*, this Court observed that certain "state design-defect claims" might "parallel the federal misbranding statute," which "requires a manufacturer to pull even an FDA-approved drug from the market when it is 'dangerous to health' even if 'used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.'" *Bartlett*, 133 S. Ct. at 2477 n.4 (quoting 21 U.S.C. § 352(j)). But as the Court further explained, the federal duty to withdraw a drug from the market under this misbranding provision arises "*only* when liability is based on new and scientifically significant information that was not before the FDA." *Id.* (emphasis added). That requires new information "that had not been made available to the FDA" rather than information "drawn from the medical literature or published FDA analyses." *Id.*; *see also Darvocet*, 756 F.3d at 930 ("Plaintiffs cannot state such a claim because they do not point to 'new and scientifically significant information' that the Generic Manufacturers possessed that was not before the FDA.").

Respondent's claims plainly do not meet the federal misbranding standard. Rather than allege that Petitioners' liability follows from new information not possessed by the FDA, Respondent instead alleges that Petitioners should have withdrawn the product based on "adverse event data *maintained by the FDA*." App. 47a (emphasis added). Respondent acknowledges that the FDA was well aware of all the risk information related to propoxyphene that she

identifies in her complaint. She notes that the FDA convened a special "Advisory Committee meeting to address the efficacy and safety of Propoxyphene" at which the agency reviewed the relevant information in January 2009. App. 48a. That was a year before Respondent's husband was prescribed propoxyphene. App. 49a. At that time, the FDA determined that the available information indicated that propoxyphene should remain on the market. App. 48a. It was only a subsequent study commissioned by the FDA that led the agency to conclude that the available safety information no longer justified continued use of the drug when alternatives were available. *Id.*; *see also supra* pages 6-9 (detailing this history).

The FDA made this determination *after* Respondent's husband had taken the medication—and, according to Respondent's own allegations, it was based on information that the FDA itself "maintained." App. 48a. Petitioners did not have relevant safety information that was not possessed by the FDA. Accordingly, Respondent has not alleged facts giving rise to a federal misbranding claim that would have required Petitioners to withdraw their product from the market—and her claims seeking withdrawal of propoxyphene cannot escape preemption under *Bartlett*.[8]

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[8] Indeed, it is far from clear that Respondent's state-law claims would survive preemption even if the underlying allegations also stated a federal misbranding claim. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (holding that common-law fraud claims which paralleled the FDCA's anti-fraud provisions were preempted because "Congress intended that the [FDCA] be enforced exclusively by the Federal Gov-

The Sixth Circuit reached this conclusion when it considered the same claim regarding the same drug. After reviewing the regulatory history of propoxyphene, the Sixth Circuit said that "Plaintiffs submit only information that was considered, reviewed, and rejected by the FDA. That the FDA approved continued marketing of propoxyphene in July 2009, notwithstanding the information Plaintiffs submit, is fatal to their misbranding claim before that time." *Darvocet*, 756 F.3d at 930. Following July 2009, the plaintiffs in that case pointed to the Xanodyne study, which "confirmed the safety risks of propoxyphene, resulting in the FDA's conclusion that the safety risks of the drug outweighed its benefit. But the Generic Manufacturers did not have access to, and thus had no ability to evaluate, that study." *Id.* In fact, "the FDA's revised risk/benefit determination was contemporaneous with its request for market withdrawal after completing *its own independent review* of the Xanodyne study's proprietary data in late 2010." *Id.* (emphasis added).

For these reasons, the Sixth Circuit concluded that "Plaintiffs have not pled sufficient 'new and scientifically significant information that was not before the FDA' in order to satisfy the requirements of a 'parallel misbranding' claim (if such exists) to survive Generic Manufacturers' motion to dismiss." *Id.*

In this case, the Illinois Appellate Court reached

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ernment") (citing 21 U.S.C. § 337(a)). As in *Bartlett*, however, the Court need "not address state design-defect claims that parallel the federal misbranding statute" here, 133 S. Ct. at 2477 n.4, because Respondent has not alleged such a claim for the reasons stated above.

the opposite conclusion based on identical facts. It did so by ignoring this Court's instruction that a state-law duty to withdraw a drug can parallel federal law—if it ever can—only "when liability is based on new and scientifically significant information that was not before the FDA." *Bartlett*, 133 S. Ct. at 2477 n.4. Instead, the appellate court held that *whenever* a plaintiff alleges that a drug should have been removed from the market—regardless of information underlying that claim—such a "stop-selling" claim is never preempted by federal law.

That holding squarely conflicts with *Bartlett*—not to mention the Sixth Circuit's decision in *Darvocet*.[9] In *Bartlett*, this Court reserved judgment on whether a state-law claim imposing liability for failing to remove a generic drug product from the market would avoid preemption when it paralleled federal law. In this case, the Illinois Appellate Court held that such a state-law claim avoids preemption *even when it does not parallel federal law*. Both the appellate court's decision and Respondent's own complaint make clear that liability in this case is based on information that was considered by the FDA—indeed, information that the FDA itself generated. That sort of state-law liability is squarely foreclosed by *Bart-*

[9] The Tenth Circuit has similarly "reject[ed] the argument that the state law warranty claims are not preempted because they simply parallel requirements imposed by federal law" because the plaintiffs in that case had not identified "new and scientifically significant information that was not before the FDA" and because "allegations of dangerousness based on 'the medical literature or published FDA analyses' [do] not qualify." *Schrock*, 727 F.3d at 1290. The decision here conflicts with that case as well.

lett.

The holding of the Illinois Appellate Court was based not on legal principle but on an explicit policy judgment. The court decided that the drugs at issue in *Bartlett* and *Mensing* were "safe and effective for the vast majority of consumers," and therefore the logic of those cases "has no application to plaintiff's claims, which are that this drug is not effective and that its risks do not outweigh its benefits for the public at large." App. 27a. The court refused to apply preemption principles because Respondent "alleges that withdrawal will result in a net public benefit." App. 28a; *see also* App. 20a-21a (arguing that state courts should engage in such "delicate policy considerations").

That is a misstatement of the allegations in *Bartlett*, where the plaintiff in fact alleged that sulindac and was not beneficial for any class of patients and should not be on the market. *See* Brief for Respondent at 8, *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013) (No. 12-142), 2013 WL 602909 ("One claim … alleged that petitioner was strictly liable for selling an 'unreasonably dangerous' drug."); *id.* at 10 ("Given … safer alternatives, an expert opined that sulindac is 'unreasonably dangerous' to the public as a whole and thus 'shouldn't be on the market.'").

But even if the Illinois Appellate Court had not misstated the facts of *Bartlett*, it still would not have the policy discretion to expand the reach of state tort law where this Court has held it conflicts with federal law. The decision below ignores that holding and requires reversal.

The Illinois Supreme Court also suggested that *Bartlett* and *Mensing* should not apply to Respondent's claims because those claims arose prior to the Food and Drug Administration Amendments Act of 2007. App. 21a-22a. The court said "the parties did not argue that the FDAAA affects our analysis of the certified questions, so we do not consider this issue at this time," App. 22a, though it repeatedly suggested that post-2007 claims were somehow outside the reach of *Bartlett* and *Mensing*. *See, e.g.*, App. 37a ("Assuming *arguendo* that *Bartlett* and *Mensing* apply to post-2007 claims…").

The appellate court's understanding of the FDAAA, and its potential impact on Respondent's claims, is incorrect. The Seventh Circuit and other courts have explained that the FDAAA does not alter the preemption analysis under *Bartlett* or *Mensing* because "the amendments still forbid a generic-drug maker from violating the duty of sameness without FDA permission." *Houston*, 2016 WL 403310, at *5; *see also In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, No. 08-008, 2011 WL 5903623, at *7 (D.N.J. Nov. 21, 2011) ("[T]he *Mensing* analysis is not affected by FDAAA because the Generic Manufacturers are still unable to unilaterally change drug labeling 'without special permission and assistance, which is dependent on the exercise of judgment by a federal agency.'"); *Whitener v. PLIVA, Inc.*, No. 10-1552, 2011 WL 6056546, at *3 (E.D. La. Dec. 6, 2011) ("Plaintiffs have not articulated, and the Court cannot find, any changes in the FDAAA to a generic drug manufacturer's ability to alter the FDA-approved brand-name label for a drug. In the ab-

sence of any such change, the *Mensing* conflict preemption analysis does not change because compliance with both state and federal requirements remains impossible.").

As this Court has made clear, the crucial inquiry for preemption purposes is whether the generic manufacturer can unilaterally change its design or labeling without the FDA's prior approval. *Mensing*, 131 S. Ct. at 2579 ("The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it."). No provision of the FDAAA authorizes generic manufacturers independently to make labeling or design changes to their products. For that reason, "[t]he FDAAA is a red herring on this issue and does not preserve [Respondent's] claims." *Whitener*, 2011 WL 6056546, at *3.

Thus, the decision of the Illinois Appellate Court was based on a mischaracterization of this Court's decision in *Bartlett* and of the applicable federal law. This Court should vindicate both the supremacy of federal law and this Court's role in authoritatively interpreting that law by summarily reversing the judgment below and instructing the Court to follow *Bartlett*.

C. The Decision Below Conflicts With Decisions Of Circuit Courts And Leads To Absurd Results.

The direct conflict with this Court's decision in *Bartlett* is enough to justify summary reversal. But it is also striking how the decision of the Illinois Appellate Court in this case departs from the uniform position of the federal appellate courts. The Seventh

Circuit, in particular, has squarely held that federal law "preempts a state-law claim against a generic manufacturer if … that claim would require the manufacturer to redesign its drug, change its labeling, or exit the market in order to avoid liability." *Houston*, 2016 WL 403310, at *4. Thus, the same stop-selling claim that was recognized as viable in Illinois state court in this case would be dismissed for failure to state a claim if it were brought by the same plaintiff in federal court.

Every other federal appellate court to address the question has similarly recognized that because "a generic may not unilaterally change its labeling or change its design or formulation, and cannot be required to exit the market or accept state tort liability …. if a generic drug manufacturer cannot satisfy a state law duty except by taking one of these four actions, that law is preempted." *Drager*, 741 F.3d at 476; *see also Johnson*, 758 F.3d at 613 ("Johnson contends that her design-defect claim is not preempted because Generic Defendants could have complied with their duties under both federal and state law by declining to sell metoclopramide. The Supreme Court rejected this 'stop-selling' rationale in *Bartlett* as 'incompatible with our pre-emption jurisprudence.'"); *Fosamax*, 751 F.3d at 165 ("Short of exiting the market—which *Bartlett* rejects—the Appellants have failed to identify anything the Generic Defendants can do to reconcile their conflicting duties under state and federal law."); *Brinkley*, 772 F.3d at 1141; *Strayhorn*, 737 F.3d at 398 ("Nor can the plaintiffs proceed on a failure-to-withdraw or stop-selling theory, a theory recently rejected by the

Supreme Court in *Bartlett*."); *Schrock*, 727 F.3d at 1290 ("We do not lend credence to the Schrocks' argument that Qualitest could have complied with its alleged duty under state tort law and with the federal requirements by simply declining to manufacture metoclopramide. The Supreme Court squarely rejected this contention in *Bartlett*.").

Aside from the conflict that the decision below creates with these circuits, the decision of the Illinois Appellate Court also leads to absurd results. Under *Bartlett* and *Mensing*, a plaintiff has failed to state a claim on which relief can be granted if she alleges that a generic drug manufacturer should have (1) altered the composition of the drug, (2) changed the warnings, or (3) stopped selling the product. Under the decision of the Illinois Appellate Court in this case, the same plaintiff can avoid a motion to dismiss if she simply deletes the first two alternatives and alleges only that the generic manufacturer should have stopped selling the product.[10] In this way, the decision below allows plaintiffs to avoid the preemptive effect of federal law through artful pleading, and it encourages plaintiffs to seek removal of drugs from the marketplace—precisely what federal law aims to prevent. *See Houston*, 2016 WL 403310, at *4 ("[G]eneric-drug makers benefit consumers when they bring FDA-approved drugs to market. For

[10] *See* App. 27a ("Since plaintiffs do not suggest that there was an improved design or label that could have cured the problem, there was no 'direct and positive conflict' with the generic manufacturer's federal duty to use the same design and label as the lead manufacturer. The only remedy was to withdraw the product.") (internal citation omitted).

that reason, market exit is precisely the outcome that the duty of sameness and *Mensing*'s preemption principle are designed to prevent.") (citing *Mensing*, 131 S. Ct. at 2578).

This Court in *Bartlett* and *Mensing* did not intend to articulate a rule that encouraged stop-selling claims, and yet the Illinois Appellate Court has interpreted those cases to do precisely that.

D. Respondent's Follow-On Claims Do Not Distinguish This Case From *Bartlett*.

Respondent's primary claim—and the gravamen of all her claims—is the same design-defect strict-liability claim this Court held preempted in *Bartlett*. That the Illinois Appellate Court held that claim not to be preempted is reason enough to summarily reverse. Yet Respondent also recasts this claim under multiple alternative theories of liability, including negligence, fraudulent misrepresentation, fraudulent concealment, and consumer fraud. App. 4a. These claims are preempted for the same reasons—as the circuit courts have recognized. *See Houston*, 2016 WL 403310, at *4 ("For the same reason, Houston's claims for defective design, negligence, consumer fraud, battery, and breach of express and implied warranties are also preempted."); *Brinkley*, 772 F.3d at 1140-41 (design-defect and implied-warranty claims); *Johnson*, 758 F.3d at 612-13 (design-defect and express-warranty claims); *Eckhardt v. Qualitest Pharm., Inc.*, 751 F.3d 674, 678-80 (5th Cir. 2014) (same); *Drager*, 741 F.3d at 476-79 (claims for negligence, design defect, breach of implied and express warranties, negligent misrepresentation and fraudu-

lent concealment); *Strayhorn*, 737 F.3d at 394-97 (claims for breach of implied warranty, fraud and misrepresentation, and design defect); *Schrock*, 727 F.3d at 1286-89 (claims for breach of express and implied warranties).

The key point is that these claims all require a generic manufacturer to (1) alter the drug's design, (2) change the warning label, or (3) exit the market to avoid liability. Federal law preempts state-law claims that impose liability on generic manufacturers for failing to take these actions. These alternative state-law theories do not change the fact that each of Respondent's claims requires Petitioners to take one of these actions to avoid liability.

In fact, the argument of the Illinois Appellate Court is even weaker with respect to these claims. There is no possible argument, for example, that a claim for fraudulent representation does not turn on the adequacy of the warning label. Under the federal law applicable to drug product labels, "[t]he term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). The FDA's regulations make clear that "labeling" includes all written statements made by the manufacturer in connection with its pharmaceutical product. 21 C.F.R. § 202.1(l)(2); *see also Mensing*, 131 S. Ct. at 2576 (citing 21 U.S.C. § 321(m) and 21 C.F.R. § 202.1(l)(2)). As this Court has explained, such statements are always subject to "an ongoing federal duty of 'sameness,'" *id.* at 2575, and must always be "consistent with and not contrary to [the drug's] approved ... la-

beling," *id.* at 2576 (quoting 21 C.F.R. § 201.100(d)(1)).

For this reason, when Respondent alleges as part of her fraudulent-misrepresentation claim that Petitioners should have made different statements when "promoting and selling Propoxyphene," App. 52a, she is necessarily arguing that Petitioners should have altered the drug's labeling. Under federal law, those statements about safety and efficacy were subject to federal requirements that prevented Petitioners from making different statements. Any state-law claim that requires changes to those statements is preempted. *Mensing*, 131 S. Ct. at 2576.

A claim for "fraudulent misrepresentation" is not equivalent to a claim alleging that a product should not be sold at all, as the appellate court suggested. App. 39a (asserting that "the very act of marketing this drug was a misrepresentation and fraud upon the public"). Such a claim depends on the statements made by the defendant. *See Jane Doe-3 v. McLean Cty. Unit Dist. No. 5 Bd. of Dirs.*, 973 N.E.2d 880, 889 (Ill. 2012) ("The elements of a fraudulent misrepresentation claim are: (1) a false statement of material fact; (2) knowledge or belief of the falsity by the person making it; (3) intention to induce the other party to act; (4) action by the other party in reliance on the truth of the statements; and (5) damage to the other party resulting from such reliance.").

In upholding such a claim on the theory that Petitioners could have stopped selling the product, the Illinois Appellate Court was plainly using the stop-selling theory as a way to reconcile Respondent's claim that Petitioners should have made different

statements on the labeling with federal law preventing Petitioners from doing just that. That is, again, a direct conflict with *Bartlett*. *Bartlett*, 133 S. Ct. at 2477 ("[A]n actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability.").

The presence of alternative claims in this case makes the Illinois Appellate Court's defiance of *Bartlett* even worse—as well as more obvious.

II. THIS COURT HAS JURISDICTION OVER THIS CASE.

Though this case arises in an interlocutory posture from a state court, this Court nevertheless has jurisdiction. Under certain circumstances, this Court has "treated state-court judgments as final for jurisdictional purposes although there were further proceedings to take place in the state court." *Florida v. Thomas*, 532 U.S. 774, 777 (2001) (quoting *Flynt v. Ohio*, 451 U.S. 619, 620-21 (1981)). In *Cox Broad. Corp. v. Cohn*, 420 U.S. 469 (1975), this Court divided cases of this kind into four categories. Two of those categories are applicable here.

First, this Court has taken jurisdiction over state-court judgments where reversal of the state court on the federal issue would be preclusive of further litigation and leaving the state-court judgment in place would erode federal policy:

> [T]here are those situations where the federal issue has been finally decided in the state courts with further proceedings pending in which the party seeking review here might prevail on the merits on nonfederal grounds,

> thus rendering unnecessary review of the federal issue by this Court, and where reversal of the state court on the federal issue would be preclusive of any further litigation on the relevant cause of action rather than merely controlling the nature and character of, or determining the admissibility of evidence in, the state proceedings still to come. In these circumstances, if a refusal immediately to review the state court decision might seriously erode federal policy, the Court has entertained and decided the federal issue, which itself has been finally determined by the state courts for purposes of the state litigation.

Id. at 482-83. This case meets those criteria. Here, the federal preemption issue has been finally decided by the state courts. If Petitioners are able to prevail in further proceedings, it can only be on nonfederal grounds because the Illinois courts have conclusively rejected Petitioners' federal-preemption defense. If this Court were to reverse the Illinois Appellate Court, however, it would preclude any further litigation on Respondent's claims. And leaving the Illinois Appellate Court's ruling in place would seriously erode federal policy because it would invite state-law causes of action that conflict with federal law.

Indeed, this Court has specifically identified "the power of the state court to proceed in the face of the preemption claim" as "an issue separable from the merits and ripe for review in this Court, particularly 'when postponing review would seriously erode'" the federal policy that underlies the preemption claim. *Id.* at 483 (quoting *Local No. 438 Const. & Gen. La-*

borers' Union, AFL-CIO v. Curry, 371 U.S. 542, 550 (1963)). Here, the underlying federal policy is to promote the availability of generic drugs that match the FDA-approved composition and labeling of their brand-name equivalents. Allowing state courts to entertain claims that manufacturers should have altered the design or labeling or removed generic drugs from the market would seriously undermine that policy—as this Court has already recognized.[11]

Thus, this case resembles the circumstances of *Cox* itself. The state court's judgment "is plainly final on the federal issue and is not subject to further review in the state courts. [Petitioners] will be liable for damages if the elements of the state cause of action are proved." *Cox*, 420 U.S. at 485. Petitioners could conceivably "prevail at trial on nonfederal grounds, it is true, but if the [Illinois] court erroneously upheld the [tort claims], there should be no trial at all. Moreover, even if [Petitioners] prevailed at trial and made unnecessary further consideration of the constitutional question, there would remain in effect the unreviewed decision" of the Illinois Appellate Court undermining this Court's preemption jurisprudence and the supremacy of federal law. *Id.*

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[11] *See Mensing*, 131 S. Ct. at 2582 ("[I]t is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public. But different federal statutes and regulations may, as here, lead to different pre-emption results."); *Bartlett*, 133 S. Ct. at 2480 (noting "Congress' decision to regulate the manufacture and sale of generic drugs in a way that reduces their cost to patients but leaves generic drug manufacturers incapable of modifying either the drugs' compositions or their warnings").

Second, this Court has exercised jurisdiction over "those cases in which there are further proceedings—even entire trials—yet to occur in the state courts but where for one reason or another the federal issue is conclusive or the outcome of further proceedings preordained." *Cox*, 420 U.S. at 479. Here, while in principle Petitioners could prevail on the state-law ground that the propoxyphene was not "unreasonably dangerous," in reality the Illinois Appellate Court has already prejudged that issue. *See* App. 28a ("The issue in the case at bar is not whether the drug companies should have stopped selling. They should have, and they did.").

In holding that Petitioners are not entitled to a preemption defense, the Illinois Appellate Court allowed Respondent to rely on the FDA's ultimate determination that propoxyphene should be removed from the market—while ignoring that the FDA did not make that determination until after Respondent suffered an injury. *See* App. 25a ("By contrast [to *Bartlett*], in the case at bar, the FDA concluded that the public at large would not benefit from this drug and ordered it withdrawn from the market."). By doing so, the Illinois Appellate Court left "the outcome of further proceedings preordained." *Cox*, 420 U.S. at 479. The court effectively resolved the question whether the propoxyphene was unreasonably dangerous when it embraced the FDA's eventual safety determination as the key fact in this case while denying the preemptive effect of FDA regulations. Accordingly, "the case was for all practical purposes concluded" by the decision below. *Id.* at 483. "In these circumstances, because the case is for all prac-

tical purposes concluded, the judgment of the state court on the federal issue is deemed final." *Id.* at 479.

For these reasons, this case exhibits those circumstances "in which the Court has treated the decision on the federal issue as a final judgment for the purposes of 28 U.S.C. § 1257 and has taken jurisdiction without awaiting the completion of the additional proceedings anticipated in the lower state courts." *Id.* at 477.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted and the judgment below should be summarily reversed.

Respectfully submitted,

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February 25, 2016

APPENDIX

Appellate Court of Illinois,
First District, Fifth Division.

NICOLE GUVENOZ,
Individually and as Representative of the
Estate of Lewis Guvenoz, Deceased,
Plaintiff-Appellee,
v.
TARGET CORPORATION and
TEVA PHARMACEUTICALS USA, INC.,
Defendants-Appellants.

2015 IL App (1st) 133940
No. 1-13-3940.
March 27, 2015.

JUSTICE GORDON delivered the judgment of the court, with opinion. Presiding Justice Palmer and Justice McBride concurred in the judgment and opinion.

¶ 1 Plaintiff Nicole Guvenoz is the widow of Lewis Guvenoz (Lewis), a 39-year-old father of five who became a spastic quadriplegic and then died allegedly as a result of taking a generic drug marketed by defendant Target Corporation, Inc. (Target), and manufactured by defendant Teva Pharmaceuticals

USA, Inc. (Teva). The third defendant, Dr. Joshua Rosenow, who was one of Lewis's physicians, is not a party to this appeal.

¶ 2 This is a permissive interlocutory appeal that this court allowed pursuant to Illinois Supreme Court Rule 308(a), which permits this court to consider purely legal questions certified by the trial court for our review. Ill. S. Ct. R. 308(a) (eff. Feb. 26, 2010). In the case at bar, after the trial court denied defendants' motions under sections 2-615 and 2-619 of the Code of Civil Procedure to dismiss (735 ILCS 5/2-615, 2-619 (West 2012)), defendants moved the trial court to certify certain legal questions, which the trial court did over plaintiff's objection. The trial court also granted defendants' motion to stay proceedings until the resolution of their application for leave to appeal.

¶ 3 The certified questions drafted by defendants are stated in their entirety in the Background section below and concern whether federal law preempts the types of state-law claims made by plaintiff.

¶ 4 Defendants ask us to adopt a position, whereby consumers of generic drugs cannot sue the brand-name manufacturer because they did not ingest the brand-name drug,[1] but they are also barred from suing the generic manufacturer because, since federal

[1] The "overwhelming" majority of courts have held that generic consumers may not sue the brand-name manufacturer. *In re Darvocet*, 756 F.3d 917, 938 (6th Cir.2014).

law requires the generic manufacturer to be in lock-step with the brand-name manufacturer, federal law then preempts their claims, thereby leaving generic consumers without any recovery. In essence, what defendants are arguing on this appeal and at this early pleading stage of the litigation is that they should be able to market a drug, even assuming that they know that it is dangerous and useless, until the Federal Drug Administration (FDA) officially stops them, and then bear no financial responsibility for the consequences.

¶ 5 We analyze the relevant case law and answer the certified questions in the last section below.

¶ 6 BACKGROUND

¶ 7 We describe below both the allegations of plaintiff's complaint and defendants' motion to dismiss it. The certified questions are provided in full, in section III below.

¶ 8 I. The Complaint

¶ 9 Plaintiff's first amended complaint is plaintiff's last filed complaint and the subject of defendants' motion to dismiss, and it alleged the following:

¶ 10 Lewis Guvenoz and his wife Nicole were residents of Illinois. Lewis was given a prescription for Darvocet and, as a result of ingesting the recommended doses, he suffered a cardiac arrest that caused serious brain injuries. (Since the filing of this complaint and this appeal, Lewis has died.)

¶ 11 Defendant Teva is a Delaware corporation that regularly conducts business in Cook County, and it was involved in the manufacture, distribution, marketing, sale and labeling of Darvocet. Defendant Target is a Minnesota corporation that regularly conducts business in Cook County, and it was involved in the distribution and sale of Darvocet.

¶ 12 The complaint alleged 11 counts: in count I, negligence against both defendants Teva and Target; in counts II and III, fraudulent misrepresentation against both defendants Teva and Target; in counts IV and VI, fraudulent concealment against both defendants Teva and Target; in count V, strict product liability and design defect against both Teva and Target; in counts VII and VIII, violations of the Illinois Consumer Fraud and Deceptive Business Practices Act (Consumer Fraud Act) (815 ILCS 505/1 *et seq.* (West 2012)), against Teva and Target; in counts IX and X, loss of consortium against Target; and in count XI, professional negligence against Dr. Joshua Rosenow, who is not a party to this appeal.

¶ 13 Propoxyphene is an opoid analgesic prescription drug for the treatment of mild to moderate pain, which was first approved by the FDA in 1957 and has been commercially available in the United States since 1976 under the name of "Darvon" or, when combined with acetaminophen, "Darvocet." Over 90% of the market share of these drugs belongs to generic manufacturers. Defendant Teva marketed

a generic form of Darvocet and distributed it until it was withdrawn from the market in November 2010.

¶ 14 Upon information and belief, adverse event data maintained by the FDA indicated "a staggering number" of serious adverse events associated with propoxyphene, including heart arrhythmias. Defendants Teva and Target knew or should have known of: (1) the correlation between the use of Darvocet and the increased risk of developing potentially fatal heart arrhythmias; (2) that propoxyphene was ineffective, or at best, marginally effective as a pain reliever; and (3) that any benefits of propoxyphene were outweighed by its risks, including serious risks of cardiovascular events that could lead to death.

¶ 15 The serious health risks associated with propoxyphene and the existence of many safer alternatives led the British government to declare a recall of the drug in 2005, because it could not identify any group of patients for whom the drug's benefits outweighed its risks.

¶ 16 In January 2009, the FDA held an Advisory Committee meeting to address the efficacy and safety of propoxyphene. After considering the data submitted, the committee voted 14 to 12 against the continued marketing of the drug, and noted that additional information about the drug's cardiac effect would be relevant in assessing its risks and benefits.

¶ 17 In June 2009, the European Medicines Agency recommended that the marketing authoriza-

tion for propoxyphene be withdrawn across the European Union due to safety concerns. In the following month, July 2009, the FDA required a new safety study addressing unanswered questions about propoxyphene's effects on the heart.

¶ 18 After the European Medicines Agency recommended the drug's withdrawal and after the FDA required a new safety study, but just six months before the FDA ordered withdrawal of the drug, Lewis Guvenoz was prescribed and did purchase and ingest 72 tablets of propoxyphene between January 8, 2010, and May 13, 2010. Guvenoz's complaint alleges that, on May 13, 2010, while taking the recommended doses of the drug, Lewis experienced a cardiac arrest and resulting anoxic encephalopathy.

¶ 19 Just six months after Lewis's cardiac arrest, on November 19, 2010, the FDA required manufacturers to withdraw any products containing propoxyphene, including Darvocet and Darvon, from the United States market. The FDA determined that the risks of the drug outweighed the benefits after a safety study showed that propoxyphene causes significant changes to the electrical activity of the heart even when taken at recommended doses.

¶ 20 Defendants Teva and Target had actual knowledge that a "qt wave interval prolongnation effect was associated with Propoxyphene" and that the drug "blocked ION channels in the heart" which is associated with "pro-arrhythmia." Defendants knew that the drug was unsafe, that its risk of car-

diac injury far exceeded any benefits, and that it should not have been marketed.

¶ 21 The complaint does not allege that Lewis purchased and ingested propoxyphene that was manufactured or marketed by defendants. However, defendants did not move to dismiss on that ground, and that issue is not before us in the questions certified by the trial court. In addition, defendants attached to their motion to dismiss a letter from plaintiff's attorney which included a photograph of a bottle of Lewis' pills which states that the manufacturer is "Teva Pharm," and that they were dispensed by "Target Pharmacy, 115 N. Randall Road, Batavia, IL 60510." Also, defendant Target conceded in its memorandum in support of its motion to dismiss: "Mr. Guvenoz's personal physician issued four separate propoxyphene prescriptions to Mr. Guvenoz. Each time, Mr. Guvenoz presented the prescriptions to Target's pharmacy. Plaintiffs do not dispute that Target's pharmacy dispensed the prescriptions to Mr. Guvenoz exactly as prescribed * * *."

¶ 22 II. Motion to Dismiss

¶ 23 Defendants Teva and Target filed combined motions pursuant to section 2-619.1 to dismiss the complaint under both section 2-615 and section 2-619(a)(9). 735 ILCS 5/2-615, 2-619(a)(9), 2-619.1 (West 2012).

¶ 24 Pursuant to section 2-615, defendants Teva and Target moved to dismiss counts II, III, IV, VII,

and VIII for fraudulent misrepresentation, fraudulent concealment and violations of the Illinois Consumer Fraud Act, on the ground that plaintiff failed to plead them with sufficient particularity.

¶ 25 Pursuant to section 2-619(a)(9), defendants Teva and Target moved to dismiss all counts on the ground that they are preempted by federal law. Federal preemption is the issue before us on this permissive appeal.

¶ 26 In support of their federal preemption argument, defendants asserted that, "at their core," plaintiff's claims were an attack on the "sufficiency of the warnings, labeling and disclosures" about the drug's risks. However, in plaintiff's response, she stated that, at their core, her claims are that the drug was simply unsafe and should not have been sold at all. Plaintiff claims that defendants are trying to shield themselves from liability simply because the drug that Lewis ingested happened to be a generic brand and that, if the court accepts this theory, then Illinois residents will have no recourse simply because they chose to purchase a less expensive product. In plaintiff's surresponse brief, she stated unequivocally: "This action is not, never has been, and never will be a failure to warn claim."

¶ 27 Plaintiff's response to defendants' motion included an affidavit from Dr. Robert Barkin, who is a full professor at Rush University Medical College in the departments of anesthesiology, family medicine and pharmacology, and who authored an article in

2006 entitled: "Propoxyphene: A Critical Review of a Weak Opiod Analgesic that Should Remain in Antiquity." The affidavit stated that, from January 2010 to May 2010, Lewis ingested 72 tablets over a 123-day period pursuant to a prescription. On May 13, 2010, the 38-year-old Lewis, who had no prior history of cardiovascular disease, experienced a cardiac arrest in his garage and, when emergency medical technicians arrived, he had no pulse. After his cardiac arrest, he suffered an anoxic encephalopathy from which there was no recovery. The affidavit repeated the history of the drug that we summarized above in our description of the complaint. Dr. Barkin concluded, to a reasonable degree of pharmacologic and scientific certainty, that Lewis's "sudden cardiac arrest with no known antecedent pathology and resultant anoxic encephalopathy was/is causally related to the ingestion of propoxyphene." He further concluded that "[a]t the time propoxyphene was prescribed to [Lewis] in January 2010, the drug was inherently dangerous and unsafe," and that the "unreasonably dangerous qualities of the drug propoxyphene were well known by the pharmaceutical industry before and during 2006."

¶ 28 On September 11, 2013, the trial court issued a written order denying defendants' combined motion to dismiss.

¶ 29 III. The Certified Questions

¶ 30 On September 30, 2013, defendants moved the trial court: (1) for the certification of certain legal

questions for immediate appellate review pursuant to Illinois Supreme Court Rule 308(a) (eff. Feb. 26, 2010); and (2) for a stay of the trial court's proceedings pending the resolution of defendants' application to the appellate court for leave to appeal.

¶ 31 The questions drafted by defendants and certified by the trial court are:

> "(1) Did the U.S. Supreme Court's decisions in *Mutual Pharmaceutical Co. Inc. v. Bartlett,* [570 U.S. __,] 133] S. Ct. 2466 (2013), *PLIVA, Inc. v. Mensing,* [564 U.S. __, __,] 131 S. Ct. 2567, 2574 (2011), and their progeny (collectively, the '*Bartlett]/Mensing*' precedent) require the dismissal on federal preemption grounds of an Illinois common law cause of action for negligence, alleging negligence in the design, manufacture, or distribution of a generic drug (commonly known as Propoxyphene) approved by the United States Food & Drug Administration (the 'FDA')?
>
> (2) Does the *Bartlett/Mensing* precedent require the dismissal on federal preemption grounds of an Illinois common law cause of action for strict product liability/design defect, alleging unreasonable dangerousness in the design or manufacture of a generic drug (commonly known as Propoxyphene) approved by the FDA?
>
> (3) Does the *Bartlett/Mensing* precedent require the dismissal on federal preemption grounds of an Illinois common law cause of action

for fraudulent misrepresentation, alleging false statements of material fact regarding the safety, risks or lack of testing of a generic drug (commonly known as Propoxyphene) approved by the FDA?

(4) Does the *Bartlett/Mensing* precedent require the dismissal on federal preemption grounds of an Illinois common law cause of action for fraudulent concealment, alleging concealment or withholding of alleged design or manufacturing defects, lack of safety, or other unreasonably high risks associated with a generic drug (commonly known as Propoxyphene) approved by the FDA?

(5) Does the *Bartlett/Mensing* precedent require the dismissal on federal preemption grounds of a cause of action under the Illinois Consumer Fraud and Deceptive Business Practices Act, alleging a generic drug (commonly known as Propoxyphene) approved by the FDA?"

In sum, defendants ask the same question with respect to each of plaintiff's causes of action, asking whether the *Bartlett/Mensing* precedent requires dismissal of each of this type of state-law claim on federal preemption grounds. However, in recognition of the fact that the lawsuit is in its early stages and the complaint could be further amended, the questions do not ask us to assess whether plaintiff's claims, as currently alleged, are sufficient. Instead the questions ask whether any state-law "cause of

action" exists for each type of claim after the *Bartlett* and *Mensing* Supreme Court decisions. Nonetheless, we interpret these question in light of plaintiff's allegations.

¶ 32 Plaintiffs objected to these certified questions and stated at oral argument before this court that the *Bartlett/Mensing* precedent did not apply. The relevant events in the *Bartlett/Mensing* precedent predated the Food and Drug Administration Amendments Act of 2007 (Pub. L. No. 110-85, 121 Stat. 823 (2007)) (the 2007 Act) while the events in the case at bar all postdated it. However, since the certified questions did not address these amendments, the parties in their briefs did not discuss them, and neither do we. As the United States Supreme Court did, we express no view on the impact of the 2007 Act on plaintiff's claims. *PLIVA, Inc. v. Mensing,* 564 U.S. __, __, 131 S. Ct. 2567, 2574 n.1 (2011). ("All relevant events in these cases predate the Food and Drug Administration Amendments Act of 2007 [citation]. We therefore refer exclusively to the pre-2007 statutes and regulations and express no view on the impact of the 2007 Act."); *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. __, __, 133 S. Ct. 2466, 2472 (2013) (the drug was first prescribed in December 2004 and respondent was already suffering by the time the FDA ordered changes to the labeling in 2005); *Wyeth v. Levine,* 555 U.S. 555, 567 (2009) ("In 2007, after [the plaintiff's] injury and lawsuit, Congress again amended the FDCA" grant-

ing broader powers to manufacturers to make unilateral labeling changes.).

¶ 33 On May 7, 2014, this court granted defendants' petition for leave to appeal pursuant to Supreme Court Rule 308(a). On July 29, 2014, this court also granted plaintiff's motion to substitute Nicole Guvenoz as representative of the estate of Lewis Guvenoz, who had since died, and to change the caption of the case accordingly. This appeal followed.

¶ 34 ANALYSIS

¶ 35 In this interlocutory appeal, we are called upon to answer certain certified questions, which we answer below.

¶ 36 I. Rule 308

¶ 37 As stated above, we permitted this appeal pursuant to Illinois Supreme Court Rule 308(a) (eff. Feb. 26, 2010) which provides in relevant part:

> "When the trial court, in making an interlocutory order not otherwise appealable, finds that the order involves a question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation, the court shall so state in writing, identifying the question of law involved. * * * The Appellate Court may thereupon in its discretion allow an appeal from the order."

¶ 38 After the trial court certifies the questions, the appellant must file an application seeking an appeal with the appellate court. Ill. S. Ct. R. 308(b) (eff. Feb. 26, 2010). The application must be "accompanied by an original supporting record." Ill. S. Ct. R. 308(c) (eff. Feb. 26, 2010). The adverse party may then file an answer, "together with an original of a supplementary supporting record containing any additional parts of the record the adverse party desires to have considered by the Appellate Court." Ill. S. Ct. R. 308(c) (eff. Feb. 26, 2010). "If leave to appeal is allowed," as it was in the case at bar, "any party may request that an additional record on appeal be prepared." Ill. S. Ct. R. 308(d) (eff. Feb. 26, 2010).

¶ 39 In the case at bar, defendants filed a supporting record, and plaintiff chose neither to submit a supplementary supporting record nor to request that an additional record be prepared. Thus, the record before us is solely the supporting record filed by defendants.

¶ 40 II. Standard of Review

¶ 41 Since a Supreme Court Rule 308 petition is limited to only "a question of law" (Ill. S. Ct. R. 308(a) (eff. Feb. 26, 2010)), our review is *de novo*. *Seith v. Chicago Sun-Times, Inc.,* 371 Ill. App. 3d 124, 133 (2007) (where an appeal concerns a question of law, we review the trial court's order *de novo*). *De novo* review means that we perform the same analysis that a trial judge would perform. *JPMorgan*

Chase Bank, National Ass'n v. Ivanov, 2014 IL App (1st) 133553, ¶65. Since our review is *de novo,* we may consider any basis appearing in the record. *Lewis v. Heartland Food Corp.,* 2014 IL App (1st) 123303, ¶7 (citing *Gatreaux v. DKW Enterprises, LLC,* 2011 IL App (1st) 103482, ¶10); *Seith,* 371 Ill. App. 3d at 133.

¶ 42 Since this appeal comes to us after the trial court's denial of a motion to dismiss and prior to the close of discovery, and since it presents a purely legal question, we accept the allegations of the complaint as true for the purposes of this appeal. *Lewis v. Heartland Food Corp.,* 2014 IL App (1st) 123303, ¶7 (when reviewing a trial court's decision on a section 2-615 motion to dismiss, we accept as true all well-pled facts in the plaintiff's complaint); *Bank of America, N.A. v. Adeyiga,* 2014 IL App (1st) 131252, ¶57 (when reviewing a trial court's decision on a 2-619 motion to dismiss, we accept as true all well-pled facts in the plaintiff's complaint).

¶ 43 III. Federal Law

¶ 44 Defendants claim that "the *Bartlett/Mensing* precedent require the dismissal on federal preemption grounds" of the types of state-law claims alleged by plaintiff.

¶ 45 "[P]re-emption is a demanding defense," and the defendant drug company has the burden of demonstrating that it applies. *Wyeth,* 555 U.S. at 573 ("Wyeth has failed to demonstrate that it was

impossible for it to comply with both federal and state requirements."); *see also Wyeth,* 555 U.S. at 581 ("Wyeth has not persuaded us * * *."). "Congress enacted the FDCA[2] to bolster consumer protection against harmful products," not to lessen it. *Wyeth,* 555 U.S. at 574. The United States Supreme Court observed: "Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1938 statute or in any subsequent amendment. Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers." *Wyeth,* 555 U.S. at 574, 574 n.7 (observing that witnesses testified before the Senate that a federal "right of action was unnecessary because common-law claims were already available under state law").

¶ 46 Thus, the defendant drug company bears the burden of demonstrating that these state rights are federally preempted.

¶ 47 "'[T]he purpose of Congress is the ultimate touchstone in every pre-emption case.'" *Wyeth,* 555 U.S. at 565 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). When Congress enlarged the FDA's powers to protect the public and ensure the safety and effectiveness of drugs, Congress included a statement of its intent with respect to state law: "No provision of this Act nor any amendment made

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[2] The "FDCA" referred to by the *Wyeth* court is the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq*. (Supp. I 2008).

by it shall be construed as indicating any intent on the part of the Congress to occupy the field in which such provision or amendment operates to the exclusion of any State law on the same subject matter, *unless there is a direct and positive conflict* between such provision or amendment and such State law *so that the two cannot be reconciled or consistently stand together*." (Emphasis added.) Pub. L. 89-74, § 10, 79 Stat. 235 (1965); *Wyeth*, 555 U.S. at 567 (discussing Congress's intent and purpose in the 1962 amendment).

¶ 48 Thus, to satisfy its burden, a defendant drug company must show a direct and positive conflict that cannot be reconciled.

¶ 49 First, we will set forth the *Bartlett/Mensing* precedent. Then, in the following section, we will apply that precedent to answer the certified questions before us.

¶ 50 A. *PLIVA v. Mensing*

¶ 51 *Mensing* concerned solely failure-to-warn claims brought against generic manufacturers. *Mensing,* 564 U.S. at __, 131 S. Ct. at 2572. The case was brought by two plaintiffs who consumed the generic drug, metocyclopramide, which is "commonly used to treat digestive tract problems." *Mensing,* 564 U.S. at __, 131 S. Ct. at 2572. The drug was, and is, commonly used, and there was no suggestion that it should not be. The issue was not whether the drug should be on the market at all, but rather what

warnings should accompany it to warn the minority of people who could be adversely affected by it. *Mensing,* 564 U.S. at __, 131 S. Ct. at 2572-73.

¶ 52 The *Mensing* plaintiffs developed tardive dyskinesia, a severe neurological disorder, which can occur in some patients who take the drug for several years. *Mensing,* 564 U.S. at __, 131 S. Ct. at 2572. Even among those patients who take the drug for several years, less than a third, or 29%, of those patients, develop this condition. *Mensing,* 564 U.S. at __, 131 S. Ct. at 2572.

¶ 53 The warnings on the drug's labels and package inserts had been strengthened and clarified several times over the years to address the potential danger associated with long-term use. *Mensing,* 564 U.S. at __, 131 S. Ct. at 2572. In 1985, the package insert stated that "'[t]herapy longer than 12 weeks * * * cannot be recommended.'" *Mensing,* 564 U.S. at __, 131 S. Ct. at 2572. In 2004, the label was changed to add that use should "'not exceed 12 weeks.'" *Mensing,* 564 U.S. at __, 131 S. Ct. at 2572. Finally, in 2009, the FDA ordered a "black box warning" which stated that treatment "'longer than 12 weeks should be avoided.'" *Mensing,* 564 U.S. at __, 131 S. Ct. at 2572-73. The *Mensing* plaintiffs took the drug in 2001 and 2002, which was when the package insert warned that "'[t]herapy longer than 12 weeks * * * cannot be recommended,'" but before the label changes in 2004 and 2009 which provided stronger warnings. *Mensing,* 564 U.S. at __, 131

S. Ct. at 2572-73. Thus, the crux of plaintiffs' claims was that these label changes should have been made earlier. *Mensing,* 564 U.S. at __, 131 S. Ct. at 2573.

¶ 54 The *Mensing* Court stated: "All relevant events in these cases predate the Food and Drug Administration Amendments Act of 2007, 121 Stat. 823 [(FDAAA)]. We therefore refer exclusively to the pre-2007 statutes and regulations and express no view on the impact of the 2007 Act." *Mensing,* 564 U.S. at __, 131 S. Ct. at 2574 n.1.

¶ 55 The *Mensing* Court held that, under pre-2007 law, the generic manufacturers could not have made the label changes earlier, because federal law required the warnings on their labels to be the same as those on the brand-name manufacturer. *Mensing,* 564 U.S. at __, 131 S. Ct. at 2575-76. As a result, plaintiffs' failure-to-warn claims, which were based on 2001 and 2002 events, were preempted. *Mensing,* 564 U.S. at __, 131 S. Ct. at 2581.

¶ 56 The Supreme Court acknowledged that, from the "perspective" of the injured consumer, the distinction between brand-name and generic manufacturers "makes little sense." *Mensing,* 564 U.S. at __, 131 S. Ct. at 2581. The Court recognized that, if the *Mensing* plaintiffs had taken "the brand-name drug prescribed by their doctors, * * * their lawsuits would not be pre-empted." *Mensing,* 564 U.S. at __, 131 S. Ct. at 2581. While "acknowledg[ing] the unfortunate hand that federal drug regulation has dealt" the plaintiffs, the Court stated that it was not

its task "to create similar pre-emption" results in federal drug regulation. *Mensing,* 564 U.S. at __, 131 S. Ct. at 2581-82.

¶ 57 Like the United States Supreme Court, the federal circuit courts of appeal have also "recognize[d] the catch-22 situation in which existing jurisprudence places" plaintiffs, in that they "cannot obtain relief from brand-name drug manufacturers" whose products they did not ingest, but their "claims against generic drug manufacturers are preempted." *Schrock v. Wyeth, Inc.,* 727 F.3d 1273, 1290 (10th Cir. 2013); *Strayhorn v. Wyeth Pharmaceuticals, Inc.,* 737 F.3d 378, 407 (6th Cir. 2014) ("Although we feel compelled to affirm the [dismissal] below in light of controlling [Supreme Court] caselaw, we cannot help but note the basic unfairness of this result" where "plaintiffs are * * * caught in a classic 'Catch-22'" barred from claims against generic manufacturers due to federal preemption and barred from claims against brand-name manufacturers whose product they did not ingest.).

¶ 58 One federal circuit court held out the hope that state courts would address this unfairness through the interpretation of their own states' tort laws. Lamenting the "potential injustice" created by recent Supreme Court law, the Tenth Circuit stated: "As a federal court, however, we have limited authority to correct this potential injustice. It is for the state courts, rather than this panel, to engage in the delicate policy considerations predicate to the expan-

sion of the scope of state tort law." *Schrock v. Wyeth, Inc.,* 727 F.3d 1273, 1290 (10th Cir.2013).

¶ 59 In a footnote, the *Mensing* Court expressed no view as to whether its holding applied to post-2007 cases like the one here. *Mensing,* 564 U.S. at __, 131 S. Ct. at 2574 n.1. *See also In re Reglan/Metoclopramide Litigation,* 81 A.3d 80, 83 (Pa. Super. Ct. 2013) (in light of footnote 1 in *Mensing,* "we decline to find post-Act claims pre-empted"); *In re Reglan/Metoclopramide Litigation,* 74 A.3d 221, 222 (Pa. Super. Ct. 2013) (post-Act claims are not preempted); *Hassett v. Dafoe*, 74 A.3d 202, 217 (Pa. Super. Ct. 2013) ("We agree with [plaintiff] that until post-Act claims are subjected to a thorough preemption analysis, dismissal of those failure to warn claims is premature."). Similarly, in *Bartlett,* which we discuss below, all the relevant events occurred before 2007. *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2472 (the drug was first prescribed in December 2004 and respondent was already suffering by the time the FDA ordered changes to the labeling in 2005); *In re Reglan,* 81 A.3d at 85 ("The FDAAA, 121 Stat. 823, was enacted on September 27, 2007.").

¶ 60 After the 2007 amendment, generic manufacturers were required to propose stronger labeling if it was warranted, and the FDA could unilaterally order it pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(o)(4) (Supp. I 2008)). *Hassett,* 74 A.3d at 217 n.13. Thus, Congress removed at least one impediment relied upon in sup-

port of preemption: the requirement that the FDA negotiate with the lead manufacturer to strengthen the warning label. *Mensing,* 564 U.S. at __, 131 S. Ct. at 2578-79. By removing at least some of the discretion afforded the lead manufacturer that made it impossible for generic manufacturers to comply with both state and federal law, the amendment arguably changes the landscape for generic manufacturers and may make their situation closer to the brand-name manufacturer that was held liable in *Wyeth v. Levine,* 555 U.S. 555 (2009), rather than the generic manufacturer that was found not liable in *Mensing*. *Hassett,* 74 A.3d at 217 n.13. In addition, Congress chose not to include an express preemption provision in the FDAAA. *In re Reglan,* 81 A.3d at 89 n.5.

¶ 61 However, the parties did not argue that the FDAAA affects our analysis of the certified questions, so we do not consider this issue at this time. The certified questions ask us to resolve what "the *Bartlett/Mensing* precedent require."

¶ 62 B. *Mutual Pharmaceutical v. Bartlett*

¶ 63 In *Bartlett,* the generic drug at issue was sulindac, which was a "NSAID," or a nonsteroidal anti-inflammatory pain reliever. *Bartlett,* 133 S. Ct. at 2471. "In a very small number of patients," NSAIDs caused a severe and serious skin reaction, which the *Bartlett* plaintiff suffered. *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2471-72. NSAIDs included not only sulindac, which the *Bartlett* plaintiff ingested, but also

common and popular drugs, such as ibuprofen. *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2471. Thus, the drug at issue in *Bartlett* was safe and effective for the vast majority of people who took it, and the issue concerned only "[the] very small number of patients" who suffered an adverse and severe reaction. *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2471.

¶ 64 The possible severe reactions were toxic epidermal necrolysis, which the *Bartlett* plaintiff suffered; and its less severe cousin, Stevens-Johns[on] Syndrome. *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2471. At the time that the *Bartlett* plaintiff was prescribed sulindac, the drug's label warned that the drug could cause "'severe skin reactions,'" and the drug's package insert listed both toxic epidermal necrolysis and Stevens-Johns[on] Syndrome as potential adverse reactions. *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2472. In 2005, once the *Bartlett* plaintiff was already suffering, the FDA adopted additional warnings for the labeling of all NSAIDs, including sulindac. *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2472.

¶ 65 The trial court dismissed the *Bartlett* plaintiff's failure-to-warn claim after her doctor admitted that he had not read either the box or the insert. *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2472. The case proceeded to trial on the plaintiff's design-defect claim alone, and a jury awarded her over $20 million in damages. *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2472. Thus, only her design-defect claim was at issue

on appeal. *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2472.

¶ 66 On appeal, the First Circuit Court of Appeals held that a generic manufacturer that was facing design-defect claims should simply stop selling the drug and thereby comply with both federal and state law (*Bartlett,* 570 U.S. at __, 133 S. Ct. at 2472), even though the drug was safe and effective for the vast majority of people taking it. *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2471. Based on this stop-selling rationale, the First Circuit found that the *Bartlett* plaintiff's design-defect claim was not preempted. *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2472.

¶ 67 The United States Supreme Court reversed and specifically rejected the "stop-selling rationale" set forth by the First Circuit. *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2470. The Court held: "In the instant case, it was impossible for [the defendant] to comply with both its state-law duty to strengthen the warnings on sulindac's label and its federal-law duty not to alter sulindac's label. Accordingly, the state law is pre-empted." *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2473. The Court explained: "Our pre-emption cases presume that an actor seeking to satisfy both his federal-and state-law obligations is not required to cease acting altogether in order to avoid liability." *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2477. However, that statement was made in the context of the *Bartlett* case, where the drug was safe and effective for

the vast majority of the people taking it, and ceasing to act would have benefitted only "[the] very small number" of people who suffered an adverse reaction. *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2471. By contrast, in the case at bar, the FDA concluded that the public at large would not benefit from this drug and ordered it withdrawn from the market.

¶ 68 Responding to the dissent, the *Bartlett* majority agreed "that federal law establishes no safe-harbor for drug companies—but it does prevent them from taking certain remedial measures." *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2479. The Court stated: "Where state law imposes a duty to take such remedial measures, it 'actual[ly] conflict[s] with federal law' by making it '"impossible for a private party to comply with both state and federal requirements."'" *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2479 (quoting *Freightliner Corp. v. Myrick,* 514 U.S. 280, 287 (1995), quoting *English v. General Electric Co.,* 496 U.S. 72, 79 (1990)). These statements presume that a plaintiff has identified "remedial measures" which could have reduced the drug's risks. By contrast, in the case at bar, the FDA concluded that no remedial measures were, in fact, possible and ordered its manufacturers to withdraw it from the market.

¶ 69 "In cases where it is impossible—in fact or by law—to alter a product's design (and thus to increase the product's 'usefulness' or decrease its 'risk of danger'), the duty to render a product 'reasonably safe' boils down to a duty to ensure 'the presence and

efficacy of a warning to avoid an unreasonable risk of harm from hidden dangers or from foreseeable uses.'" *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2480 (quoting *Vautour v. Body Masters Sports Industries, Inc.*, 784 A.2d 1178, 1182 (N.H. 2001)). This reasoning assumes that there exists a warning that would cure the problem of an otherwise unreasonable risk of harm. By contrast, in the case at bar, the FDA concluded that no warning would suffice and ordered the drug entirely withdrawn from public sale.

¶ 70 Reconciling the *Bartlett* Court's unequivocal and unanimous endorsement of the statement that "federal law establishes no safe-harbor for drug companies," with the majority's holding that federal law does preempt "certain remedial measures," leads to the conclusion that, where there is no possible remedy, there is no safe harbor. *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2479.

¶ 71 C. Summary

¶ 72 The facts in the case at bar are very different from the facts in both *Bartlett* and *Mensing*. In the case at bar, plaintiff alleges that there was no group of patients for whom the drug's benefits outweighed its risks. By contrast, in both *Bartlett* and *Mensing,* the drug was safe for the vast majority of patients taking it, and only a "very small number of patients" suffered an adverse and severe reaction. *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2471; *see also Mensing,* 564 U.S. at __, 131 S. Ct. at 2572 (a severe neurological disorder occurred in less than a third of

the patients who took the drug for several years). In the case at bar, plaintiff alleged that the drug was simply unsafe and should not have been sold at all, and there was no warning that could have cured the problem. By contrast, in both *Bartlett* and *Mensing*, the problem was addressed by the FDA with an improved warning. *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2472; *Mensing,* 564 U.S. at __, 131 S. Ct. at 2572-73.

¶ 73 In the case at bar, since no remedy was possible, there was no safe harbor. *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2479. Since plaintiffs do not suggest that there was an improved design or label that could have cured the problem, there was no "direct and positive conflict" with the generic manufacturer's federal duty to use the same design and label as the lead manufacturer. Pub. L. 89-74, § 10, 79 Stat. 235 (1965) (discussed in *Wyeth*, 555 U.S. at 568). The only remedy was to withdraw the product.

¶ 74 While it made little sense in *Bartlett* and *Mensing* to require a company to withdraw from the market a drug which is still actively used and which is safe and effective for the vast majority of consumers, that logic has no application to plaintiff's claims, which are that this drug is not effective and that its risks do not outweigh its benefits for the public at large. Thus, while withdrawing the drug in *Bartlett* and *Mensing* would not have resulted in a net public benefit, plaintiff alleges that withdrawal will result

in a net public benefit and, in fact, the FDA agreed and ordered the drug pulled from the market.

¶ 75 The issue in the case at bar is not whether the drug companies should have stopped selling. They should have, and they did. However, defendants argue that federal law provided them with a safe harbor for failing to stop earlier. Unfortunately for defendants, the *Bartlett* Court has already rejected that idea. *Bartlett,* 570 U.S. at __, 133 S. Ct. at 2479.

¶ 76 For these reasons, the logic of *Bartlett* and *Mensing* does not apply to plaintiff's claims, and their holdings do not preempt the state-law claims in this case, as we explain in greater detail below.

¶ 77 IV. Certified Questions

¶ 78 A. Overview

¶ 79 Now, having set forth the *Bartlett/Mensing* precedent, we will now apply this discussion to the specific state law claims and certified questions before us.

¶ 80 Since *Bartlett,* most claims against generic manufacturers have been dismissed *E.g.,*[3] *Strayhorn,* 737 F.3d at 407 ("despite the 'Catch–22' dilemma" faced by plaintiffs, "we affirm" the trial court's dismissal); *In re Fosamax (Alendronate Sodi-*

[3] Although we provide only an "*e.g.*" cite here, a more complete list of cases is provided *infra* in paragraph 82, with their approximate complaint-filing dates.

um) Products Liability Litigation (NO. II), 751 F.3d 150, 157-58, 165 (3d Cir. 2014) (strict-liability claim against a generic manufacturer, which was based on a risk-utility analysis of an alleged design defect, was preempted).

¶ 81 In contrast, a substantial minority of courts have allowed claims against generic manufacturers to proceed. *Fullington v. Pfizer, Inc.,* 720 F.3d 739, 745-47 (8th Cir. 2013) (reversing the trial court's dismissal of plaintiff's breach of implied warranty claim and strict-liability design-defect claim against generic manufacturers and remanding for reconsideration); *Huck v. Wyeth, Inc.,* 850 N.W.2d 353, 356 (Iowa 2014) (reversing summary judgment for generic manufacturer and remanding for further proceedings on defendant's failure to update its label with "a stronger warning approved by the FDA"); *Hassett,* 74 A.3d at 215, 217 (holding that federal drug law does "not pre-empt claims based upon the marketing of defective products, a lack of due care in testing, or a product's failure to conform to express and implied warranties," and "fraud and misrepresentation in the advertising and promotion of * * * generic drugs," and, thus, the trial court was correct in not dismissing those claims); *In re Reglan,* 81 A.3d at 96 (holding that federal preemption does not apply to claims that "do not sound in failure to warn, arose after the passage of the 2007 Act, or involve a generic manufacturer's failure to conform its label to that of the name brand"); *Franzman v. Wyeth, Inc.,* 451 S.W.3d 676, 679 (Mo. Ct. App. 2014) (reversing dis-

missal of plaintiff's "failure-to-warn claim relating to the Generic Defendants' failure to update their warning labels"); *Fisher v. Pelstring,* 817 F. Supp. 2d 791, 805, 814, 818, 821, 823-24 (D.S.C. 2012) (denying summary judgment for generic manufacturer on claims for failure to update, fraud by concealment, manufacturing defect and breach of implied warranty of merchantability); *see also Bell v. Pfizer, Inc.,* 716 F.3d 1087, 1096 (8th Cir. 2013) (remanding, 10 days before *Bartlett* was decided, plaintiff's "design defect and breach of implied warranty claims" for reconsideration); *In re Fosamax,* 751 F.3d at 158 ("we withhold comment on whether negligence-based design-defect claims are or are not preempted"); *Wyeth, Inc. v. Weeks,* No. 1101397, 2014 WL 4055813, at *22 (Ala. Aug. 15, 2014) (a generic consumer can sue the brand-name manufacturer).

¶ 82 However, the majority of dismissing cases were in a different procedural posture from the instant case. *In re Reglan/Metoclopramide Litigation,* 81 A.3d 80, 90 n.6 (Pa. Super. Ct. 2013) (noting the importance of distinguishing between cases that "were amended in light" of Supreme Court precedent and those that were not). In most of the dismissing cases, the courts were asked to consider whether the complaint in front of them, which was drafted prior to *Bartlett*, survived the subsequently decided Supreme Court case. *Drager v. PLIVA USA, Inc.,* 741 F.3d 470, 473-74 (4th Cir. 2014) (the complaint was filed before either *Mensing* or *Bartlett*, and the trial court denied plaintiff leave to amend after *Mensing*);

In re Fosamax, 751 F.3d at 154 (the complaint at issue was filed on February 28, 2011, before either *Mensing* or *Bartlett*); *Johnson v. Teva Pharmaceuticals USA, Inc.,* 758 F.3d 605, 610 (5th Cir. 2014) (the complaint was filed in March 2010, before either *Mensing* or *Bartlett*); *Schrock v. Wyeth, Inc.,* 727 F.3d 1273, 1278 (10th Cir. 2013) (the complaint was amended on April 14, 2010, before either *Mensing* or *Bartlett*); *Lashley v. Pfizer, Inc.,* 750 F.3d 470, 472-73 (5th Cir. 2014) (the suits were filed in 2009 and June 2011, before *Bartlett*); *Eckhardt v. Qualitest Pharmaceuticals, Inc.,* 751 F.3d 674, 677 (5th Cir. 2014) (the complaint was amended before *Bartlett*); *In re Darvocet, Darvon, and Propoxyphene Products Liability Litigation,* 756 F.3d 917, 925-26 (6th Cir. 2014) (the cases were consolidated prior to *Bartlett*); *Strayhorn,* 737 F.3d at 387 (the complaints at issue were amended after *Mensing* but before *Bartlett*); *Brinkley v. Pfizer, Inc.,* 772 F.3d 1133, 1136 (8th Cir. 2014) (the complaint was amended on August 30, 2011, after *Mensing* but before *Bartlett*).

¶ 83 The courts found that the allegations, viewed from hindsight after *Bartlett,* were insufficient. *E.g., Eckhardt,* 751 F.3d at 679-80 (although a state claim for failure to provide FDA-approved warnings was not preempted, plaintiff failed to adequately plead it); *Drager,* 741 F.3d at 474-75 (plaintiff's "failure to update" claim is not before the court because he failed to move the trial court to amend the complaint to add it); *In re Darvocet,* 756 F.3d at 931 (although "'failure to update' claims against ge-

neric manufacturers are not preempted," "[p]laintiff's claims falter because they did not plead them properly"); *Johnson v. Teva Pharmaceuticals USA, Inc.,* 758 F.3d 605, 613 (5th Cir. 2014) (even if plaintiff could bring a design defect claim based on "a safer alternative product" rather than "a safer alternative design," plaintiff failed to allege the safer product in her complaint); *Strayhorn,* 737 F.3d at 399 (although federal law does not preempt a "failure to update" claim, plaintiff's complaint failed to plead that the generic label "was not updated during the time that a particular plaintiff was using its product"); *Schrock,* 727 F.3d at 1290 (plaintiffs failed to advance a claim that new and scientifically significant information was not before the FDA).

¶ 84 For example, in *In re Darvocet,* 756 F.3d at 930, 932, which concerned the same drug at issue in the instant case, the Sixth Circuit held that the plaintiffs had failed to adequately plead what new information was not before the FDA or which generic manufacturers had failed to update their labels with FDA-approved warnings.

¶ 85 The questions in front of us are different. The certified questions do not ask us to consider the sufficiency of plaintiff's complaint but rather whether "a cause of action" could survive under Illinois law. Plaintiff's last amended complaint was filed after *Mensing* but before *Bartlett.* However, we do consider the questions in light of plaintiff's allegations.

¶ 86 B. Negligence

¶ 87 The first certified question asks: "Did the U.S. Supreme Court's decisions in *[Mutual Pharmaceutical] Co. Inc. v. Bartlett*, [133] S. Ct. 2466 (2013), *PLIVA, Inc. v. Mensing*, 131 S. Ct. [2567], 2574 (2011), and their progeny (collectively, the '*Bartlett/Mensing precedent*') require the dismissal on federal preemption grounds of an Illinois common law cause of action for negligence, alleging negligence in the design, manufacture, or distribution of a generic drug (commonly known as Propoxyphene) approved by the United States Food & Drug Administration (the 'FDA')?"

¶ 88 Although the certified questions are not limited to claims against generic manufacturers and distributors, and although at least one Illinois court has recognized a suit by the consumer of a generic drug against a brand-name manufacturer, we interpret the certified questions to concern only claims against generic manufacturers and distributors, since plaintiff has not sued the brand-name manufacturer here. *Dolin v. SmithKline Beecham Corp.,* No. 12 C 6403, 2014 WL 804458, at *6 (N.D. Ill. Feb. 28, 2014) (holding that the brand-name manufacturer had a duty to the generic consumer).

¶ 89 For a plaintiff to state a cause of action for negligence in Illinois, the complaint must allege facts sufficient to establish three elements: (1) the existence of a duty of care owed to the plaintiff by the defendant; (2) a breach of that duty, and (3) an

injury proximately caused by that breach. *Calles v. Scripto-Tokai Corp.,* 224 Ill. 2d 247, 270 (2007); *Lewis,* 2014 IL App (1st) 123303, ¶8 (citing *Marshall v. Burger King Corp.,* 222 Ill. 2d 422, 430 (2006)).

¶ 90 The key distinction between a negligence claim and a strict liability claim, which we discuss later, lies in the concept of fault. *Calles,* 224 Ill. 2d at 270 (citing *Coney v. J.L.G. Industries, Inc.,* 97 Ill. 2d 104, 117 (1983)). While the focus in a strict liability claim is primarily on the condition of the product, a defendant's fault is at issue in a negligence claim, in addition to the product's condition. *Calles,* 224 Ill. 2d at 270 (citing *Coney,* 97 Ill. 2d at 117-18).

¶ 91 A manufacturer has a nondelegable duty to design reasonably safe products. *Calles,* 224 Ill. 2d at 270; *Coney,* 97 Ill. 2d at 117. To determine whether the manufacturer's conduct was reasonable in a negligent-design case, a court asks whether the manufacturer should have foreseen, in the exercise of ordinary care, that the design would be hazardous to someone. *Calles,* 224 Ill. 2d at 270. To show that the manufacturer acted unreasonably, the plaintiff must show that the manufacturer knew or should have known of the risk posed by the product design at the time of the product's manufacture. *Calles,* 224 Ill. 2d at 270. In the case at bar, plaintiff has alleged that defendants knew or should have known of the risks posed by the drug at the time of its manufacture.

¶ 92 Defendants claim that, even if plaintiff's allegations are true, her negligence claims are

preempted under the *Bartlett/Mensing* precedent because federal law prevented defendants from altering the design or warnings of the drug. However, plaintiff does not allege that defendants should have altered either the design or the warnings of the drug. Thus, to the extent that the *Mensing/Bartlett* precedent applies to post-2007 claims, it does not bar plaintiff's negligence claims.

¶ 93 C. Strict Liability

¶ 94 The second certified question asks: "Does the *Bartlett/Mensing* precedent require the dismissal on federal preemption grounds of an Illinois common law cause of action for strict product liability/design defect, alleging unreasonable dangerousness in the design or manufacture of a generic drug (commonly known as Propoxyphene) approved by the FDA?"

¶ 95 To succeed in Illinois on a strict liability claim, a plaintiff must prove that a product was sold in an unreasonably dangerous condition. *Jablonski v. Ford Motor Co.,* 2011 IL 110096, ¶ 86 ("the balancing test developed for strict liability claims * * * examines whether a product is unreasonably dangerous"); *Calles v. Scripto-Tokai Corp.,* 224 Ill. 2d 247, 254 (2007); *Korando v. Uniroyal Goodrich Tire Co.,* 159 Ill. 2d 335, 343 (1994) (to recover for a defective product under strict liability, a plaintiff must prove that the product left the manufacturer in an unreasonably dangerous condition). Illinois courts utilize two tests to determine whether a product was unreasonably dangerous: the consumer expectation test

and the risk utility test. *Calles,* 224 Ill. 2d at 254-56. A plaintiff may succeed by proving the elements of either test. *Calles,* 224 Ill. 2d at 255. Under the consumer expectation test, a plaintiff succeeds by proving that "the product failed to perform as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner." *Calles,* 224 Ill. 2d at 256. Under the risk utility test, a plaintiff succeeds by proving that "the magnitude of the danger outweighs the utility of the product, as designed." *Calles,* 224 Ill. 2d at 259. *See also Jablonski v. Ford Motor Co.,* 2011 IL 110096, ¶ 85 (discussing the "risk-utility" test).

¶ 96 Plaintiff has alleged both that the product failed to perform as an ordinary consumer would expect when used in the intended dosage and that the high risk of dangerous side effects outweighed the marginal effectiveness of the product as designed. On this appeal, defendants claim that, even if these allegations are true, plaintiff's strict liability claim is preempted under *Bartlett* and *Mensing.*

¶ 97 Neither plaintiff's claim pursuant to the consumer expectation test nor her claim pursuant to the risk utility test under Illinois law is preempted by the *Bartlett/Mensing* precedent. Defendants are liable if they inject into the market a drug that fails to perform as an ordinary consumer would expect or that has a marginal effectiveness which is easily outweighed by its high risks. Federal law does not provide the drug companies with a "safe harbor" to

avoid liability for dangerous drugs (*Bartlett,* 570 U.S. at __, 133 S. Ct. at 2479), and there was no direct and positive conflict with their federal duty of sameness, when the drug should not have been sold. Pub. L. 89-74, § 10, 79 Stat. 235 (1965) (discussed in *Wyeth,* 555 U.S. at 568). Assuming *arguendo* that *Bartlett* and *Mensing* apply to post-2007 claims, we cannot find that they preempt plaintiff's strict liability claim.

¶ 98 D. Fraudulent Misrepresentation

¶ 99 The third certified question asks: "Does the *Bartlett/Mensing* precedent require the dismissal on federal preemption grounds of an Illinois common law cause of action for fraudulent misrepresentation, alleging false statements of material fact regarding the safety, risks or lack of testing of a generic drug (commonly known as Propoxyphene) approved by the FDA?"

¶ 100 In Illinois, the elements of a fraudulent misrepresentation claim are: (1) a false statement of material fact; (2) knowledge or belief of the falsity by the person making it; (3) intention to induce the other party to act; (4) action by the other party in reliance on the truth of the statements; and (5) damage to the other party resulting from such reliance. *Doe-3 v. McLean County Unit District No. 5 Board of Directors,* 2012 IL 112479, ¶ 28 (citing *Board of Education of City of Chicago v. A, C & S, Inc.,* 131 Ill. 2d 428, 452 (1989)). A claim for negligent misrepresentation has essentially the same elements as fraudu-

lent misrepresentation, except that the defendant's mental state is different. *Doe–3,* 2012 IL 112479, ¶ 28. For a negligent misrepresentation claim, a plaintiff need allege only that the defendant was careless or negligent in ascertaining the truth of the statement, and that the defendant had a duty to convey accurate information to the plaintiff. *Doe–3,* 2012 IL 112479, ¶ 28. We provided the elements of negligent misrepresentation, although the certified question did not ask about it, in order to better illustrate the mental state required for a fraud claim.

¶ 101 Plaintiff alleged facts to support each of the four elements of fraudulent representation. Specifically, she alleged: (1) that, in the act of promoting and selling the drug, defendants made false statements of material facts and advertised to the general public that the drug was safe and effective when it was not; (2) that defendants knew the statements they were making were false; (3) that defendants intended the general public to rely on their statements; (4) that Lewis relied on these statements in taking the drug; and (5) that, as a result, Lewis became seriously ill and died. At this very early stage of the litigation, we must accept plaintiff's allegations as true. *Lewis,* 2014 IL App (1st) 123303, ¶ 7; *Adeyiga,* 2014 IL App (1st) 131252, ¶ 57.

¶ 102 In response, defendants claim that, even if these allegations are true, defendants are still not liable to plaintiff because her claim is preempted under the *Bartlett/Mensing* precedent. Defendants

argue that, even assuming *arguendo* that the statements were false, defendants could not have altered them because any changes would have violated the generic drug company's federal duty to provide the same exact statements as the brand-name or lead manufacturer.

¶ 103 However, this response overlooks the heart of plaintiff's argument. Plaintiff is not arguing that defendants *should have* altered their statements. Instead, plaintiff claims that the very act of marketing this drug was a misrepresentation and fraud upon the public. Assuming *arguendo* the truth of plaintiff's allegations, there was no way to market this drug, which was effectively useless and full of unreasonable risk, without fraudulently misrepresenting its qualities. According to plaintiff, this was like marketing snake oil. Thus, to the extent that *Bartlett* and *Mensing* apply to post-2007 claims, they do not bar plaintiff's fraudulent representation claims against defendant generic manufacturer and distributor.

¶ 104 E. Fraudulent Concealment

¶ 105 The fourth certified question asks: "Does the *Bartlett/Mensing* precedent require the dismissal on federal preemption grounds of an Illinois common law cause of action for fraudulent concealment, alleging concealment or withholding of alleged design or manufacturing defects, lack of safety, or other unreasonably high risks associated with a ge-

neric drug (commonly known as Propoxyphene) approved by the FDA?"

¶ 106 Defendants are correct that, in order to state a claim for fraudulent concealment, a plaintiff must allege "that the defendant concealed a material fact when it was under a duty to disclose to the plaintiff." *W.W. Vincent & Co. v. First Colony Life Insurance Co.,* 351 Ill. App. 3d 752, 762 (2004) (citing *Connick v. Suzuki Motor Co., Ltd.,* 174 Ill. 2d 482, 500 (1996)). Defendants cite in support *W.W. Vincent,* which states: "The concealment of a material fact during a business transaction is actionable if 'done "with the intention to deceive under circumstances creating an opportunity and duty to speak."'" *W.W. Vincent,* 351 Ill. App. 3d at 762 (quoting *Perlman v. Time, Inc.,* 64 Ill. App. 3d 190, 195 (1978), quoting *Lagen v. Lagen,* 14 Ill. App. 3d 74, 79 (1973)). "A statement that is technically true may nevertheless be fraudulent where it omits qualifying material since a 'half-truth' is sometimes more misleading than an outright lie." *W.W. Vincent,* 351 Ill. App. 3d at 762 (citing *Perlman,* 64 Ill. App. 3d at 195, citing *St. Joseph Hospital v. Corbetta Construction Co.,* 21 Ill. App. 3d 925, 953 (1974)).

¶ 107 A duty to disclose a material fact may arise out of several situations. *Connick,* 174 Ill. 2d at 500. First, if a plaintiff and defendant are in a fiduciary or confidential relationship, then a defendant is under a duty to disclose all material facts. *Connick,* 174 Ill. 2d at 500. Second, a duty to disclose material

facts may arise out of a situation where a plaintiff places trust and confidence in a defendant, thereby placing a defendant in a position of influence and superiority over plaintiff. *Connick,* 174 Ill. 2d at 500. This position of superiority may arise by reason of friendship, agency or experience. *Connick,* 174 Ill. 2d at 500.

¶ 108 Defendants do not argue on this appeal that they were *not* in a position of superiority to plaintiff but argue that plaintiff's claim for fraudulent concealment is preempted pursuant to *Bartlett* and *Mensing*. Thus, we assume for the purposes of this appeal that defendants were in a position of superiority.

¶ 109 The alleged half-truths or lies which led consumers to believe that the drug was effective and safe, when, according to plaintiff's allegations, defendants knew it was useless and risky, state a claim for fraudulent concealment. This claim is not preempted since plaintiff is not claiming that the statements should have been changed. Plaintiff claims instead that there were no warnings which would have magically transformed this allegedly useless and risky drug into a drug that was safe and effective. Thus, the only possible means of protecting the vast majority of consumers, namely, to not market this useless and risky drug, also posed no conflict with the generic drug company's duty of sameness.

¶ 110 Thus, to the extent that the *Mensing/Bartlett* precedent applies to post-2007 claims, it

does not bar plaintiff's fraudulent concealment claims against the generic manufacturer and distributor.

¶ 111 F. Statutory Claim

¶ 112 The fifth certified question asks: "Does the *Bartlett/Mensing* precedent require the dismissal on federal preemption grounds of a cause of action under the Illinois Consumer Fraud and Deceptive Business Practices Act [(815 ILCS 505/1 *et seq.* (West 2012))], alleging a generic drug (commonly known as Propoxyphene) approved by the FDA?"

¶ 113 The elements of a claim for consumer fraud in Illinois are: (1) a deceptive act or practice by the defendant; (2) the defendant's intent that the plaintiff rely on the deception; and (3) that the deception occurred in the course of conduct involving trade and commerce. *Connick,* 174 Ill. 2d at 501; 815 ILCS 505/10a (West 2012) ("Any person who suffers actual damage as a result of a violation of this Act committed by any other person may bring an action against such person."); 815 ILCS 505/2 (West 2012) (describing violations of the Act).

¶ 114 Plaintiff's reliance is not an element of statutory consumer fraud. *Connick,* 174 Ill. 2d at 501; 815 ILCS 505/2 (West 2012) (the Act is violated "whether any person has in fact been misled, deceived or damaged thereby"). However, a plaintiff must allege that defendant's consumer fraud proxi-

mately caused plaintiff's injury. *Connick,* 174 Ill.2d at 501.

¶ 115 The first element of consumer fraud requires a showing of a deceptive act or practice, which the Act defines as "including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression, or omission of such material fact, or the use or employment of any practice described in Section 2 of the 'Uniform Deceptive Trade Practices Act,' approved August 5, 1965, in the conduct of any trade or commerce." 815 ILCS 505/2 (West 2012).

¶ 116 Plaintiff alleges: (1) that defendants engaged in deceptive practices when they advertised the drug as safe and effective and it was not, and when they promoted the sale of the drug through misrepresentation, concealment and omission of such material fact; (2) that defendants intended the public to rely on their statements; and (3) that the deception occurred during the commerce and promotion of the drug.

¶ 117 Defendant does not contest plaintiff's allegations on this appeal, arguing instead that the claim is preempted pursuant to *Bartlett* and *Mensing*. In the sections above, we have already addressed plaintiff's claims for defendant's alleged fraud, misrepresentation and concealment. Plain-

tiff's consumer fraud claim for defendants' alleged fraud, misrepresentation and concealment is not preempted for the same reasons.

¶ 118 Thus, to the extent that the *Mensing/Bartlett* precedent applies to post-2007 claims, they do not bar plaintiff's consumer fraud claim.

¶ 119 CONCLUSION

¶ 120 We answered each of the certified questions above. In sum, to the extent that the *Mensing/Bartlett* precedent applies to post-2007 claims, plaintiff's Illinois state-law claims are not preempted.

¶ 121 The case is remanded for further proceedings consistent with this opinion.

¶ 122 Certified questions answered; remanded for further proceedings.

In the Circuit Court of Cook County, Illinois
County Department, Law Division

LEWIS GUVENOZ and NICOLE GUVENOZ,
Plaintiffs,

v.

TARGET CORPORATION,
TEVA PHARMACEUTICALS USA, INC., and
JOSHUA ROSENOW, M.D.,
Defendants.

No. 12-L-5162

FIRST AMENDED COMPLAINT AT LAW

NOW COME the Plaintiffs, LEWIS GUVENOZ and NICOLE GUVENOZ, by and through their attorneys, MOTHERWAY & NAPLETON, LLP, and complaining of the Defendants, TARGET CORPORATION, TEVA PHARMACEUTICALS USA, INC., and JOSHUA ROSENOW, M.D., and each of them, and alleges as follows:

FACTS

1. Plaintiffs, LEWIS GUVENOZ and NICOLE GUVENOZ, are residents of Illinois.

2. Defendant Teva Pharmaceuticals USA, Inc. ("TEVA") is a Delaware corporation with a principal place of business in Pennsylvania. Defendant TEVA regularly conducts business in Cook County, Illinois.

Defendant TEVA was involved in the manufacture, distribution, marketing, sale, and labeling of Darvocet.

3. Defendant Target Corporation ("TARGET") is a Minnesota corporation with a principal place of business in Minnesota. Defendant TARGET regularly conducts business in Cook County, Illinois. Defendant TARGET was involved in the distribution and sale of Darvocet.

4. Defendant Joshua Rosenow, M.D., ("ROSENOW") is [a] resident of Chicago, Cook County, Illinois.

5. This suit arises out of severe and permanent injuries sustained by Plaintiffs due to the wrongful conduct of the Defendants. Lewis Guvenoz was given a prescription for Darvocet and as a result of ingesting the recommended doses, Lewis Guvenoz suffered a cardiac arrest that caused serious brain injuries.

6. Propoxyphene is an opioid analgesic prescription drug for the treatment of mild to moderate pain. It was first approved by the FDA in 1957 and has been commercially available in the United States since 1976 under the name of Darvon or, combined with acetaminophen, Darvocet.

7. Defendant TEVA began marketing a generic form of Darvocet called Propoxyphene napsylate-acetaminophen and distributed the drug until it was withdrawn from the market in November 2010. Over

90% of the market share of these drugs belongs to generic manufacturers.

8. Upon information and belief, adverse event data maintained by the FDA indicates a staggering number of serious adverse events associated with Propoxyphene, including heart arrhythmias, atrial fibrillation, tachycardia, bradycardia, myocardial infarction, and/or sudden death.

9. At all times relevant hereto, Defendants TEVA and TARGET knew or should have known of the correlation between the use of Darvocet and the increased risk of developing potentially fatal heart arrhythmias.

10. Defendants TEVA and TARGET knew or should have known that Propoxyphene was ineffective, or at best, marginally effective, and that any benefits of Propoxyphene were outweighed by its risks, including serious risks of adverse cardiovascular events that could result in death, as well as other injuries.

11. Critics of Propoxyphene have maintained for years that the addictiveness of the drug is its most well-known characteristic, even though it is relatively ineffective as a pain reliever. In fact, one comprehensive review of randomized clinical trials found that, for most types of pain, Tylenol alone is as effective as Propoxyphene at controlling pain.

12. The serious health risks associated with Propoxyphene and the fact that there are many safer

alternative[s] available led the British government to declare [a] recall in [] 2005 because it could not identify any group of patients for whom the benefits of Propoxyphene outweighed its risks.

13. In January 2009, the FDA held an Advisory Committee meeting to address the efficacy and safety of Propoxyphene. After considering the data submitted, the committee voted 14 to 12 against the continued marketing of products containing Propoxyphene, noting that additional information about the drug's cardiac effect will be relevant in weighing its risks and benefits.

14. In June 2009, the European Medicines Agency recommended that the marketing authorizations for Propoxyphene be withdrawn across the European Union due to safety concerns.

15. In July 2009, the FDA required a new safety study addressing unanswered questions about Propoxyphene's effects on the heart.

16. On November 19, 2010, prompted by the results of that study, the FDA required manufacturers to withdraw its products containing Propoxyphene, including Darvocet and Darvon, from the United States market after it determined that the risks of the drug outweighed the benefits. The study showed that Propoxyphene causes significant changes to the electrical activity of the heart even when taken at recommended doses. The known cardiovascular effects of Propoxyphene include abnormal cardiac

rhythm, interruption of cardiac conduction, slowed heart beat, absence of contractions, diminished myocardial contractility, hypotension, other adverse cardiovascular events, including sudden death.

17. Between January 8, 2010 and May 13, 2010, Plaintiff, Lewis Guvenoz, was prescribed and did purchase and ingest Propoxyphene.

18. On May 13, 2010, while taking the recommended doses of Propoxyphene, Plaintiff, Lewis Guvenoz, experienced a cardiac arrest and resultant anoxic encephalopathy.

19. As a direct and proximate result of acts and omissions of Defendants TEVA, TARGET, and ROSENOW, Plaintiff, Lewis Guvenoz, suffered severe and permanent injuries.

CAUSES OF ACTION

COUNT I — NEGLIGENCE

NOW COMES the Plaintiff, LEWIS GUVENOZ, by his attorneys, MOTHERWAY & NAPLETON, LLP, and complaining of the Defendants, TEVA and TARGET, and each of them, and alleges as follows:

1. The Plaintiff, Lewis Guvenoz, repeats and realleges the allegations in paragraphs 1-19 as if fully set forth herein.

2. On and prior to May 14, 2011, Defendants TEVA and TARGET, and each of them, were engaged in the business of formulating, preparing, dis-

tributing, supplying, and/or selling a certain product, commonly known as Propoxyphene.

3. That the aforementioned Defendants, and each of them, participated in the preparation, manufacturing, distribution, supplying and/or sale of the aforesaid product and/or its appurtenances, while said product was in an unreasonably dangerous condition with regard to its acknowledged, intended, and foreseeable uses, and was so at the time the aforesaid product left the control of the Defendants in that:

a. A qt wave interval prolongation effect was associated with Propoxyphene;

b. The aforesaid drug blocked ION channels in the heart which is in effect associated with proarrhythmia.

c. Propoxyphene was unsafe for normal, or reasonably anticipated, handling and use.

d. The drug contained dangerous design and manufacturing defects and was not reasonably safe as intended to be used, subjecting the Plaintiff, Lewis Guvenoz, to an unreasonably high risk of injury;

e. The drug created unreasonably high risk of cardiac injury which exceeded the benefits of the drug;

f. The drug was more dangerous than an ordinary consumer would expect and more dangerous

than similar pain relievers that were already on the market;

g. Defendants elected to continue selling or prescribing a drug which Defendants knew or should have known was dangerous.

4. At all relevant times, Defendants TEVA and TARGET, and each of them, owed a duty to the public and to the Plaintiff, Lewis Guvenoz, to exercise reasonable care in the design, manufacture, testing, distribution, promotion, and sale of Propoxyphene.

5. Defendants TEVA and TARGET negligently breached that duty to the Plaintiff, Lewis Guvenoz, in that the Defendants knew or should have known that the use of Propoxyphene created a high risk of dangerous side effects, including but not limited to, heart arrhythmia, tachycardia, interruption of cardiac conduction, slowed heart beat, absence of contractions, diminished myocardial contractility, hypotension, and death.

6. Between January 8, 2010 and May 13, 2010, Plaintiff, Lewis Guvenoz, ingested seventy-two (72) tablets of Propoxyphene at recommended doses.

7. On May 13, 2010, Plaintiff, Lewis Guvenoz, experienced a cardiac arrest and resultant anoxic encephalopathy.

8. As a direct and proximate result of one or more of the aforesaid negligent acts and/or omissions of Defendants TEVA and TARGET, and each of them,

the Plaintiff sustained severe and permanent injuries.

WHEREFORE, Plaintiff, Lewis Guvenoz, demands judgment against the Defendants, TEVA and TARGET, and each of them, in an amount in excess of the jurisdictional limits of the Circuit Court of Cook County, Law Division.

COUNT II — FRAUDULENT MISREPRESENTATION (TEVA)

NOW COMES the Plaintiff, LEWIS GUVENOZ, by his attorneys, MOTHERWAY & NAPLETON, LLP, and complaining of Defendant, TEVA, alleges as follows:

1. The Plaintiff, Lewis Guvenoz, repeats and realleges the allegations in paragraphs l-19 as if fully set forth herein.

20. That Defendants TEVA knew or should have known the following:

a. That Propoxyphene was unsafe.

b. That the benefits of taking Propoxyphene did not outweigh the risks.

c. That Propoxyphene had not been adequately tested.

21. That in the act of promoting and selling Propoxyphene in spite of the foregoing, Defendant, TEVA made false statements of material facts.

22. That Defendant, TEVA, advertised to the general public that the drugs they were manufacturing were safe and effective.

23. That Defendant, TEVA knew the statements were false or made the statements in reckless disregard of whether they were true or false.

24. That Defendant, TEVA made the statements with the intent to induce the Plaintiff, Lewis Guvenoz, to take Propoxyphene.

25. That the Plaintiff, Lewis Guvenoz, reasonably believed the statements and took Propoxyphene in justifiable reliance on the truth of the statements.

26. Between January 8, 2010 and May 13, 2010, Plaintiff, Lewis Guvenoz, ingested seventy-two (72) tablets of Propoxyphene at recommended doses.

27. As a direct and proximate result of his reliance on the truth of Defendants' statements, the Plaintiff, Lewis Guvenoz, sustained severe and permanent injuries.

WHEREFORE, Plaintiff, LEWIS GUVENOZ, demands judgment against Defendants TEVA, and each of them, in an amount in excess of the jurisdictional limits of the Circuit Court of Cook County, Law Division.

COUNT III — FRAUDULENT MISREPRESENTATION (TARGET)

NOW COMES the Plaintiff, LEWIS GUVENOZ, by his attorneys, MOTHERWAY & NAPLETON,

LLP, and complaining of Defendant, TARGET, alleges as follows:

1. The Plaintiff, Lewis Guvenoz, repeats and realleges the allegations in paragraphs 1-19 as if fully set forth herein.

20. That Defendant, TARGET knew or should have known the following:

a. That Propoxyphene was unsafe.

b. That the benefits of taking Propoxyphene did not outweigh the risks.

c. That Propoxyphene had not been adequately tested.

21. That in the act of promoting and selling Propoxyphene in spite of the foregoing, Defendant, TARGET made false statements of material facts.

22. That Defendant, TARGET[,] advertised to the general public that they were a pharmacy.

23. That Defendant, TARGET, advertised to the general public that they sold safe and effective drugs.

24. That Defendant, TARGET[,] knew the statements were false or made the statements in reckless disregard of whether they were true or false.

25. That Defendant, TARGET[,] made the statements with the intent to induce the Plaintiff, Lewis Guvenoz, to take Propoxyphene.

26. That the Plaintiff, Lewis Guvenoz, reasonably believed the statements and took Propoxyphene in justifiable reliance on the truth of the statements.

27. Between January 8, 2010 and May 13, 2010, Plaintiff, Lewis Guvenoz, ingested seventy-two (72) tablets of Propoxyphene at recommended doses.

28. As a direct and proximate result of his reliance on the truth of Defendants' statements, the Plaintiff, Lewis Guvenoz, sustained severe and permanent injuries.

WHEREFORE, Plaintiff, LEWIS GUVENOZ, demands judgment against Defendants TARGET, and each of them, in an amount in excess of the jurisdictional limits of the Circuit Court of Cook County, Law Division.

COUNT IV — FRADULENT CONCEALMENT (TEVA)

NOW COMES the Plaintiff, LEWIS GUVENOZ, by his attorneys, MOTHERWAY & NAPLETON, LLP, and complaining of the Defendant, TEVA, and alleges as follows:

1. The Plaintiff, Lewis Guvenoz, repeats and realleges the allegations in paragraphs 1-19 as if fully set forth herein.

20. That the Defendant, TEVA knowingly concealed or withheld from the Plaintiff, Lewis Guvenoz, the following facts:

a. A qt wave interval prolongation effect was associated with Propoxyphene;

b. The aforesaid drug blocked ION channels in the heart which is in effect associated with pro-arrhythmia.

c. Propoxyphene was unsafe for normal, or reasonably anticipated, handling and use.

d. The drug contained dangerous design and manufacturing defects and was not reasonably safe as intended to be used, subjecting the Plaintiff, Lewis Guvenoz, to an unreasonably high risk of injury;

e. The drug created unreasonably high risk of cardiac injury which exceeded the benefits of the drug;

f. The drug was more dangerous than an ordinary consumer would expect and more dangerous than similar pain relievers that were already on the market.

[g]. That the facts concealed or withheld were material facts.

21. At all times material, Defendant, TEVA had actual knowledge of the aforementioned facts.

22. Defendant, TEVA affirmatively withheld research from plaintiff that propoxyphene was unsafe.

23. That Defendant, TEVA[,] advertised to the general public that the drugs they were manufacturing were safe and effective.

24. That Defendant, TEVA[,] concealed or withheld the facts with the intent to deceive the Plaintiff, Lewis Guvenoz, and to induce the Plaintiff to take Propoxyphene[.]

25. That the Plaintiff, Lewis Guvenoz, took Propoxyphene in justifiable reliance on the facts as he knew them.

26. Between January 8, 2010 and May 13, 2010, Plaintiff, Lewis Guvenoz, ingested seventy-two (72) tablets of Propoxyphene at recommended doses.

27. As a direct and proximate result of the concealment or withholding of material facts by the Defendants, the Plaintiff, Lewis Guvenoz, sustained severe and permanent injuries.

WHEREFORE, Plaintiff, Lewis Guvenoz, demands judgment against the Defendant, TEVA, in an amount in excess of the jurisdictional limits of the Circuit Court of Cook County, Law Division.

COUNT V — STRICT PRODUCT LIABILITY/DESIGN DEFECT

NOW COMES the Plaintiff, LEWIS GUVENOZ, by his attorneys, MOTHERWAY & NAPLETON, LLP, and complaining of the Defendants, TEVA and TARGET, and each of them, and alleges as follows:

1. The Plaintiff, Lewis Guvenoz, repeats and realleges the allegations in paragraphs 1-19 as if fully set forth herein.

20. That the Plaintiff, Lewis Guvenoz, was injured as a result of the use of the a certain product, commonly known as Propoxyphene.

21. That there existed in the Propoxyphene at the time it left the control of the Defendants a condition which made Propoxyphene unreasonably dangerous in one or more of the following respects:

a. A qt wave interval prolongation effect was associated with Propoxyphene;

b. The aforesaid drug blocked ION channels in the heart which is in effect associated with pro-arrhythmia;

c. The drug contained dangerous design and manufacturing defects and was not reasonably safe as intended to be used, subjecting the Plaintiff, Lewis Guvenoz, to an unreasonably high risk of injury;

d. The drug created unreasonably high risk of cardiac injury which exceeded the benefits of the drug;

e. The drug was more dangerous than an ordinary consumer would expect and more dangerous than similar pain relievers that were already on the market;

22. Between January 8, 2010 and May 13, 2010, Plaintiff, Lewis Guvenoz, ingested seventy-two (72) tablets of Propoxyphene at recommended doses. In taking Propoxyphene at the recommended doses,

Propoxyphene did not perform in the manner reasonably to be expected in light of its nature and intended function.

23. That one or more of the conditions enumerated in paragraph 3 of Count V was a proximate cause of the Plaintiff's injuries.

24. That there was no other reasonable cause of the product's failure to perform.

25. As a direct and proximate result of the unreasonably dangerous condition of the Propoxyphene, the Plaintiff: Lewis Guvenoz, sustained severe and permanent injuries.

26. In fact, there exist many thousands of people similarly harmed by Propoxyphene. Defendant TEVA, as the manufacture[r] of this product, faces significant financial exposure and may not have sufficient financial resources to satisfy all of these claims.

WHEREFORE, Plaintiff, LEWIS GUVENOZ, demands judgment against the Defendants TEVA and TARGET, and each of them, in an amount in excess of the jurisdictional limits of the Circuit Court of Cook County, Law Division.

COUNT VI — FRAUDULENT CONCEALMENT (TARGET)

NOW COMES the Plaintiff, LEWIS GUVENOZ, by his attorneys, MOTHERWAY & NAPLETON,

LLP, and complaining of the Defendant, TARGET, and alleges as follows:

1. The Plaintiff, Lewis Guvenoz, repeats and realleges the allegations in paragraphs 1-19 as if fully set forth herein.

20. That the Defendants TARGET knowingly concealed or withheld from the Plaintiff, Lewis Guvenoz, the following facts:

a. A qt wave interval prolongation effect was associated with Propoxyphene;

b. The aforesaid drug blocked JON channels in the heart which is in effect associated with pro-arrhythmia.

c. Propoxyphene was unsafe for normal, or reasonably anticipated, handling and use.

d. The drug contained dangerous design and manufacturing defects and was not reasonably safe as intended to be used, subjecting the Plaintiff, Lewis Guvenoz, to an unreasonably high risk of injury;

e. The drug created unreasonably high risk of cardiac injury which exceeded the benefits of the drug;

f. The drug was more dangerous than an ordinary consumer would expect and more dangerous than similar pain relievers that were already on the market.

[g]. That the facts concealed or withheld were material facts.

21. At all times material, Defendant, TARGET had actual knowledge of the aforementioned facts.

22. That Defendant, TARGET affirmatively withheld facts from plaintiff that the drug was dangerous.

23. Defendant, TARGET, advertised to the general public that the drugs they sold were safe and effective drugs.

24. That Defendant, TARGET concealed or withheld the facts with the intent to deceive the Plaintiff, Lewis Guvenoz, and to induce the Plaintiff to take Propoxyphene[.]

25. That the Plaintiff, Lewis Guvenoz, took Propoxyphene in justifiable reliance on the facts as he knew them.

26. Between January 8, 2010 and May 13, 2010, Plaintiff, Lewis Guvenoz, ingested seventy-two (72) tablets of Propoxyphene at recommended doses.

27. As a direct and proximate result of the concealment or withholding of material facts by the Defendants, the Plaintiff, Lewis Guvenoz, sustained severe and permanent injuries.

WHEREFORE, Plaintiff, Lewis Guvenoz, demands judgment against the Defendant, TARGET, in an amount in excess of the jurisdictional limits of the Circuit Court of Cook County, Law Division.

COUNT VII — CONSUMER FRAUD ACT (TEVA)

NOW COMES the Plaintiff, LEWIS GUVENOZ, by his attorneys, MOTHERWAY & NAPLETON, LLP, and complaining of Defendant, TEVA and alleges as follows:

1. The Plaintiff, Lewis Guvenoz, repeats and realleges the allegations in paragraphs 1-19 as if fully set forth herein.

20. That Defendant, TEVA knew or should have known the following:

a. That Propoxyphene was unsafe.

b. That the benefits of taking Propoxyphene did not outweigh the risks.

c. That Propoxyphene had not been adequately tested.

21. Defendant, TEVA, advertised to the general public that the drugs they were manufacturing were safe and effective.

22. That it was a deceptive act or practice for Defendant, TEVA to promote and sell Propoxyphene in spite of the foregoing.

23. That in the course of promoting and selling Propoxyphene, Defendant, TEVA[,] engaged in further deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresenta-

tion, or the concealment, suppression or omission of such material fact.

27. That Defendant, TEVA intended for consumers, including Plaintiff, Lewis Guvenoz, to rely on Defendants' aforementioned deceptive acts or practices.

28. That Defendant, TEVA engaged in the aforementioned deceptive acts or practices in the course of conduct involving trade or commerce.

29. Between January 8, 2010 and May 13, 2010, Plaintiff, Lewis Guvenoz, ingested seventy-two (72) tablets of Propoxyphene at recommended doses.

30. As a direct and proximate result of his reliance on the deception of Defendant, TEVA, the Plaintiff, Lewis Guvenoz, sustained severe and permanent injuries.

WHEREFORE, Plaintiff, LEWIS GUVENOZ, demands judgment against Defendant, TEVA[,] in an amount in excess of the jurisdictional limits of the Circuit Court of Cook County, Law Division.

COUNT VIII — CONSUMER FRAUD ACT / TARGET

NOW COMES the Plaintiff, LEWIS GUVENOZ, by his attorneys, MOTHERWAY & NAPLETON, LLP, and complaining of Defendant, TARGET[,] and alleges as follows:

1. The Plaintiff, Lewis Guvenoz, repeats and realleges the allegations in paragraphs 1-19 as if fully set forth herein.

20. That Defendant, TARGET[,] knew or should have known the following:

a. That Propoxyphene was unsafe.

b. That the benefits of taking Propoxyphene did not outweigh the risks.

c. That Propoxyphene had not been adequately tested.

21. Defendant, TARGET, advertised to the general public that the drugs they sold were safe and effective drugs.

22. That it was a deceptive act or practice for Defendant, TARGET[,] to promote and sell Propoxyphene in spite of the foregoing.

23. That in the course of promoting and selling Propoxyphene, Defendant, TARGET[,] engaged in further deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation, or the concealment, suppression or omission of such material fact.

24. That Defendant, TARGET[,] intended for consumers, including Plaintiff, Lewis Guvenoz, to rely on Defendants' aforementioned deceptive acts or practices.

25. That Defendant, TARGET, engaged in the aforementioned deceptive acts or practices in the course of conduct involving trade or commerce.

26. Between January 8, 2010 and May 13, 2010, Plaintiff, Lewis Guvenoz, ingested seventy-two (72) tablets of Propoxyphene at recommended doses.

27. As a direct and proximate result of his reliance on the deception of Defendant, TARGET, the Plaintiff, Lewis Guvenoz, sustained severe and permanent injuries.

WHEREFORE, Plaintiff, LEWIS GUVENOZ, demands judgment against Defendant, TARGET[,] in an amount in excess of the jurisdictional limits of the Circuit Court of Cook County, Law Division.

COUNT IX — LOSS OF CONSORTIUM / TEVA

NOW COMES the Plaintiff, NICOLE GUVENOZ, by her attorneys, MOTHERWAY & NAPLETON, LLP, and complaining of the Defendant, TEVA[,] and alleges as follows:

1. The Plaintiff, Nicole Guvenoz, repeats and realleges the allegations in paragraphs l-19 as if fully set forth herein.

20. The Plaintiff, Nicole Guvenoz, repeats and realleges the allegations in Counts I through VII as if fully set forth herein.

21. At all times herein mentioned, the Plaintiff, Nicole Guvenoz, was and she remains the lawful spouse of Lewis Guvenoz.

22. As a direct and proximate result of one or more of the []foregoing negligent acts and/or omissions of each Defendant, that Plaintiff, Lewis Guvenoz, was injured and suffered damages of a personal and pecuniary nature.

23. As a proximate result of one or more of the aforesaid negligent acts or omissions of each Defendant, the Plaintiff, Nicole Guvenoz, suffered injury to the marital relationship and a loss of consortium to her spouse.

WHEREFORE, Plaintiff. NICOLE GUVENOZ, demands judgment against the Defendant, TEVA[,] in a sum in excess of the jurisdictional limits of the Circuit Court of Cook County, Law Division.

COUNT X — LOSS OF CONSORTIUM / TARGET

NOW COMES the Plaintiff, NICOLE GUVENOZ, by her attorneys, MOTHERWAY & NAPLETON, LLP, and complaining of the Defendant, TARGET and alleges as follows:

1. The Plaintiff, Nicole Guvenoz, repeats and realleges the allegations in paragraphs 1-19 as if fully set forth herein.

20. The Plaintiff, Nicole Guvenoz, repeats and realleges the allegations in Counts I through VII as if fully set forth herein.

21. At all times herein mentioned, the Plaintiff, Nicole Guvenoz, was and she remains the lawful spouse of Lewis Guvenoz.

22. As a direct and proximate result of one or more of the aforegoing negligent acts and/or omissions of each Defendant, that Plaintiff: Lewis Guvenoz, was injured and suffered damages of a personal and pecuniary nature.

23. As a proximate result of one or more of the aforesaid negligent acts or omissions of each Defendant, the Plaintiff, Nicole Guvenoz, suffered injury to the marital relationship and a loss of consortium to her spouse.

WHEREFORE, Plaintiff, NICOLE GUVENOZ, demands judgment against the Defendant, TARGET[,] in a sum in excess of the jurisdictional limits of the Circuit Court of Cook County, Law Division.

COUNT XI — PROFESSIONAL NEGLIGENCE / JOSHUA ROSENOW, M.D.

NOW COMES the Plaintiff, LEWIS GUVENOZ, by and through his attorneys, MOTHERWAY & NAPLETON, LLP, and complaining of Defendant ROSENOW, states:

1. At all times herein mentioned, the Defendant, JOSHUA ROSENOW, M.D., was a physician licensed to practice medicine in the State of Illinois and he specialized in physical medicine and rehabilitation.

2. On July 19, 2010, Plaintiff, Lewis Guvenoz, was admitted to Northwestern Memorial Hospital under the care of Defendant ROSENOW for the purpose of installing a baclofen pump.

3. On July 19, 2010, Defendant ROSENOW installed the catheter tip of the baclofen pump in the spinal canal at the C4 region of the Plaintiff, Lewis Guvenoz's cervical spine causing the fluid to accumulate in the intrathecal or subdural space.

4. On June 1, 2011, a CT scan revealed a localized collection of contrast fluid in the dorsal subspace of C4 and the catheter tip entered the subdural space at approximately L1 and continuing cephalad until C4.

5. On June 9, 2011, Plaintiff, Lewis Guvenoz, was admitted to Advocate Christ Medical Center in Oak Lawn, Illinois, for a revision of the baclofen intrathecal catheter.

6. On July 19, 2010, Defendant ROSENOW was negligent in one or more of the following respects:

a. Failed to properly place the intrathecal baclofen catheter in its correct anatomical position;

b. Failed to identify that the intrathecal baclofen catheter was not placed in its correct anatomical position;

c. Failed to perform a CT with contrast dye to evaluate catheter placement;

d. Failed to identify a subdural catheter when other causes of failed drug delivery have been eliminated;

7. As a proximate result of one or more of the []foregoing negligent acts or omissions of Defendant ROSENOW, the Plaintiff, Lewis Guvenoz, suffered injuries of a personal and pecuniary nature.

8. Attached hereto and made part hereof is an affidavit and medical report pursuant to 735 ILCS 5/2-622.

WHEREFORE, Plaintiff, LEWIS GUVENOZ, demands judgment against Defendant ROSENOW in a sum in excess of the jurisdictional limits of the Law Division of the Circuit Court of Cook County in Illinois.

Pursuant to Illinois Supreme Court Rule 222(b). the undersigned counsel for the Plaintiff avers that the money damages herein sought exceed FIFTY THOUSAND ($50,000.00) DOLLARS.

In the Circuit Court of Cook County, Illinois

GUVENOZ

v.

TEVA et al.

No. 12-L-5162

ORDER

This case coming to be heard on defendants', Teva Pharmaceuticals USA, Inc. (Teva) and Target Corporation, Motion to Dismiss Plaintiffs' First Amended Complaint pursuant to Section 2-615, 2-619(a)(9), and 2-619-1 of the Illinois Code of Civil Procedure, due notice been given and the Court being fully advised in its premises: Defendants' motion is DENIED.

Defendants are granted until 10/10/13 to answer and file any affirmative defenses; Plaintiff is granted until 11/7/13 to reply to any affirmative defenses. A status as to pleadings is set for 11/14/13 at 10:00 am.

Entered: Assoc. Judge Moira S. Johnson
Dated: Sep. 11, 2013

Supreme Court of Illinois

Wednesday, September 30, 2015

The following cases on the leave to appeal docket were disposed of as indicated:

No. 119226 – Nicole Guvenoz, Indv., etc., respondent, v. Target Corporation et al., petitioners. Leave to appeal, Appellate Court, First District. (1-13-3940)

Petition for leave to appeal denied.

Supreme Court of Illinois

Monday, November 16, 2015

ADVISEMENT DOCKET

No. 119226 – Nicole Guvenoz, Indv., etc., respondent, v. Target Corporation et al., petitioners.

Motion by petitioners for leave to file a motion for reconsideration of the order denying petition for appeal as a matter of right or, in the alternative, petition for leave to appeal.

Motion denied.

Order entered by the Court.