Illinois Official Reports

Appellate Court

***Guvenoz v. Target Corp.*, 2015 IL App (1st) 133940**

Appellate Court Caption	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 (Joshua Rosenow, M.D., Defendant).
District & No.	First District, Fifth Division Docket No. 1-13-3940
Filed	March 27, 2015
Decision Under Review	Appeal from the Circuit Court of Cook County, No. 12-L-005162; the Hon. Moira S. Johnson, Judge, presiding.
Judgment	Certified questions answered; remanded for further proceedings.
Counsel on Appeal	Gregory E. Ostfeld and Caitlin Annatoyn, both of Greenberg Traurig, LLP, of Chicago, and Lori G. Cohen and Victoria Davis Lockard, both of Greenberg Traurig, LLP, of Atlanta, Georgia, for appellant Teva Pharmaceuticals USA, Inc. Emily L. Hussey and Richard Foster, both of Donohue Brown Matthewson & Smith LLC, of Chicago, and Bryan T. Pratt, of Shook, Hardy & Bacon LLP, of Kansas City, Missouri, for appellant Target Corporation. Kevin M. Forde and Joanne R. Driscoll, both of Forde Law Offices LLP, and Robert J. Napleton and Bradley Z. Schulman, both of Motherway & Napleton, LLP, both of Chicago, for appellee.

Panel

JUSTICE GORDON delivered the judgment of the court, with opinion.

Presiding Justice Palmer and Justice McBride concurred in the judgment and opinion.

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 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.

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

¶ 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 opioid 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 authorization 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 cardiac 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 Opioid 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 questions 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. ___, ___ n.1, 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," granting 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 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*." (Emphases added.) Pub. L. No. 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.

[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)).

¶ 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 that 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 ___ n.1, 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 expansion 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 ___ n.1, 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 pre-emption 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 support 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 an "NSAID," or a nonsteroidal anti-inflammatory pain reliever. *Bartlett*, 570 U.S. at ___, 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 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 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. No. 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 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 Sodium) 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 dismissal 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

[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.

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, & 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 generic 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 *Bartlett Co. Inc. v. Bartlett*, 123 S. Ct. 2466 (2013), *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2507, 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 *Bartlett*/*Mensing* 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. No.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 fraudulent 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 generic 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.*, 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 *Bartlett*/*Mensing* 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 proximately 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. Plaintiff'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 *Bartlett*/*Mensing* 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 *Bartlett*/*Mensing* 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.