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UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

GLORIA STRAYHORN, et al.,
Plaintiffs-Appellants,

v.

WYETH PHARMACEUTICALS, INC., et al.,
Defendants-Appellees.

Nos. 12-6195/ 6198/ 6200/ 6203/ 6208/ 6209/ 6210

Appeal from the United States District Court
for the Western District of Tennessee at Memphis.
Nos. 2:11-cv-02058; 2:11-cv-02059; 2:11-cv-02060; 2:11-cv-02083; 2:11-cv-02095; 2:11-cv-02134; 2:11-cv-02145—S. Thomas Anderson, District Judge.

Argued: July 31, 2013

Decided and Filed: December 2, 2013

Before: GILMAN, GRIFFIN, and STRANCH, Circuit Judges.

COUNSEL

ARGUED: Collyn A. Peddie, LAW OFFICES OF COLLYN PEDDIE, Houston, Texas, for Appellants. Henninger S. Bullock, MAYER BROWN LLP, New York, New York, for Appellees Schwarz and Alaven. Jeffrey F. Peck, ULMER & BERNE LLP, Cincinnati, Ohio, for Appellees Watson, Duramed, PLIVA, and Barr. Richard A. Oetheimer, GOODWIN PROCTER LLP, Boston, Massachusetts, for Appellee TEVA. **ON BRIEF:** Julie L. Rhoades, MATTHEWS & ASSOCIATES, Houston, Texas, for Appellants. Henninger S. Bullock, Andrew J. Calica, MAYER BROWN LLP, New York, New York, for Appellees Schwarz and Alaven. Kannon K. Shanmugam, WILLIAMS & CONNOLLY LLP, Washington, D.C., for Wyeth Appellees. Jeffrey F. Peck, Linda E. Maichl, Joseph P. Thomas, ULMER & BERNE LLP, Cincinnati, Ohio, Richard A. Oetheimer, GOODWIN PROCTER LLP, Boston, Massachusetts, Irene C. Keyse-Walker, Julie A. Callsen, Michael J. Ruttinger, TUCKER ELLIS LLP, Cleveland, Ohio, Kathleen Kelly, HINSHAW & CULBERTSON LLP, Boston, Massachusetts, Katherine Frazier, BAKER & WHITT, PLLC, Memphis, Tennessee, Daniel J. Herling, KELLER AND HECKMAN LLP, San Francisco, California, Shea Sisk Wellford, MARTIN TATE MORROW & MARTSON, Memphis, Tennessee, Mark S. Cheffo, Rachel B. Passaretti-Wu, SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP, New York, New York, Albert C. Harvey, THOMASON, HENDRIX, HARVEY, JOHNSON

& MITCHELL, Memphis, Tennessee, Jonathan I. Price, GOODWIN PROCTER LLP, New York, New York, William F. Sheehan, GOODWIN PROCTER LLP, Washington, D.C., Habib Nasrullah, Kelly A. Laudenslager, WHEELER TRIGG O'DONNELL LLP, Denver, Colorado, for Appellees.

GILMAN, J., delivered the opinion of the court, in which GRIFFIN, J., joined and STRANCH, J., joined in part. STRANCH, J. (pp. 40–55), delivered a separate opinion concurring in part and dissenting in part.

OPINION

RONALD LEE GILMAN, Circuit Judge. These seven consolidated cases are among the many that have been filed nationwide against the manufacturers of both the prescription drug Reglan and its generic equivalent, metoclopramide. The plaintiffs allege that they ingested generic metoclopramide and, as a result, developed a serious neurological disorder known as tardive dyskinesia. They filed suit against both the generic and brand-name manufacturers, alleging a wide variety of product-liability claims.

The makers of the generic metoclopramide moved to dismiss the claims against them, arguing that all of the plaintiffs' claims are preempted by the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301-399f, under the Supreme Court decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). And the brand-name manufacturers moved for summary judgment, contending that they are not liable to the plaintiffs because none of the plaintiffs ingested Reglan.

The district court granted both motions. For the reasons set forth below, we **AFFIRM** the judgment of the district court and **DENY** the plaintiffs' pending motion to certify a proposed question to the Tennessee Supreme Court.

I. BACKGROUND

A. Factual background

The basic facts are undisputed, and the lawsuits filed in the district court for each of the consolidated cases are identical to one another. We will therefore refer to the seven consolidated cases as "the present case."

The manufacturers of Reglan are Alaven Pharmaceuticals LLC; Pfizer, Inc.; Schwarz Pharma, Inc.; Wyeth Pharmaceuticals, Inc.; Wyeth LLC; and Wyeth, Inc. We will refer to these defendants collectively as the Brand-Name Manufacturers. The makers of generic metoclopramide are Actavis Elizabeth LLC; Barr Pharmaceuticals, Inc.; Duramed Pharmaceuticals, Inc.; Generics Bidco I LLC; McKesson Corporation; Mutual Pharmaceutical Co.; Northstar RX, LLC; PLIVA, Inc.; Ranbaxy Pharmaceuticals, Inc.; TEVA Pharmaceuticals USA, Inc.; The Harvard Drug Group; United Research Laboratories, Inc.; and Watson Laboratories, Inc. We will refer to these defendants collectively as the Generic Manufacturers.

The district court took the following facts from the plaintiffs' amended complaint as true for the purpose of ruling on the Generic Manufacturers' Motion to Dismiss:

> Reglan is a prescription drug, and metoclopramide is its generic bioequivalent. (Am. Compl. ¶ 6.) Reglan and metoclopramide's product labeling recommends them for use as short-term therapies for symptomatic gastroesophageal reflux—heartburn—and acute and recurrent diabetic gastric stasis—bloating. (*Id.* ¶ 13.) The labels recommend therapy for up to twelve weeks in adults for heartburn, but they did not contain a durational limit for bloating. (*Id.* ¶ 14.) At no time have Reglan or metoclopramide been shown to be either efficacious or safe when used for long-term treatment. (*Id.* ¶ 15.)
>
> Reglan and metoclopramide affect the brain's movement center, typically causing involuntary, repetitive movements. (*Id.* ¶ 7.) Overuse of Reglan and metoclopramide can result in extra-pyramidal symptoms including, but not limited to, tardive dyskinesia, dystonia, and akathisia, Parkinsonism, and Reglan-induced tremors. (*Id.* ¶ 8.) Reglan and metoclopramide have also been associated with central nervous system disorders, depression with suicidal ideation, visual disturbances, and

memory loss. (*Id.*) Tardive dyskinesia, dystonia, and akathisia are serious neurological movement disorders resulting in involuntary and uncontrollable movements of the head, neck, face, arms, or truck [sic], as well as involuntary facial grimacing and tongue movements, including tongue thrusting, tongue chewing, extreme anxiety, and restlessness or other involuntary movements. (*Id.* ¶ 9.) These disorders have no known cure. (*Id.* ¶ 10.)

Patients using Reglan or metoclopramide for longer periods of time are at an "unreasonably dangerous increased risk of developing one or more severe and permanent neurological movement disorders, significantly and substantially greater than disclosed or suggested in the product labeling for the drug or in any other materials disseminated by the defendants to either the medical community or the public." (*Id.* ¶ 16.) Ordinary consumers would not appreciate the risk of developing one or more incurable severe neurological movement disorders when taking Reglan or metoclopramide as discussed above. (*Id.* ¶ 17.) Similarly, a prudent manufacturer would not market Reglan or metoclopramide due to the risk of severe and permanent neurological movement disorders and the availability of less dangerous alternative treatments. (*Id.* ¶ 18.)

Reglan is the reference listed drug ("RLD") in abbreviated new drug applications ("ANDAs") for generic versions of metoclopramide. (*Id.* ¶ 25.) ANDAs for new drugs must disclose to the Food and Drug Administration ("FDA") the drug's chemistry, pharmacology, and other matters, including its proposed labeling. (*Id.* ¶ 26.) For the FDA to approve a drug's ANDA, its ANDA must include proposed labeling which discusses data and information about the risks and side effects of the drug, the drug's test results, results of animal studies, results of clinical studies, and the drug's bioavailability, all of which enable physicians or other foreseeable prescribers to use the drug safely. (*Id.*) Federal law requires the owner of an FDA-approved ANDA to ensure that the drug's labeling remains accurate and adequate, to conduct safety surveillance for adverse drug effects, and to periodically report to the FDA data related to the safety of the drug or the accuracy of its label. (*Id.* ¶ 27.) The FDA has not approved Reglan and metoclopramide for long-term or pediatric use. (*Id.* ¶ 28.)

The Amended Complaint contains three categories of claims: those against the Brand Name Defendants, the Generic Defendants, and all Defendants. . . . Plaintiffs allege that all Defendants knew or should have known that most physicians did not know or fully appreciate the seriousness of the risks associated with Reglan or metoclopramide. (*Id.* ¶ 31.) Moreover, all Defendants knew that physicians commonly prescribed the drug for inappropriate long term and pediatric use, as well

as short term use for certain adults. (*Id.*) Thus, all Defendants "should have known that the Physician's Desk reference monograph for Reglan and the package inserts for Reglan and metoclopramide were deficient, inaccurate, [or] false and misleading in communicating [information] to the medical community in general, to physicians, or to the public." (*Id.*) Plaintiffs allege that all Defendants "failed to adequately inform physicians and misled [them] about the risks associated with their metoclopramide drug products." (*Id.* ¶ 33.)

Plaintiffs aver that all Defendants "knew or . . . should have known that the labeling for Reglan and generic metoclopramide substantially understated the frequency of acute and long term side effects of the drug." (*Id.* ¶ 35.) Thus, all Defendants "failed to use reasonable care to ascertain or communicate to physicians or to the public information that would constitute adequate and effective warnings." (*Id.*) Additionally, all Defendants knew through their own studies or "publicly available published literature" that doctors commonly prescribed metoclopramide for longer than twelve weeks, for pediatric use, or in other unsafe situations. (*Id.* ¶ 37.) All Defendants also knew that their "individual and collective failure to communicate [information] to the medical community . . . about the risks of long term and other metoclopramide therapy would . . . likely . . . result in serious injury." (*Id.* ¶ 38.) Defendants failed to adequately communicate this information and failed to exercise due care to ensure that their warnings were effectively communicated; Defendants also had a duty to adequately communicate these warnings. (*Id.* ¶ 38–39.) All Defendants breached this duty in a number of ways. (*Id.* ¶ 40a–40g.) Moreover, all Defendants "failed to make reasonable efforts to ensure that accurate and adequate information regarding metoclopramide was provided to the medical community" and consumers or "to inform the FDA of the need for changes to its label." (*Id.* ¶ 48.)

The Amended Complaint also contains facts related directly to the Generic Defendants' "failure to communicate adequate warnings." (*Id.* at 22.) The Food, Drug, and Cosmetic Act ("FDCA") requires a generic drug's ANDA to include proposed labeling identical to the brand-name RLD in all material respects. (*Id.* ¶ 43.) Accordingly, the Generic Defendants submitted ANDAs for metoclopramide containing labels identical to the FDA-approved label for Reglan. (*Id.* ¶ 44.) The Generic Defendants had several duties, including the duty to ensure that their metoclopramide labels contained accurate information regarding the drug's intended uses and other common uses, to conduct post-market safety surveillance, to review adverse drug event information, to make timely revisions to the labels after revisions were made to the RLD label, and to ensure that information regarding the drug's safety was

> communicated to the medical community and consumers. (*Id.* ¶ 46.) The Generic Defendants were also required to effectively communicate the labels and their warnings to physicians and patients. (*Id.*) Plaintiffs allege that the Generic Defendants violated these duties in a number of ways, including by failing to "actually and effectively communicate" the labels and their warnings, to properly evaluate and understand how physicians and patients were using metoclopramide, to properly research, test, and market metoclopramide, to periodically review all medical literature, to independently monitor metoclopramide sales to alert them that it was widely overprescribed due to inadequate warnings, and to engage in marketing practices designed to minimize the risks associated with metoclopramide. (*Id.* ¶ 47a–47f.)
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> On February 26, 2009, the FDA exercised its new agency powers and ordered all Defendants to add a black box warning to Reglan's label. (*Id.* ¶ 49.) This new warning—the strongest available under FDA regulations—highlighted the "high risk of tardive dyskinesia with long term, high dose, or pediatric use of metoclopramide, even after the drugs are no longer taken." (*Id.*) The FDA also required all Defendants to create a Risk Evaluation and Mitigation Strategy to ensure that they communicated information regarding the risks associated with metoclopramide directly to the consumers of the drug. (*Id.* ¶ 50.) Plaintiffs allege that prior to 2007, when the FDA did not have the authority to demand such action from drug companies, all Defendants knew that the metoclopramide and Reglan warnings were insufficient, but they "did nothing to communicate accurate information to individuals prescribing and consuming metoclopramide." (*Id.* ¶ 51.) Plaintiffs aver that they were injured due to overexposure to Reglan or metoclopramide caused by all Defendants' failure "to monitor the safety of their drug products, to provide accurate and complete information to the FDA, to use reasonable means to correct inaccuracies appearing in their labels, to communicate to the medical community, physicians, Plaintiffs' physicians, Plaintiffs[,] and other foreseeable users of the drug adequate warnings about risks associated with common and foreseeable uses of their metoclopramide products." (*Id.* ¶ 54.) "Concurrently, Plaintiffs' injuries came about as a foreseeable and proximate result of [all D]efendants' inaccurate, misleading, materially incomplete, and otherwise false information concerning the potential effects of exposure to the drug substance metoclopramide and the ingestion of metoclopramide products manufactured and sold by [all] Defendants." (*Id.*)

Strayhorn v. Wyeth Pharm., Inc., 887 F. Supp. 2d 799, 804-806 (W.D. Tenn. 2012) (alterations other than [sic] in original).

In a separate order granting summary judgment to the Brand-Name Manufacturers, the district court noted an additional material fact not in dispute by the parties: "Plaintiffs in this case never took Reglan; rather, they ingested only generic metoclopramide manufactured by companies other than [the] Brand Name Defendants." *Strayhorn v. Wyeth Pharm., Inc.*, 882 F. Supp. 2d 1020, 1025 (W.D. Tenn. 2012).

B. Procedural background

In November 2011, after the Supreme Court's decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), the plaintiffs filed amended complaints, all of which are identical. The Generic Manufacturers moved to dismiss the amended complaints, arguing that the plaintiffs' various claims boiled down to the single claim that the Generic Manufacturers had failed to provide adequate warnings to medical professionals about the dangers of long-term use of metoclopramide. These defendants argued that, under *Mensing*, state-law failure-to-warn claims against generic drug manufacturers are preempted because federal law prohibits generic manufacturers from unilaterally altering their warning labels; therefore, generic manufacturers cannot simultaneously comply with both federal and state law.

The district court agreed that *Mensing* controlled. It concluded that the plaintiffs had abandoned their claims for unfair and deceptive trade practices/conspiracy and for unjust enrichment, and further determined that all of the plaintiffs' other claims against the Generic Manufacturers were essentially failure-to-warn claims preempted under *Mensing*. The plaintiffs do not challenge the court's determination regarding those claims deemed abandoned, but they do challenge the dismissal of all of their other claims.

The Brand-Name Manufacturers separately moved for summary judgment on the ground that the Tennessee Products Liability Act, Tenn. Code Ann. §§ 29-28-101 *et seq.* (TPLA), allows for recovery solely against the manufacturer or the seller of the product actually causing the harm. Because the plaintiffs did not ingest Reglan, but only generic metoclopramide, the Brand-Name Manufacturers argued that they could not be held

liable. Agreeing with the Brand-Name Manufacturers, the district court granted summary judgment in their favor.

II. ANALYSIS

A. Standard of review

1. Motion to dismiss

To survive a motion to dismiss for failure to state a claim, a complaint must allege sufficient facts that, accepted as true, "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). When determining facial plausibility, the court must construe the complaint in the light most favorable to the plaintiff. *Lambert v. Hartman*, 517 F.3d 433, 439 (6th Cir. 2008). The district court's grant of a motion to dismiss is reviewed de novo. *Paige v. Coyner*, 614 F.3d 273, 277 (6th Cir. 2010).

2. Motion for summary judgment

Summary judgment is proper when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the district court must construe the evidence and draw all reasonable inferences in favor of the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). The central issue is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251–52 (1986). We review de novo a district court's grant of summary judgment. *Huckaby v. Priest*, 636 F.3d 211, 216 (6th Cir. 2011).

B. Claims against the Generic Manufacturers

Our analysis of the claims against the Generic Manufacturers is guided by two recent decisions of the United States Supreme Court: *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), and *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013). We will therefore begin with a detailed discussion of these two decisions.

1. PLIVA, Inc. v. Mensing

In *Mensing*, which involved consolidated appeals from decisions by the Fifth and Eighth Circuits, the Supreme Court held that state-law failure-to-warn claims against generic manufacturers of metoclopramide are preempted by federal law. The Court first noted that the Louisiana and Minnesota tort laws at issue "require a drug manufacturer that is or should be aware of its product's danger to label that product in a way that renders it reasonably safe." *Mensing*, 131 S. Ct. at 2573. Federal law, on the other hand, imposes different requirements. A brand-name manufacturer must prove that its proposed drug is "safe and effective and that the proposed label is accurate and adequate," which occurs by way of clinical testing. *Id.* at 2574. But under the 1984 Drug Price Competition and Patent Term Restoration Act, 98 Stat. 1585 (popularly known as the Hatch-Waxman Amendments to the FDCA), generic drugs may be approved if their active ingredients are equivalent to a reference listed drug (RLD)—generally a brand-name drug—that has already been approved by the FDA. Generic drugs' proposed labels must be "the same as the labeling approved for the brand-name drug" in order to gain approval by the FDA. *Id.* (brackets and internal quotation marks omitted). The issue was therefore whether "it was impossible" for generic drug manufacturers to simultaneously comply with both state and federal labeling laws. *Id.* at 2578.

Although the plaintiffs in *Mensing* argued that generic manufacturers could unilaterally change their labels under the FDA's "changes-being-effected" (CBE) process, which permits certain preapproval labeling changes that add or strengthen a warning to improve drug safety, the FDA contended that the CBE process could not be

used by generic manufacturers in this manner. This is because the FDA "interprets the CBE regulation to allow changes to generic drug labels only when a generic drug manufacturer changes its label to match an updated brand-name label or to follow the FDA's instructions." *Id.* at 2575. Nor could the generic manufacturers have used "Dear Doctor" letters to send warnings to healthcare professionals because, according to the FDA, such letters are considered "labeling" and must match the prescription drug's approved labeling. *Id.* at 2576.

The Supreme Court acknowledged that "[h]ad Mensing and Demahy taken Reglan, . . . *Wyeth* [*v. Levine*, 555 U.S. 555 (2009),] would control and their lawsuits would not be pre-empted." *Id.* at 2581. In *Levine*, the Supreme Court held that state-law failure-to-warn claims against a brand-name manufacturer are not preempted by federal law because such manufacturers have the capability of complying with both state and federal law. 555 U.S. at 571. The *Mensing* Court noted that, from the plaintiffs' perspective, "finding pre-emption [in *Mensing*] but not in *Wyeth* makes little sense." *Mensing*, 131 S. Ct. at 2581. Despite the apparent unfairness of the result, the Court rested its decision on the fact that "the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers." *Id.* at 2582. It further commented that the unique regulation of generic drugs has allowed the generic-drug industry to flourish and has brought cheaper drugs to the market. *Id.* The Court declined to "decide whether the statutory scheme established by Congress is unusual or even bizarre," noting that "Congress and the FDA retain the authority to change the law and regulations if they so desire." *Id.* (internal quotation marks omitted).

2. Mutual Pharmaceutical Co. v. Bartlett

The Supreme Court recently reaffirmed *Mensing* in *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013). Bartlett took sulindac, a generic nonsteroidal anti-inflammatory drug. She developed toxic epidermal necrolysis, a condition in which the skin deteriorates or turns into an open wound. Bartlett sued the manufacturer of generic

sulindac in New Hampshire, asserting failure-to-warn and design-defect claims. New Hampshire's strict-liability regime imposes a duty on manufacturers "to ensure that the drugs they market are not unreasonably unsafe." *Bartlett*, 133 S. Ct. at 2470. On appeal, the First Circuit affirmed the jury's finding of liability and its award of $21 million in damages to Bartlett. In concluding that Bartlett's design-defect claim was not preempted under *Mensing*, the First Circuit reasoned that the generic manufacturer "could simply choose not to make the drug at all and thus comply with both federal and state law." *Id.* at 2472 (internal quotation marks omitted).

The Supreme Court reversed. It first noted that "New Hampshire's design-defect cause of action imposes affirmative duties on manufacturers," including the "duty to design [a] product reasonably safely for the uses which [the manufacturer] can foresee." *Id.* at 2473 (internal quotation marks omitted). Specifically, design-defect liability is imposed in New Hampshire when "the design of the product create[s] a defective condition unreasonably dangerous to the user." *Id.* at 2474 (internal quotation marks omitted). A product is unreasonably dangerous under the New Hampshire Supreme Court's "risk-utility approach" "if the magnitude of the danger outweighs the utility of the product." *Id.* This inquiry balances

> the usefulness and desirability of the product to the public as a whole, whether the risk of danger could have been reduced without significantly affecting either the product's effectiveness or manufacturing cost, and the presence and efficacy of a warning to avoid an unreasonable risk of harm from hidden dangers or from foreseeable uses.

Id. at 2475 (internal quotation marks omitted).

The Supreme Court reasoned that the first two factors (increasing the usefulness and desirability of the product and reducing the risk of harm) would require redesign of the product, which is not possible under FDA regulations that require generic drugs to have the same active ingredients as brand-name drugs. Redesign of the product was also not possible because sulindac is a one-molecule drug. Therefore, "the only way for [the generic manufacturer] to ameliorate the drug's 'risk-utility' profile—and thus to escape

liability [under New Hampshire law]—was to strengthen 'the presence and efficacy'" of the drug's warning. *Id.* But the warnings provided for a generic drug must be the same as the warnings found in the labeling approved for the brand-name drug in order to gain approval by the FDA. *Mensing*, 131 S. Ct. at 2574. As a result, the generic manufacturer could not possibly comply with both state and federal laws. *Bartlett*, 133 S. Ct. at 2477.

In reaching this conclusion, the Supreme Court rejected the First Circuit's "stop-selling" rationale as a basis for finding that the generic manufacturer could comply with both state and federal laws, stating that the Court's "pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether to avoid liability." *Id.* at 2477. Such a narrow reading would render the impossible-to-comply preemption doctrine "all but meaningless." *Id.* (internal quotation marks omitted). "Adopting the First Circuit's stop-selling rationale would mean that . . . the vast majority—if not all—of the cases in which the Court has found impossibility pre-emption[] were wrongly decided." *Id.* at 2478. The Court therefore held that "state-law design-defect claims that turn on the adequacy of a drug's warnings are pre-empted by federal law under [*Mensing*]." *Id.* at 2470.

Perhaps acknowledging that its preemption jurisprudence might be viewed as unjust because it bars plaintiffs from recourse against generic manufacturers, the Court stated:

> Suffice to say, the Court would welcome Congress' "explicit" resolution of the difficult pre-emption questions that arise in the prescription drug context. That issue has repeatedly vexed the Court—and produced widely divergent views—in recent years. . . . [T]he FDCA's treatment of prescription drugs includes neither an express pre-emption clause (as in the vaccine context, 42 U.S.C. § 300aa–22(b)(1)), nor an express non-pre-emption clause (as in the over-the-counter drug context, 21 U.S.C. §§ 379r(e), 379s(d)). In the absence of that sort of "explicit" expression of congressional intent, we are left to divine Congress' will from the duties the statute imposes.

Id. at 2480. This invitation for congressional action echoes the one in *Mensing*. *See* 131 S. Ct. at 2582.

3. Failure-to-warn claims

The relevant preemption question after *Mensing* is whether a generic manufacturer can simultaneously comply with both its state and federal duties. *See id.* at 2577. *Mensing* considered Louisiana and Minnesota laws that "require a drug manufacturer that is or should be aware of its product's danger to label that product in a way that renders it reasonably safe." *Id.* at 2573. Louisiana law states that "a manufacturer's duty to warn includes a duty to provide adequate instructions for safe use of a product." *Id.* (internal quotation marks omitted). Minnesota law similarly states that "where the manufacturer . . . of a product has actual or constructive knowledge of danger to users, the . . . manufacturer has a duty to give warning of such dangers." *Id.* (internal quotation marks omitted) (alterations in original). That is, "[i]n both States, a duty to warn falls specifically on the manufacturer." *Id.* In the two consolidated cases before the Supreme Court, the parties admitted that if the generic manufacturers knew of a danger associated with their product that their labels did not adequately warn of, then they were obligated under state law to "use [] different, safer label[s]." *Id.* at 2574.

The plaintiffs in the present case read *Mensing* narrowly and argue that the Supreme Court's decision was based on the fact that Louisiana and Minnesota laws "would require a manufacturer to actually change the content of its label"—that is, "provide different, additional warnings." They further contend that, under *Mensing*, only claims "based on the adequacy of the information contained in the drug's label" are preempted, not claims based on "a manufacturer's duty to provide a warning" beyond the label. The Generic Manufacturers, they argue, "could have sought FDA approval for a labeling change, or they could have notified health care professionals by other means, or could have ceased selling their products but chose not to do so." In particular, they argue that the Generic Manufacturers, on their own initiative, could have distributed "Dear Health Care Professional" or "Dear Doctor" letters to medical professionals to

warn them of the dangers of metoclopramide that were not adequately communicated on the drug's label. Finally, they argue that generic manufacturer PLIVA failed to update its labels to include information found on the labels of Reglan as of 2004.

The plaintiffs' narrow reading of *Mensing* has been soundly rejected by all circuits to consider the argument. These circuits have interpreted *Mensing* to broadly preempt claims that are, at their core, claims that the generic manufacturer failed to provide additional warnings beyond that which was required by federal law of the brand-name manufacturers. *See Schrock v. Wyeth, LLC*, 727 F.3d 1273, 1287-90 (10th Cir. 2013) (holding that federal law preempts breach-of-warranty claims premised on a theory that generic manufacturers provided improper descriptions or warnings); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1247-49 (11th Cir. 2013) (holding that the plaintiff's state-law claims against the generic manufacturer for not "adequately warn[ing] medical providers of the risks associated with long-term use of metoclopramide" were all claims "premised upon an allegedly inadequate warning" and therefore preempted under *Mensing*); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1095-96 (8th Cir. 2013) (rejecting the plaintiff's argument that *Mensing*'s preemption analysis "applies only to allegations that a generic manufacturer should have unilaterally changed the content of its metoclopramide label," finding this to be an "unduly narrow view of *Mensing*" and holding that the plaintiff's claims for negligence and misrepresentation under the Arkansas Product Liability Act were "preempted failure to warn claims" (emphasis omitted)); *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) (per curiam) (holding that "*Mensing* forecloses such [failure-to-communicate] claims because failure to 'communicate' extends beyond just a label change" and includes "affirmative steps to alert consumers, doctors, or pharmacists of changes in the drug label," actions that the generic manufacturer is prohibited from taking unilaterally under federal law); *see also Gaeta v. Perrigo Pharm. Co.*, 469 F. App'x 556 (9th Cir. 2012), *aff'g* 562 F. Supp. 2d 1091 (N.D. Cal. 2008) (granting summary judgment in favor of the generic manufacturer of over-the-counter ibuprofen because the plaintiff's state-law claims for negligence, breach of express warranty, and breach of implied warranty based on an inadequate

warning were preempted). Furthermore, the plaintiffs conceded at oral argument that the majority of their claims do not survive after *Bartlett*.

We may not, of course, rest our holding on such broad language from other circuits, but must evaluate the plaintiffs' claims in light of Tennessee law. As the district court correctly noted,

> [t]he TPLA governs products liability actions in Tennessee and defines "product liability action[s]" as "all actions brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packing, or labeling of any product." The TPLA also encompasses several different theories of products liability: "strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation, concealment, or nondisclosure, whether negligent or innocent; or under any other substantive legal theory in tort or contract whatsoever."

Strayhorn v. Wyeth Pharm., Inc., 887 F. Supp. 2d 799, 813 (W.D. Tenn. 2012) (internal footnotes omitted). The TPLA governs all of the plaintiffs' claims because the claims were brought for or on account of personal injury resulting from the design, warning, instruction, marketing, packaging, and labeling of metoclopramide. *See, e.g.*, *Richardson v. GlaxoSmithKline*, 412 F. Supp. 2d 863, 868 (W.D. Tenn. 2006) (stating that although the plaintiff's complaint for personal injuries against a drug manufacturer under the theories of negligence, strict liability, and breach of warranty "does not cite the specific basis for his allegations, product liability suits in Tennessee are governed by the Tennessee Products Liability Act"). A manufacturer or seller of a product in Tennessee "shall not be liable for any injury to a person or property caused by the product unless the product is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller." Tenn. Code Ann. § 29-28-105(a).

Under the TPLA, a product is deemed defective when it is in a condition "that renders it unsafe for normal or anticipatable handling and consumption." *Id.* § 29-28-102(2). In contrast, a product is considered unreasonably dangerous if it is

> dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics, or [if] the product because of its dangerous condition would not be put on the market by a reasonably prudent manufacturer or seller, assuming that the manufacturer or seller knew of its dangerous condition.

Id. § 29-28-102(8). The TPLA provides two tests to determine whether a product is unreasonably dangerous: the consumer-expectation test and the prudent-manufacturer test. Under the consumer-expectation test, a product is deemed unreasonably dangerous if it would be "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." *Ray by Holman v. Bic Corp.*, 925 S.W.2d 527, 530 (Tenn. 1996) (internal quotation marks omitted).

"[T]he prudent manufacturer test," on the other hand, "requires proof about the reasonableness of the manufacturer or seller's decision to market a product assuming knowledge of its dangerous condition." *Id.* at 531. The two tests are not mutually exclusive; either or both might be applicable to cases where the product is alleged to be unreasonably dangerous, but "the prudent manufacturer test will often be the only appropriate means for establishing the unreasonable dangerousness of a complex product about which an ordinary consumer has no reasonable expectation." *Id.*

With respect to the duty to warn, the Tennessee Supreme Court has stated that

> [m]anufacturers of prescription drugs, like the manufacturers of any other unavoidably dangerous product, have a duty to market and distribute their products in a way that minimizes the risk or danger. They may discharge their duty by distributing the drugs with proper directions and adequate warnings to those who foreseeably could be injured by the use of their products. . . . Warnings concerning prescription drugs generally are adequate when they contain a full and complete disclosure of the

> potential adverse reactions to the drug. A reasonable warning not only conveys a fair indication of the dangers involved, but also warns with the degree of intensity required by the nature of the risk.

Pittman v. Upjohn Co., 890 S.W.2d 425, 428, 429 (Tenn. 1994). Tennessee law thus appears to track the laws of Louisiana and Minnesota discussed in *Mensing*, which impose a similar duty on the manufacturer to warn of known dangers associated with its product. *See PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2573-74 (2011).

In the present case, the plaintiffs essentially argue that the Generic Manufacturers have a duty to warn under state law, ignoring the limitations imposed on that duty by the federal labeling requirements. *See* Am. Compl. Count I - Strict Liability, ¶ 57 ("Each of the . . . defendants is liable under the common law and/or Product Liability Act for . . . failure to give adequate warnings and/or to effectively communicate adequate warnings . . . bearing on the . . . foreseeable uses of the specific metoclopramide product . . . ."); Count III - Negligence, ¶ 87b ("[Defendants] failed to use ordinary care in marketing, labeling, and communicating adequate warnings about their respective products . . . ."); Count V - Fraud, Misrepresentation, and Suppression, ¶ 99 ("Defendants are liable [for] willful and fraudulent misrepresentations to physicians[] regarding the safety, efficacy, and risk/benefit ratio" of the drugs); Count VII - Breach of Express and Implied Warranties, ¶ 123 ("[Defendants] fail[ed] to deliver products that were safe for their intended uses . . . in light of the substantially greater risk of dangerous side effects associated with its ordinary and expected uses . . . than disclosed and warranted in the product label and/or other advertising and promotional representations."); Count XI - Civil Conspiracy, ¶ 153 ("Defendants acted with a common purpose to intentionally and/or fraudulently withhold information from the medical community and physicians regarding the safety of" the drugs).

A few recent decisions have permitted claims similar to these to go forward. Two such decisions were issued on the same day by the Pennsylvania Superior Court in *Hassett v. Dafoe*, 74 A.3d 202 (Penn. Super. Ct. 2013), and in *In re Reglan/Metoclopramide Litig.*, — A.3d —, 2013 WL 3874905 (Penn. Super. Ct. July 29,

2013). The majority opinion in both cases discounted "the tsunami of [federal] cases applying *Mensing* to pre-empt virtually all state tort claims against generic manufacturers," criticizing those decisions for their general failure to explicitly identify "state law duties associated with various causes of action" and explain "how they conflict with federal law." *Hassett*, 74 A.3d at 211-12 (internal quotation marks omitted).

In particular, the Pennsylvania court majority discussed claims for breach of express and implied warranties and for fraud and misrepresentation. It stated that the claims for breach of express and implied warranties sought to impose liability "for failing to deliver products that conformed to the properties described in the label and promotional materials," and that such claims were "not premised on the inadequacy of the label but rather on the product's failure to live up to or conform to its label and advertising." *Id.* at 215. Advertising and promotional materials did not fall into the FDCA's definition of "labeling," the majority further reasoned. *Id.* The claims were therefore not deemed preempted. With respect to the fraud and misrepresentation claims, the majority found that these claims were also not preempted because the plaintiff pled that the generic manufacturers fraudulently misrepresented the safety of the drugs "in their advertising and promotional materials, not just [on] their labels." *Id.*

Although the Pennsylvania court majority criticized the federal courts for not engaging in a nuanced comparison of federal and state duties, the dissent pointed out that the majority "offer[ed] virtually no state statutory or caselaw . . . in support of its conclusion that Appellees have presented allegations of state law tort claims which survive preemption." *Id.* at 220 (Platt, J., concurring in part and dissenting in part). We are obviously not bound by the majority opinion of the Pennsylvania Superior Court, and the omission pointed out by the dissent undermines the persuasive force of these outlier cases.

Moreover, we reject as unpersuasive the Pennsylvania Superior Court's reasoning that breach-of-warranty claims avoid federal preemption to the extent that they

are "not premised on the inadequacy of the label but rather on the product's failure to live up to or conform to its label and advertising." *Hassett*, 74 A.3d at 215. Under the FDCA, "labeling" embraces "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 Supreme Court has held that the first clause "clearly embraces advertising or descriptive matter that goes with the package in which the articles are transported." *Kordel v. United States*, 335 U.S. 345, 349-50 (1948). With respect to the second clause, "[o]ne article or thing is accompanied by another when it supplements or explains it. . . . No physical attachment one to the other is necessary." *Id.* Furthermore, the Code of Federal Regulations includes brochures, booklets, mailings, catalogues, films, sound recordings, and literature, among other things, in the definition of "labeling." 21 C.F.R. § 202.1(*l*)(2). Such labeling must be consistent with the drug's approved labeling. 21 C.F.R. § 201.100(d)(1); *see also* 21 C.F.R. § 202.1(e)(4) (prohibiting advertisements that "recommend or suggest" any use that is not in the labeling approved by the FDA).

Because such advertising and promotional materials are considered labeling, and because labeling is limited by federal law to the information contained in the brand-name drug's labeling, all of the warranty claims against the Generic Manufacturers based on these materials are preempted under *Mensing*. This follows from the fact that the Generic Manufacturers cannot meet their alleged state-law duty to provide an adequate warning without violating their federal duty of conformity to the Reglan label. *See PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577-78 (2011).

Somewhat closer to home are two recent decisions by the Eighth Circuit Court of Appeals, which remanded design-defect and breach-of-warranty claims for reconsideration. One of these decisions is *Bell v. Pfizer*, 716 F.3d 1087 (8th Cir. 2013), where the court determined that the "vast majority" of Bell's allegations were essentially "preempted failure to warn claims" based on inadequate warning or labeling, but it remanded for reconsideration the design-defect and breach-of-implied-warranty claims that appeared not to be based on the warnings. *Id.* at 1096. The district court had simply

construed all the claims as failure-to-warn claims and had not analyzed whether the plaintiffs "adequately state[d] viable claims under Arkansas law" or whether the claims were barred by "impossibility preemption." *Id.* And in *Fullington v. Pfizer*, 720 F.3d 739 (8th Cir. 2013), the Eighth Circuit remanded the plaintiff's design-defect claim for reconsideration in light of *Bartlett* because, under Arkansas's consumer-expectation test, "it [was] not immediately clear" whether generic drug manufacturers in that state could "somehow alter an otherwise unreasonably dangerous drug" without running afoul of federal law. *Id.* at 747.

In the present case, we find no similar inadequacy of analysis by the district court. We also conclude, unlike the Eighth Circuit in *Bell* and *Fullington*, that the plaintiffs' implied-warranty claims boil down to the failure to give additional warnings. The plaintiffs allege that the Generic Manufacturers "fail[ed] to deliver products that were safe for their intended uses, including long term metoclopramide therapy, in light of the substantially greater risk of dangerous side effects associated with its ordinary and expected uses, including long term therapy, than disclosed and warranted in the product label and/or other advertising and promotional materials." Am. Compl. ¶ 123. These claims are clearly based on the alleged inadequacy of the warnings given.

Before further analyzing the plaintiffs' implied-warranty claims, we note that their express-warranty claims are without merit because the labels never explicitly warranted that metoclopramide was safe for long-term use. In fact, the plaintiffs do not allege that the Generic Manufacturers ever made such an affirmative representation; they instead allege that the labeling failed to strongly warn that the product was *not* appropriate for such use. *See* Am. Compl. ¶¶ 13-15 ("The 'indications' (recommended uses) listed in the product labeling for Reglan/metoclopramide include adult short-term therapy . . . for up to twelve (12) weeks in adults, for gastroesophogeal reflux (heartburn), and specified no durational limit in therapy for gastric stasis or gastroparesis (bloating). . . . [But the drug has never] been shown to be either efficacious or safe when used for long term treatment."); ¶¶ 33-34 ("The defendants failed to adequately inform physicians . . . about the risks associated with . . . metoclopramide . . . [and therefore]

Plaintiffs' physicians did not know or appreciate fully the risks of side affects associated with the use, particularly with the long term use, of the drug.")

In order to establish a prima facie claim for breach of express warranty in Tennessee, a plaintiff must prove that: (1) the seller made an affirmation of fact intending to induce the buyer to purchase the goods, (2) the buyer was in fact induced by the seller's acts, and (3) the affirmation of fact was false regardless of the seller's knowledge of the falsity or intention to create a warranty. *Coffey v. Dowley Mfg., Inc.*, 187 F. Supp. 2d 958, 969 (M.D. Tenn. 2002), *aff'd*, 89 F. App'x 927 (6th Cir. 2003). The plaintiffs' allegations in the present case do not identify any affirmation of fact made on the product labeling that they allege to be *false*; rather, they allege that the labeling was *inadequate*. We thus find no merit in their express-warranty claims.

The plaintiffs' implied-warranty claims under Tenn. Code Ann. § 47-2-314 fare no better because they are entirely premised on a failure-to-warn theory. In particular, the plaintiffs do not allege that the generic metoclopramide they took was ineffective for treating the gastrointestinal conditions for which it was prescribed; only that it was unsafe when used long-term because of the drug's dangerous side effects. *See* Am. Compl. ¶ 15. Any long-term use, they further allege, was due to the Generic Manuacturers' failure to warn about the consequences of such use. *Id.* ¶ 31. Indeed, the plaintiffs allege that the Generic Manufacturers delivered products that were "[un]safe for their intended uses . . . *in light of* . . . the product label and/or other advertising or promotional representations." *Id.* ¶ 123 (emphasis added). In order to escape liability for such an alleged defect, the Generic Manufacturers would have had to give a stronger warning than they were permitted to give under federal law. But such implied-warranty claims are preempted by both *Mensing* and *Bartlett*.

To the extent that the plaintiffs allege that the Generic Manufacturers should have unilaterally changed the label to reflect any danger posed by long-term use of the drug, this claim is clearly preempted. *See PLIVA, Inc. v. Mensing*, 131 S. Ct 2567, 2578 (2011). And to the extent that the plaintiffs allege that the drug itself should have been

modified to conform to the properties described in the label, generic manufacturers are prohibited by their federal duty of sameness from designing their drugs differently from the RLD. *See Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2475 (2013) (noting that "the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based"). When a generic manufacturer cannot obey federal law without being held liable under a state-law warranty action, the state action is preempted. *See Mensing*, 131 S. Ct. at 2577.

Our conclusion is consistent with this court's previous decision in *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011), *cert. denied*, 132 S. Ct. 2103 (2012), which affirmed the district court's determination that the plaintiffs' state-law claims—centering on a failure to warn under Kentucky law that included claims for breach of implied warranty—were preempted. We further note that Kentucky's implied-warranty regime is substantially the same as that of Tennessee. *Compare* Ky. Rev. Stat. § 355.2-314 *with* Tenn. Code Ann. § 47-2-314. To not find preemption in the present case would require us to disregard this court's binding precedent.

Nor does the Pennsylvania Superior Court's evaluation of the fraud and misrepresentation claims in *Hassett* help the plaintiffs in the present case. As an initial matter, the plaintiffs' allegations with respect to these claims appear to relate only to the Brand-Name Manufacturers. *See* Am. Compl. ¶ 100 ("Through its [sic] actions and omissions in advertising and other activities to promote the use of Reglan, defendants intentionally and fraudulently made misrepresentations of material facts . . . ."); ¶ 105 ("BRAND NAME DEFENDANTS made these material misrepresentations and omissions to physicians knowing that they were not true, and knowing and intending that physicians would consider the misinformation disseminated to be reliable . . . ."); ¶ 106 ("In the alternative, BRAND NAME DEFENDANTS made the false material representations and omissions with reckless disregard of whether these representations were true or not."); ¶ 110 ("BRAND NAME DEFENDANTS overstated the benefits and safety of Reglan and concomitantly downplayed the risks in its use . . . .").

But even if the complaint is read to assert these claims against the Generic Manufacturers, the claims boil down to an alleged duty to provide additional information about generic metoclopramide. *See* Am. Compl. ¶ 108 ("Each of the DRUG COMPANY DEFENDANTS . . . is obligated to give physicians and their patients . . . accurate and material scientific information and data regarding the association between exposure to metoclopramide and the [risks of the drug]."); ¶ 111 ("The DRUG COMPANY DEFENDANTS passively assented to and indirectly cooperated in the misrepresentations, concealment, suppression and omissions made directly by the BRAND NAME DEFENDANTS . . . ."). These claims are essentially failure-to-warn claims that are preempted under *Mensing*.

The plaintiffs' design-defect claims suffer a similar fate under *Bartlett* because all of their claims rest on inadequate warnings. Although Tennessee caselaw has not yet addressed whether the prudent-manufacturer test or the consumer-expectation test applies to design-defect claims involving prescription drugs, the former test would appear to be the appropriate choice in this case because the ordinary consumer would not have the medical knowledge necessary to have a reasonable expectation about the safety of metoclopramide. *See Ray by Holman v. Bic Corp.*, 925 S.W.2d, 527, 531 (Tenn. 1996) ("By definition, [the consumer-expectation test] could be applied only to those products in which everyday experience of the product's users permits a conclusion. For example, ordinary consumers would have a basis for expectations about the safety of a can opener or coffee pot, but, perhaps, not about the safety of a fuel-injection engine or an air bag." (ellipsis, emphasis, internal citation, and internal quotation marks omitted)).

In analyzing whether a product is unreasonably dangerous under Tennessee's prudent-manufacturer test, the court engages in a risk-utility analysis similar to New Hampshire's by considering

> (1) the product's usefulness and desirability; (2) the product's safety aspects—the likelihood and probable seriousness of injury; (3) the availability of a substitute product that would safely meet the same need; (4) the manufacturer's ability to eliminate the product's unsafe character without hindering its usefulness or causing the maintenance of its utility

> to be too expensive; (5) the ability of the operator or user to avoid danger through the exercise of care in using the product; (6) the user's anticipated awareness of the product's inherent dangers and their avoidability; and (7) the feasibility of the manufacturer spreading the loss by setting the price of the product or maintaining liability insurance.

Brown v. Crown Equip. Corp., 181 S.W.3d 268, 282-83 (Tenn. 2005). The Supreme Court in *Bartlett* considered factors such as these to effectively require either a redesign of the product or a stronger warning to avoid liability for a design defect, with neither course of action being available to a generic manufacturer under federal law. *See Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2475-76 (2013). In any event, we need not decide which test applies in the present case because the plaintiffs conceded at oral argument that *Bartlett* forecloses their design-defect claims.

We next turn to the plaintiffs' argument that the Generic Manufacturers should have sent Dear Doctor letters to communicate additional warnings. Such letters, however, would violate the duty of conformity, as explained in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2576 (2011):

> A Dear Doctor letter that contained substantial new warning information would not be consistent with the drug's approved labeling. Moreover, if generic drug manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly "misleading." [] [*S*]*ee* 21 CFR § 314.150(b)(3) (FDA may withdraw approval of a generic drug if "the labeling of the drug . . . is false or misleading in any particular"). . . . Accordingly, we conclude that federal law did not permit the Manufacturers to issue additional warnings through Dear Doctor letters.

See also Fulgenzi v. PLIVA, Inc., 711 F.3d 578, 581 n.1 (6th Cir. 2013) (noting that the term "labeling" is broadly construed and includes Dear Doctor letters).

As the Fifth Circuit recently explained, "the inquiry is whether the brand-name manufacturers sent out a warning, not whether the proposed warning to be disseminated contains substantially similar information as the label. Because no brand-name manufacturer sent a warning based on the 2004 label change, the generic manufacturers

were not at liberty to do so." *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) (per curiam). Nor can the plaintiffs proceed on a failure-to-withdraw or stop-selling theory, a theory recently rejected by the Supreme Court in *Bartlett*.

Finally, the plaintiffs argue that *Mensing* does not control, and that their claims instead survive preemption under *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431 (2005), and *Altria Group, Inc., v. Good*, 555 U.S. 70 (2008). These latter cases involved federal statutes that expressly preempt certain state-law failure-to-warn claims, but leave available other state-law causes of action such as express warranty, conspiracy, and design defect.

But express preemption is not at issue in the present case. The Supreme Court clearly based its decision in *Mensing* on conflict or impossibility preemption, which requires a comparison of the conflicts between state and federal duties to determine "whether the private party could independently do under federal law what state law requires of it." *Mensing*, 131 S. Ct. at 2579. Simply because certain claims survived express preemption in other cases does not mean that they will survive conflict preemption in this case. *See id.* at 2577 n.5 ("[T]he absence of express pre-emption is not a reason to find no *conflict* pre-emption." (emphasis in original)). The plaintiffs' attempt to avoid *Mensing* by analogizing their claims to the express-preemption cases is therefore unavailing. We find no error in the district court's dismissal of the plaintiffs' claims that are, at their core, all failure-to-warn claims.

4. Failure-to-conform claims

In their complaint, the plaintiffs alleged that several of the Generic Manufacturers "were negligent in failing to include information present in the label for the RLD and in failing to implement changes to their own labels to ensure that the information they provided was current and not outdated" and, in some cases, "waited years to conform their labels to the RLD label." Am. Compl. ¶ 87*l*. And in the plaintiffs' brief on appeal, they argue that "PLIVA failed to include instrumental warnings in its label for metoclopramide that had been approved by the FDA and were

in use by the name brand manufacturers in their FDA approved labeling." The district court characterized these allegations as "failure-to-conform claims." Other courts refer to claims of this nature as "failure-to-update claims."

In *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013), this court held that the plaintiff stated a claim by alleging that the generic manufacturer failed to update its label in 2004 to match that of the prescription drug Reglan. The court held that the claim was not barred by the impossibility-preemption doctrine because the generic manufacturer could have complied with federal law by using the same label as the brand-name manufacturer (and in fact was required to do so). *Fulgenzi*, 711 F.3d at 584. Because the claim survived preemption, Fulgenzi was free to argue that the outdated warning was inadequate. That decision, however, is based on facts clearly distinguishable from the present case.

The plaintiff in *Fulgenzi* alleged that "in July of 2004, the FDA approved Schwarz's request to add a sentence to the Reglan label as follows: 'Therapy should not exceed 12 weeks in duration.' Consequently, the name brand warning label for Reglan contained the foregoing warning against treatment in excess of 12 weeks after this date." *Fulgenzi v. PLIVA, Inc.*, No. 5:09-cv-1767, Second Am. Compl. (D.E. 60) ¶ 46. Fulgenzi amended her complaint after *Mensing* to include a claim that PLIVA, the generic manufacturer, "failed to update its . . . label(s) as to metoclopramide to include the July, 2004 label change warning against any therapy in excess of 12 weeks." *Id.* ¶ 60. She also specifically alleged that she ingested PLIVA-manufactured metoclopramide during the time when the generic's label was not updated, *i.e.*, "September, 2004; September, 2006; December, 2006; March, 2007; June, 2007; and August, 2007," *id.* ¶ 17, allowing this court to conclude that "PLIVA's label was not updated the entire time Fulgenzi was prescribed the drug," *Fulgenzi*, 711 F.3d at 582.

In the present case, nothing in the complaint indicates when the plaintiffs ingested generic metoclopramide. They simply allege that "several" of the Generic Manufacturers "fail[ed] to include information present in the label for the RLD and

fail[ed] to implement changes to their own labels," and that some Generic Manufacturers "waited years to conform their labels to the RLD label." Am. Compl. ¶ 87*l*. The plaintiffs attempt to enlarge their pleadings on appeal by arguing that "PLIVA failed to include instrumental warnings in its label for metoclopramide that had been approved by the FDA and were in use by the name brand manufacturers in their FDA approved labeling." But "[t]he appropriate method for adding new factual allegations to a complaint is not via an appellate brief, but by filing an amended complaint." *Harvey v. Great Seneca Fin. Corp.*, 453 F.3d 324, 328 (6th Cir. 2006). Moreover, these new statements still fail to allege when the metoclopramide was ingested and by whom it was used with regard to specific generic manufacturers, facts essential to show that a particular generic manufacturer's label was not updated during the time that a particular plaintiff was using its product.

In evaluating whether a complaint states a claim for relief, we "should not assume facts that were not pled." *Id.* at 328. We will instead consider "only those facts alleged in [the plaintiffs'] complaint and the reasonable inferences that can be drawn from those facts." *Id.* at 329. So even assuming that the failure-to-conform claims are not preempted under *Fulgenzi*, the plaintiffs have nonetheless failed to "state a claim to relief that is plausible on its face," *see Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see also Bowman v. Wyeth, LLC*, No. 10-1946, 2012 WL 684116, at *7 (D. Minn. Mar. 2, 2012) (declining to reach the question whether the failure-to-conform claim was preempted because the plaintiff's complaint did not allege that he ingested metoclopramide after July 2004 or that he ingested metoclopramide for more than twelve weeks, nor did it allege any specific facts relating to the 2004 labeling change).

The plaintiffs requested at oral argument an opportunity to amend their complaint once more in light of *Fulgenzi*, but they have offered no argument as to why they were unable to include the dates during which they took the drugs in their first amended complaint. Contrary to the plaintiffs' assertion at oral argument that such information need not be in the complaint, such a factual averment is critical to the question of

whether the plaintiffs' alleged injuries are in any way connected to the alleged failure to conform.

The plaintiffs are responsible for pleading their cause of action and are "not entitled to an advisory opinion from the Court informing them of the deficiencies of the complaint and then an opportunity to cure those deficiencies." *Winget v. JP Morgan Chase Bank, N.A.*, 537 F.3d 565, 573 (6th Cir. 2008) (brackets and internal quotation marks omitted). This is especially true here, where the plaintiffs were already given leave to amend their complaint once and where the key facts that might make their claims plausible are easily within their own knowledge. We therefore find no error in the district court's dismissal of the plaintiffs' failure-to-conform claims.

5. Civil conspiracy

In their brief on appeal, the plaintiffs argue that they have adequately pled a cause of action for civil conspiracy. The district court held that the plaintiffs had not alleged any facts in support of their civil-conspiracy claim, and that such a claim was in substance another failure-to-warn claim. We find no error in the district court's analysis. The plaintiffs' complaint with regard to this claim does no more than recite the elements of a cause of action for civil conspiracy; on appeal, they simply reiterate their pleadings. Because "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" to state a claim, *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), the complaint fails to state a claim for civil conspiracy. Moreover, even if the civil-conspiracy claim was adequately supported by factual allegations, the essence of such a claim is that there was a tacit agreement between the manufacturers not to warn, or not to adequately warn, about the dangers of long-term metoclopramide use—a failure-to-warn claim that, for the reasons already discussed, is preempted under *Mensing*.

6. Punitive damages

The plaintiffs further argue that "*Mensing* clearly does not mandate dismissal of the punitive damages claim as to the Generic Defendants." But their claims for punitive damages are "derivative in nature." *See Graham v. Am. Cyanamid Co.*, 350 F.3d 496, 514-15 (6th Cir. 2003). "A derivative cause of action may not provide greater relief than that available under the primary cause of action." *Id.* at 515 (internal citation omitted). Because the district court did not err in dismissing the plaintiffs' substantive claims against the Generic Manufacturers, it did not err in dismissing their punitive-damages claims.

C. Claims against the Brand-Name Manufacturers

Turning now to the Brand-Name Manufacturers, the plaintiffs contend that the information disseminated by them was "materially false, incomplete, and misleading" and that this deficiency proximately caused the plaintiffs' injuries. They assert that the Brand-Name Manufacturers had an affirmative duty under the FDA regulations to accurately label their products because a medical professional could foreseeably rely on that information in prescribing metoclopramide, the generic equivalent of Reglan. The Brand-Name Manufacturers respond that none of the plaintiffs took Reglan, only the generic metoclopramide, so the plaintiffs' claims against them are barred by the TPLA.

Agreeing with the Brand-Name Manufacturers, the district court held that the plaintiffs, who conceded that they never took Reglan, could not meet the "threshold requirement" of a Tennessee products-liability claim—*i.e.*, "that the plaintiff assert that the defendant's product caused the plaintiff's injury." *Strayhorn v. Wyeth Pharm., Inc.*, 882 F. Supp. 2d 1020, 1029 (W.D. Tenn. 2012). The court found that *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011), *cert. denied* 132 S. Ct. 2103 (2012), a decision involving Kentucky law, controlled the present case.

The *Smith* plaintiffs sued Wyeth and Schwarz, both makers of Reglan, alleging fraud and tortious misrepresentation. Examining the Kentucky Product Liability Act

(KPLA), this court noted that the Act "defines a product liability action as any action brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formulation[,] . . . warning, instructing, marketing, advertising, packaging or labeling of any product." *Id.* at 423 (internal quotation marks omitted) (second alteration in original). This court further noted that the Kentucky Supreme Court had held that the KPLA "applies to all damages claims arising from the use of products, regardless of the legal theory advanced." *Id.* (internal quotation marks omitted). Kentucky law also requires that the plaintiffs assert, as a threshold matter, "that the defendant's product caused the plaintiff's injury." *Id.* But the *Smith* plaintiffs, just as the plaintiffs in the present case, had ingested only generic metoclopramide, not Reglan.

This court in *Smith* also rejected the plaintiffs' argument that "the name-brand defendants' liability stems from the fact that the regulatory structure governing name-brand and generic drugs makes it foreseeable that patients and their physicians will rely on the name-brand labels to use and prescribe generic drugs." *Id.* at 423-24. It noted that the "leading case" on this issue, *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994), held that "the manufacturer of a name-brand drug has no duty to patients who ingested only a generic version of the drug manufactured by the name-brand drug company's competitors." *Smith*, 657 F.3d at 424. This court therefore joined "the majority of courts to address this question" and held that the plaintiffs could not bring their state-law tort claims against the brand-name defendants. *Id.*

The plaintiffs' arguments in the instant case track those of the *Smith* plaintiffs. They contend that their suit is not governed by the TPLA and that they have stated viable causes of action for negligent and fraudulent misrepresentation and for breach of express and implied warranties under *Wyeth v. Levin*e, 555 U.S. 555 (2009) (finding no preemption against the brand-name manufacturer), and *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89 (2008) (holding that an injured plaintiff may hold a brand-name manufacturer liable for its alleged misrepresentations even though the actual injury was caused by a generic manufacturer's drug). That is, they focus their arguments on

whether the TPLA even applies to them. The plaintiffs do not challenge the district court's dismissal of their remaining claims against the Brand-Name Manufacturers.

Unfortunately for the plaintiffs, the relevant language in the TPLA is essentially the same as the language of the KPLA discussed in *Smith*. Both statutes define a "product liability action" to include all harm caused by a product regardless of the legal theory advanced. *Compare* Tenn. Code Ann. § 29-28-102(6) *with* Ky. Rev. Stat. § 411.300(1).

The TPLA's definition of "product liability action" has been interpreted broadly. *See, e.g.*, *Richardson v. GlaxoSmithKline*, 412 F. Supp. 2d 863 (W.D. Tenn. 2006) (concluding that although the plaintiff's complaint for personal injuries against a drug manufacturer under the theories of negligence, strict liability, and breach of warranty "does not cite the specific basis for his allegations, product liability suits in Tennessee are governed by the Tennessee Products Liability Act"); *Spence v. Miles Labs., Inc.*, 810 F. Supp. 952, 959 (E.D. Tenn. 1992) ("Whether formulated as a 'strict liability' claim for damages resulting from untested blood products . . . or as a negligence claim, the plaintiff's claims manifestly relate to a product [and] clearly fall within Tennessee's broad definition of products liability actions."), *aff'd*, 37 F.3d 1185 (6th Cir. 1994); *Penley v. Honda Motor Co.*, 31 S.W.3d 181 (Tenn. 2000) (applying the TPLA to the plaintiff's express- and implied-warranty claims for injuries caused by an all-terrain vehicle).

As relevant to the present case, the TPLA clearly applies to the plaintiffs' claims for breach of warranty against the Brand-Name Manufacturers. And although the definition of a "product liability action" does not explicitly state whether fraudulent misrepresentation claims are covered, *see* Tenn. Code Ann. § 29-28-102(6) (stating that the TPLA covers claims for "misrepresentation, concealment, or nondisclosure, whether negligent, or innocent"), we conclude that such a cause of action is fairly encompassed in the catch-all provision of this section, *see id.* (stating that a "product liability action" includes "any other substantive legal theory in tort or contract whatsoever").

The plaintiffs' injuries allegedly caused by the Brand-Name Manufacturers' purported fraudulent misrepresentations in the present case are the result of the Brand-Name Manufacturers' "advertising, promotions, in-office and group presentations[,] . . . sponsored education and continuing education programs and seminar speakers, the planning, sponsorship, ghost-writing, and arranged publication of non-scientific and misleading medical research," as well as their failure to warn the medical community about the true risks of Reglan. *See* Am. Compl. ¶¶ 101-03. In other words, they are the result of the "warning, instruction, marketing, packaging or labeling of" Reglan. *See* Tenn. Code Ann. § 29-28-102(6).

These are essentially the same allegations made against the brand-name manufacturers in *Smith*. *See Smith v. Wyeth, Inc.*, No. 5:07-CV-18-R, 2008 WL 2677051, at *3 (W.D. Ky. June 30, 2008) ("Specifically, Plaintiff argues that Defendants distributed false and misleading information concerning Reglan . . . . In effect, Plaintiff is arguing that Defendants' *warning, labeling, and marketing concerning Reglan* should also be seen as the warning, labeling, and marketing of [competing generic manufacturers]." (emphasis added)). We thus conclude that the TPLA applies to all of the plaintiffs' claims against the Brand-Name Manufacturers. This determination is consistent with the determination in *Smith* that the KPLA covers product-liability actions for fraud and misrepresentation despite the lack of any specific language to that effect in the statute. *See Smith v. Wyeth, Inc.*, 657 F.3d 420, 423 (6th Cir. 2011), *cert. denied* 132 S. Ct. 2103 (2012) (holding that the KPLA "applies to all damages claims arising from the use of products, regardless of the legal theory advanced") (internal quotation marks omitted).

Similar to the KPLA, the TPLA contains multiple references to manufacturers and sellers. *See* Tenn. Code Ann. § 29-28-102(4), (7) (defining the terms "manufacturer" and "seller"); § 103(a) (setting forth the statute of limitations for "[a]ny action against a manufacturer or seller of a product for injury to person"); § 104(a) (discussing the rebuttable presumption that a product is not unreasonably dangerous if the manufacturer or seller complied with federal and state regulations). These references

fairly imply that a claim falling under the definition of a "product liability action" may be asserted only against the manufacturer or the seller of the product that harmed the plaintiff. *See Maness v. Boston Sci.*, 751 F. Supp. 2d 962, 968 (E.D. Tenn 2010) ("Only sellers and manufacturers may be held liable under the TPLA.").

The plaintiffs' citation to *Gaines v. Excel Industries, Inc.*, 667 F. Supp. 569 (M.D. Tenn. 1987), does not persuade us otherwise. In that case, the plaintiffs were injured by stamp presses in their employer's plant. They sued the parent corporation of their employer, alleging under a "Good Samaritan" theory that the parent corporation assumed a duty of care to the plaintiffs by performing safety-inspection tours of the plant and negligently failed to implement appropriate safety measures. In response, the defendant argued that because the claim was one for injuries resulting from the construction, assembly, testing, service, or instruction of a product (the stamp presses and related safety devices) under a negligence theory, the TPLA's statute of limitations operated to bar the claim.

The district court in *Gaines* disagreed with the defendant because the Good Samaritan claim was "not based on any actions defendant took in a role as 'manufacturer' or 'seller,'" as those terms are defined in the TPLA. *Id.* at 574. Rather, the claim against the parent corporation was due to its role as a safety inspector. The court, however, was careful to note that any claims relating to the parent corporation's role in "designing, fabricating, or assembling the safety apparatus attached to the presses" were in the nature of its role as a manufacturer or seller and, therefore, fell under the TPLA. *Id.*

In contrast to the Good Samaritan theory in *Gaines*, all of the claims against the Brand-Name Manufacturers in the present case are based on these defendants' status as the manufacturers of Reglan. As such, the Brand-Name Manufacturers were responsible for proposing an accurate and adequate label to the FDA (as well as for updating that label), which, in turn, controlled the label for the Generic Manufacturers through the ANDA process. They were also responsible for distributing adequate warnings about

the product. But they undertook no separate duties as did the parent corporation in *Gaines*.

The TPLA therefore applies to all of the plaintiffs' claims against the Brand-Name Manufacturers. Unfortunately for the plaintiffs, however, these defendants were not the manufacturers or sellers of the generic drugs that injured the plaintiffs. Yet "[i]n order to recover [under the TPLA], a plaintiff must show that the product manufactured and sold by the defendant . . . caused the injuries he alleges to have sustained." *Richardson v. GlaxoSmithKline*, 412 F. Supp. 2d 863, 868 (W.D. Tenn. 2006) (brackets and internal quotation marks omitted); *see also* Tenn. Code Ann. § 29-28-105(a) ("A manufacturer or seller of a product shall not be liable for any injury to a person or property *caused by the product* unless the product is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller." (emphasis added)); *Wyatt v. Winnebago Indus., Inc.* 566 S.W.2d 276, 280 (Tenn. Ct. App. 1978) (stating that the "first requirement [of proximate cause] is that the defendant's act or, in this products liability case, the defect in the product, be a cause in fact of the injury").

The Supreme Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009), is not to the contrary. In *Levine*, the Court held that state-law tort claims against brand-name manufacturers are not preempted by federal law because "it is not impossible for [a brand-name manufacturer] to comply with its state and federal obligations." 555 U.S. at 581. Specifically, the CBE process permits brand-name manufacturers to strengthen their warnings without prior approval from the FDA, thus allowing brand-name manufacturers to comply with both state and federal law. But unlike in the present case, Levine was injured by the brand-name manufacturer's own product.

The plaintiffs nonetheless argue that the Brand-Name Manufacturers are liable because they could foresee that physicians would rely on the information provided by the Brand-Name Manufacturers when prescribing metoclopramide. But simply because a particular harm is foreseeable "is not dispositive in determining the existence of a legal

duty." *Burroughs v. Magee*, 118 S.W.3d 323, 333 (Tenn. 2003); *accord Satterfield v. Breeding Insulation Co.*, 266 S.W.3d 347, 366 (Tenn. 2008) ("[F]oreseeability alone is insufficient to create a duty."). Finding the existence of a duty requires a substantive public-policy determination. *See Bradshaw v. Daniel*, 854 S.W.2d 865, 869-70 (Tenn. 1993) (stating that, to determine the existence of a duty, the court considers whether "a relation exists between the parties that the community will impose a legal obligation upon one for the benefit of the others—or, more simply, whether the interest of the plaintiff which has suffered invasion was entitled to legal protection at the hands of the defendant").

Despite the above considerations, our dissenting colleague embraces the plaintiffs' theory of brand-name-manufacturer liability. She repeatedly quotes the concurring opinion in *Fullington v. Pfizer, Inc.*, 720 F.3d 739, 748 (8th Cir. 2013), to support her argument that the basis for insulating brand-name manufacturers from suit has been "severely eroded" since this court decided *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011). In our opinion, however, three factors militate against reaching such a conclusion. First, the Eighth Circuit in *Fullington* in fact *affirmed* the district court's grant of summary judgment in favor of the brand-name manufacturers, relying on its prior decision in *Bell v. Pfizer, Inc.*, 716 F.3d 1087 (8th Cir. 2013). Judge Murphy's four-paragraph concurrence in *Fullington* indeed questions the soundness of *Bell* and similar decisions, but is hardly enough for us to overrule our own circuit's decision in *Smith*.

Second, we are bound by *Smith*'s holding even if, as our dissenting colleague contends, its analysis might be flawed. *See United States v. Dunlap*, 209 F.3d 472, 481 (6th Cir. 2000) ("[A] subsequent panel of this circuit court is powerless to revisit, modify, amend, abrogate, supersede, set aside, vacate, avoid, nullify, rescind, overrule, or reverse any prior Sixth Circuit panel's published precedential ruling of law."); *see also Salmi v. Sec'y of Health & Human Servs.*, 774 F.2d 685, 689 (6th Cir. 1985) ("The prior decision remains controlling authority unless an inconsistent decision of the United States Supreme Court requires modification of the decision or this Court sitting en banc

overrules the prior decision."). Because *Smith* ruled in favor of the brand-name manufacturers in a case virtually identical to the one before us, the dissent's reliance on the concurring opinion in *Fullington* to reach a contrary result strikes us as misplaced.

Finally, and perhaps most importantly, we have no basis to conclude in this diversity case that the Tennessee Supreme Court would overrule its prior decisions holding that a manufacturer owes no duty of care to consumers of products made by others. Tennessee law instead "requires manufacturers to warn of hidden and unknown dangers in *their* product." *Pemberton v. Am. Distilled Spirits Co.*, 664 S.W.2d 690, 693 (Tenn. 1984) (emphasis added) (internal quotation marks omitted). Furthermore, "[d]rug manufacturers have a duty to exercise ordinary and reasonable care not to expose the public to an unreasonable risk of harm from the use of *their* products." *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 428 (Tenn. 1994) (emphasis added). In Tennessee, a relationship exists between manufacturers and "those who foreseeably could be injured by the use of *their* products," not those persons injured by some other product. *See id.* (emphasis added). This court has previously interpreted this principle to mean that "[a]lthough a product manufacturer generally has a duty to warn of the dangers of its own products, it does not have a duty to warn of the dangers of another manufacturer's products." *Barnes v. Kerr Corp.*, 418 F.3d 583, 590 (6th Cir. 2005) (holding that a dental-amalgam manufacturer had satisfied its duty to warn about the dangers posed by the mercury in its products even though it did not warn that those dangers remained when combined with other manufacturers' dental-amalgam ingredients).

The plaintiffs have presented no authority indicating that manufacturers of a brand-name drug have a duty under Tennessee law to consumers of the brand-name manufacturers' competitors, and we are loath to expand Tennessee's substantive law without direction from the Tennessee Supreme Court. *See Combs v. Int'l Ins. Co.*, 354 F.3d 568, 577 (6th Cir. 2004) ("[W]hen given a choice between an interpretation of [state] law which reasonably restricts liability, and one which greatly expands liability, we should choose the narrower and more reasonable path." (second alteration in original) (internal quotation marks omitted)).

Nor does *Conte v. Wyeth*, 168 Cal. App. 4th 89 (2008), save the plaintiffs' claims. In *Conte*, the California Court of Appeal stated that it "ha[d] no difficulty concluding that [the brand-name manufacturer] should reasonably perceive that there could be injurious reliance on its product information by a patient taking generic metoclopramide." *Id.* at 104. But this court in *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011), *cert. denied*, 132 S. Ct. 2103 (2012), considered *Conte* and characterized it as an outlier, choosing instead to follow *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994), and the majority of other courts that have rejected such a theory. *See also Mensing v. Wyeth, Inc.*, 588 F.3d 603, 613-14 (8th Cir. 2009) ("Whatever the merits of *Conte* under California law, . . . under Minnesota law Mensing has not shown that the name brand manufacturers owed her a duty of care necessary to trigger liability."), *rev'd in part on other grounds sub nom. PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

Although our decision is grounded in Tennessee law, we would note that every federal court of appeals to consider this issue has held that brand-name manufacturers are not liable to plaintiffs who are injured by a generic manufacturer's drug, whether under a state's product-liability act or under general principles of duty. *See, e.g.*, *Schrock v. Wyeth, LLC*, 727 F.3d 1273, 1284-86 (10th Cir. 2013) (noting that every federal circuit court has rejected—and that the Oklahoma Supreme Court would not recognize—brand-name liability under these circumstances); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1251-53 (11th Cir. 2013) (noting the "overwhelming national consensus" on the issue); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1092 (8th Cir. 2013) (same); *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 182-83 (5th Cir. 2012) (per curiam), *petition for cert. filed*, 81 U.S.L.W. 3519 (U.S. Mar. 7, 2013) (No. 12-1093) (same). And this court, following the majority view in *Foster*, has previously come to the same conclusion in *Smith*. *See Smith*, 657 F.3d at 424 ("As have the majority of courts to address this question, we reject the argument that a name-brand drug manufacturer owes a duty of care to individuals who have never taken the drug actually manufactured by that company.").

Only three cases to our knowledge have decided the other way: *Conte v. Wyeth*, 168 Cal. App. 4th 89 (2008), *Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010), and *Wyeth v. Weeks*, — So.3d —, 2013 WL 135753 (Ala. Jan. 11, 2013) (reargument granted June 13, 2013). For differing reasons, we find each of these cases either unpersuasive or distinguishable. As explained above, this court rejected *Conte* in *Smith* and we do so again in the present case. The district court in *Kellogg*, on the other hand, recognized that common-law actions for fraud and negligence with regard to product-liability claims remain viable in Vermont, the state having no statute comparable to the TPLA. 762 F. Supp. 2d at 704, 707. As such, the court concluded that determining whether the plaintiff had ingested the defendant's product was not essential to the claim. *Id.* at 709. The court also concluded that, under Vermont law, there was a duty on the part of the brand-name defendant to the generic's consumer, *id.* at 708-09, a legal principle that is contrary to Tennessee law. Finally, the Alabama Supreme Court has decided to rehear *Weeks*, which makes its ultimate outcome far from certain. In sum, none of these cases persuade us to alter our analysis as set forth above. We therefore find no error in the district court's grant of summary judgment in favor of the Brand-Name Defendants.

D. Motion to certify a question to the Tennessee Supreme Court

Finally, the plaintiffs have moved to certify the following question to the Tennessee Supreme Court: "Is there a duty on the manufacturer of a pharmaceutical drug to cease sales of a product, if that product is 'unreasonably dangerous' under [the] Tennessee Products Liability Act?" The Supreme Court recently rejected this very stop-selling rationale "as incompatible with [its] pre-emption jurisprudence," *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2477 (2013), and the plaintiffs conceded at oral argument that *Bartlett* forecloses reliance on this theory. Accordingly, the plaintiffs' motion has no merit.

E. "Catch 22" dilemma

Although we feel compelled to affirm the judgment below in light of the controlling caselaw, we cannot help but note the basic unfairness of this result. The

plaintiffs' problem is that all of their claims fall within the purview of the TPLA as a "product liability action." *See* Tenn. Code Ann. § 29-28-102(6). This is true despite their most artful efforts to dress up a relatively simple failure-to-warn claim in a great variety of tort and contract causes of action. The plaintiffs are therefore caught in a classic "Catch 22," barred from all claims against the Generic Manufacturers whose drugs they ingested (due to federal preemption) and from all claims against the Brand-Name Manufacturers (due to the TPLA). *See PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2592 (2011) (Sotomayor, J., dissenting) ("If a consumer takes a brand-name drug, she can sue the manufacturer for inadequate warnings . . . . If, however, she takes a generic drug, as occurs 75 percent of the time, she now has no right to sue.").

This unfairness has been acknowledged by the Supreme Court in both *Mensing* (*see supra* p. 10) and *Bartlett* (*see supra* pp. 12-13), but the Court has suggested that any resolution of this dilemma rests with Congress. Relief could also come from the Tennessee General Assembly revising the TPLA to allow claims against brand-name manufacturers whose labels control the warnings that the generic manufacturers are compelled by federal law to duplicate. But unless or until such change comes, we find no basis to afford the plaintiffs any relief.

III. CONCLUSION

For all of the reasons set forth above, and despite the "Catch-22" dilemma, we **AFFIRM** the judgment of the district court and **DENY** the plaintiffs' motion to certify their proposed question to the Tennessee Supreme Court.

CONCURRING IN PART AND DISSENTING IN PART

JANE B. STRANCH, Circuit Judge, concurring in part and dissenting in part. Before this panel comes another of the developing line of pharmaceutical cases in which a grievous harm is found to be without remedy for a large subset of the injured. The universal explanation for finding such a remediless wrong is that existing law drives these cases into the proverbial box canyon of precedent from which there is no hope of escape. I do not agree that case precedent consigns this group of plaintiffs to such an inequitable result. Accordingly, I respectfully concur in part and dissent in part from the majority opinion.

In the cases before us, plaintiffs' physicians prescribed generic metoclopramide for stomach distress. After taking the drug for more than twelve weeks, the plaintiffs developed an irreversible, incurable, life-altering neurological disorder called tardive dyskinesia. This disorder causes involuntary and rhythmic muscle movements, such as chewing, grimacing and frowning, eye blinking, lip puckering, and tongue rolling. *See United States v. Grigsby*, 712 F.3d 964, 966 n.1 (6th Cir. 2013). Evidence indicates that the manufacturers of generic metoclopramide and the brand-name drug Reglan knew that tardive dyskinesia occurs with much greater frequency than they warned about on their product labels. Now that the damage has been done, must the plaintiffs alone bear the burden of the harm they have suffered? The majority opinion says they must bear this

burden alone because the law does not permit plaintiffs to pursue any state-law tort remedies against the generic or brand-name manufacturers.

I cannot agree that recent changes in the law leave plaintiffs such as those before us with absolutely no remedy to redress their harm. While these plaintiffs may not be able to press all of their causes of action against the generic manufacturers, they should be permitted to pursue the failure-to-conform claim against them. As to the brand manufacturers, moreover, there exists a potentially viable path to recovery.

A. Generic drug manufacturers

I address the generic drug manufacturers first because the law concerning them is more settled, at least at the present time. Unfortunately I find myself compelled to join that portion of the majority's decision holding that plaintiffs cannot, under current law, bring design-defect or failure-to-warn claims against generic drug manufacturers because such claims are preempted by the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301–399f. *See Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). In both *Mensing* and *Bartlett* the Supreme Court adopted the position of the Food and Drug Administration (FDA) at that time that a generic drug manufacturer may not use the federal "changes-being-effected" (CBE) regulation to act independently of the brand-name manufacturer to strengthen a warning label so that known risks are adequately disclosed to medical providers and patients. *See Bartlett*, 133 S. Ct. at 2476; *Mensing*, 131 S. Ct. at 2575 (citing U.S. Brief at 15–16; 21 U.S.C. § 355(j)(4)(G); 21 C.F.R. §§ 314.94(a)(8)(iii),

314.150(b)(10)). Although state tort laws place "a duty directly on all drug manufacturers to adequately and safely label their products[,]" the CBE regulation as interpreted by the FDA prevents generic manufacturers from complying with federal law and state law relating to failure-to-warn and design-defect claims at the same time. *Mensing*, 131 S. Ct. at 2577. As a result, state tort law is preempted by federal law, leaving the plaintiffs without state-law tort remedies for these types of claims. *Id.*; *Bartlett*, 133 S. Ct. at 2476–77.

This analysis "strips generic-drug consumers of compensation when they are injured by inadequate warnings" even though "Congress would [not] have intended to pre-empt state law in these cases." *Mensing*, 131 S. Ct. at 2592 (Sotomayor, J., dissenting). Regrettably, *Mensing* and *Bartlett* prevent the plaintiffs from pursuing their failure-to-warn and design-defect claims against the manufacturers of generic metoclopramide, a medication that caused them permanent, debilitating harm. I follow *Mensing* and *Bartlett* because I am bound to apply Supreme Court law. My views on the liability of generic drug manufacturers on failure-to-warn and design-defect claims, however, coincide with those of the well-reasoned dissents in *Mensing*, 131 S. Ct. at 2582–93, and *Bartlett*, 133 S. Ct. at 2480–96.

Mensing and *Bartlett*, moreover, do not seal the doorway to all claims. In *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 584–85 (6th Cir. 2013), this court permitted a failure-to-conform claim to proceed against a generic drug manufacturer of metoclopramide where the plaintiff alleged that the generic manufacturer did not update its label beginning in 2004 to match the label of the brand-name drug, Reglan, and the

plaintiff specifically alleged the time periods during which she ingested the drug. The majority invokes *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007), to reject the failure-to-conform claim alleged against generic manufacturers in this case solely on the basis that the plaintiffs failed to allege facts specifying when they ingested metoclopramide. Because *Fulgenzi* issued in 2013 after the filing of the Amended Complaint in this case in 2011, I would grant the plaintiffs one additional opportunity to amend their complaint to specify more precisely the dates they ingested metoclopramide, thereby drawing the link between their use of the drug during a time period when the generic manufacturers failed to conform their labels to the label of the brand-name drug, Reglan. Accordingly, I dissent from subsection II.B.4. of the majority opinion, but otherwise I concur in sections II.A and II.B.

B. Brand-name drug manufacturers

Turning to the brand-name drug manufacturers, I further part ways with my colleagues. Brand-name drug manufacturers stand in a far different posture than generic drug manufacturers. Plaintiffs injured by brand-name prescription drugs retain state-law tort remedies against the manufacturers of those drugs. *See Wyeth v. Levine*, 555 U.S. 555 (2009). Proper application of federal and Tennessee law does not absolve brand-name drug manufacturers of all responsibility for the plaintiffs' harm simply because the plaintiffs ingested generic metoclopramide and not brand-name Reglan. The plaintiffs' state-law causes of action against the brand-name drug manufacturers are based on the lack of an adequate warning by the entity responsible for providing that warning. For

the reasons explained below, I respectfully dissent from subsection II.C. of the majority opinion.

In *Wyeth*, the plaintiff suffered an arm amputation following an injection of Phenergan, a drug that was administered to curb her nausea from a migraine headache. *Id.* at 558–59. She alleged that Phenergan's warning label was defective because it did not instruct medical clinicians to use the IV-drip method of intravenous administration rather than the higher-risk IV-push method. *Id.* at 560. "More broadly, she alleged that Phenergan is not reasonably safe for intravenous administration because the foreseeable risks of gangrene and loss of limb are great in relation to the drug's therapeutic benefits." *Id.*

Wyeth asserted that Levine's claims were preempted because Wyeth could not possibly comply simultaneously with the duties imposed upon it by state tort laws and federal labeling laws. *Id.* at 568. This argument was comprised of several components.

First, Wyeth contended that the CBE regulation was not implicated in the case because a 2008 amendment allowed a manufacturer to change its label only to reflect newly acquired information. *Id.* Because Levine had not pointed to any new information about the risks of the IV-push method of drug administration, Wyeth asserted that it could not fulfill its state-law duty to provide a stronger warning about that method of drug administration without violating federal law. *Id.* at 568–69. The Supreme Court disagreed, pointing out that Wyeth could have revised the Phenergan label even under the 2008 amendment because "newly acquired information" includes

"new analyses of previously submitted data." *Id.* at 569 (internal quotation marks omitted). "Wyeth could have analyzed the accumulating data" on the frequency of amputations and "added a stronger warning about IV-push administration of the drug." *Id.* at 569–70.

The same is true in this case. The brand manufacturers could have analyzed the accumulating data on the frequency of tardive dyskinesia and added a stronger warning on the Reglan label without waiting for the FDA to approve a supplemental application.

The brand manufacturer also argued in *Wyeth* that, if it had added a stronger warning without first obtaining the FDA's approval, it would have violated federal laws on misbranding and unauthorized distribution of its drug. *Id.* at 570. These arguments were not persuasive to the Court because strengthening the warning would not make Phenergan a "new drug" distributed without FDA authorization nor would such a warning misbrand the drug. *Id.* "[B]ecause the statute contemplates that federal juries will resolve most misbranding claims," the Court explained, "the FDA's belief that a drug is misbranded is not conclusive." *Id.*

The same reasoning applies here. Strengthening the warning label would not make Reglan a new drug distributed without FDA authorization, nor would it misbrand the drug. And because "[f]ederal law does not dictate the text of each generic drug's label, but rather ties those labels to their brand-name counterparts," *Mensing*, 131 S. Ct. at 2578, generic manufacturers have a duty to replicate the strengthened brand-name

label to intensify the warnings on their own labels for metoclopramide. *See Fulgenzi*, 711 F.3d at 584.

The brand-name manufacturer cannot shift the duty to warn to the FDA. The Supreme Court made this clear in *Wyeth* when it stated that it is a "central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." Wyeth, 555 U.S. at 570–71. The manufacturer must produce an adequate drug label initially and then ensure that the warnings on the label remain adequate throughout the time the drug is marketed. *Id.* at 571. Prior to 2007, the FDA did not have authority to order manufacturers to revise their labels, but "[w]hen Congress granted the FDA this authority, it reaffirmed the manufacturer's obligations and referred specifically to the CBE regulation, which both reflects the manufacturer's ultimate responsibility for its label and provides a mechanism for adding safety information to the label prior to FDA approval." *Id.* at 571. The FDA can reject labeling changes made under the CBE regulation, "[b]ut absent clear evidence that the FDA would not have approved a change to Phenergan's label," the Supreme Court declined to "conclude that it was impossible for Wyeth to comply with both federal and state requirements." *Id.*

The same principles apply here. The responsibility to draft a warning label that is accurate at the time the product is issued and remains adequate during the entire time the product is on the market lies solely with the brand-name manufacturer, not the FDA.

Finally, in *Wyeth* the brand-name manufacturer argued that the purposes and objectives of federal drug labeling regulation would be obstructed if Wyeth had to comply with a state-law duty to provide a stronger warning. *Id.* at 573. Once the FDA approves a drug's label, Wyeth posited, a state court jury "may not deem the label inadequate, regardless of whether there is any evidence that the FDA has considered the stronger warning at issue." *Id.* at 573–74. The Supreme Court rejected this contention because it relied on an "untenable interpretation of congressional intent and an overbroad view of an agency's power to pre-empt state law." *Id.* at 573. The "most glaring problem" with the argument, the Supreme Court said, was "that all evidence of Congress' purposes is to the contrary." *Id.* at 574. "Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs" because it evidently "determined that widely available state rights of action provided appropriate relief for injured consumers." *Id.* State-law tort claims remain intact because if "Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history." *Id.* Because Congress has not adopted an express preemption provision for prescription drugs, "[i]ts silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 574–75.

In declining to preempt state-law tort claims against brand-name drug manufacturers, the Supreme Court refused to defer to the FDA's "newfound opinion," first expressed in 2006, that state law frustrates the agency's implementation of the

FDCA. *Id.* at 580. The Court reasoned that a "complex and extensive" regulatory history "undercut the FDA's recent pronouncements of pre-emption, as they reveal the longstanding coexistence of state and federal law and the FDA's traditional recognition of state-law remedies—a recognition in place each time the agency reviewed Wyeth's Phenergan label." *Id.* at 580–81 (internal quotation marks omitted). Likewise, the Court refused to give deference to the *amicus* brief of the United States because "the Government's explanation of federal drug regulation departs markedly from the FDA's understanding at all times relevant to this case." *Id.* at 580 n.13. Unfortunately for the plaintiffs, however, two years later the Supreme Court fully deferred to the FDA's "newfound opinion," as again expressed in an *amicus* brief of the United States, and found the claims against a generic manufacturer subject to federal preemption. *Mensing*, 131 S. Ct. at 2574–76.

The upshot is that *Wyeth*, *Mensing*, and *Bartlett* draw a sharp distinction between brand-name and generic drug manufacturers. Injured plaintiffs can bring state-law tort claims against brand-name manufacturers. *Wyeth*, 555 U.S. at 581. Injured plaintiffs may not bring certain state-law tort claims against generic manufacturers. *Bartlett*, 133 S. Ct. at 2476; *Mensing*, 131 S. Ct. at 2577. "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." *Mensing*, 131 S. Ct. at 2582.

Mensing's acceptance of the FDA's "newfound opinion" created a different landscape in pharmaceutical litigation. Brand-name drug manufacturers now stand in direct relationship with consumers who ingest generic drugs because only the brand-

name manufacturers can control and change labeling to strengthen warnings about drug safety. *Mensing* and *Bartlett* "stripped any discretionary authority from the generic manufacturers to ensure the safety of their products or the adequacy of their labels, instead placing the burden entirely on the brand manufacturers." *Fullington v. Pfizer, Inc.*, 720 F.3d 739, 748 (8th Cir. 2013) (Murphy, J., concurring). The "privileged position accorded to the brand manufacturers may alter their state law relationship to the generic drugs whose composition and labeling they control, since at this point such a manufacturer is the party that actually controls the manufacturing and labeling of the product in question." *Id.* (internal quotation marks omitted).

Concomitantly, it is now reasonably foreseeable to brand-name drug manufacturers that medical providers and consumers rely on brand-name labeling to warn them about risks inherent in the use of brand-name *and* generic medications. *See Fulgenzi*, 711 F.3d at 586–88 (permitting failure-to-conform claim to proceed where plaintiff alleged that generic drug manufacturer failed to update its warning to match brand-name manufacturer's new warning). Any defect or omission in the labeling for the brand-name drug will necessarily be repeated in the labeling for the generic drug, *see id.* at 581–82, causing reasonably foreseeable harm to a patient who ingests only the generic product. *See Wyeth, Inc. v. Weeks*, ___ So.3d ___, 2013 WL 135753, *15 (Ala. Jan. 11, 2013), *argument granted*, (June 13, 2013). Further, because Tennessee and all other states have laws requiring pharmacists to substitute less-expensive generic drugs for higher-priced brand-name drugs to lower health care costs, *see* Tenn. Code Ann. § 53-10-204; *Mensing*, 131 S. Ct. at 2583 (Sotomayor, J., dissenting), it is reasonably

foreseeable to brand-name manufacturers that most prescriptions will be filled with a generic version of the drug prescribed, unless the physician insists that the patient receive the brand-name drug only. *See Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 315 (Cal. Ct. App. 2008).

In Tennessee, "[d]rug manufacturers have a duty to exercise ordinary and reasonable care not to expose the public to an unreasonable risk of harm from the use of their products." *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 428 (Tenn. 1994). Drug manufacturers, "like the manufacturers of any other unavoidably dangerous product, have a duty to market and distribute their products in a way that minimizes the risk or danger. They may discharge their duty by distributing the drugs with proper directions and adequate warnings to those who foreseeably could be injured by the use of their products." *Id.* Drug manufacturers may reasonably rely on "learned intermediaries" such as physicians "to transmit their warnings and instructions" to patients, thereby potentially avoiding liability for failure to warn of known risks. But "physicians can be learned intermediaries only when they have received adequate warnings" from the drug companies. *Id.* at 429.

A reasonable warning "conveys a fair indication of the dangers involved, but also warns with the degree of intensity required by the nature of the risk." *Id.* Whether a drug manufacturer's warning is adequate is a question of fact based on several factors, including whether the warning adequately indicates the scope of the danger and reasonably communicates the extent or seriousness of the harm that could result from misuse of the drug. *Id.* Other pertinent factors are whether the warning alerts a

reasonably prudent person of the danger and the consequences that might result from failure to follow the warning, and whether the means to convey the warning is adequate. *Id.* The adequacy of a drug warning is a question of law only if the warning is accurate and unambiguous. *Id.* at 429–30.

The record evidence suggests that the brand-name drug manufacturers knew that the drug they created—metoclopramide by generic title and Reglan by brand-name—caused tardive dyskinesia to occur far more frequently, especially with long-term use of the drug, than was disclosed in the labeling. Yet they failed to warn physicians or patients about this known incidence rate. Under the changed landscape created by *Mensing* and *Bartlett*, the duty to warn of these dangers of Reglan and generic metoclopramide rests with the brand manufacturers. Tennessee law defines the parameters of that duty to warn. I cannot agree with my colleagues that the duty to warn as assigned by these cases simply ceases to exist because the plaintiffs ingested generic metoclopramide and not brand-name Reglan where the same warning—crafted by the brand-name manufacturer—is required as to both. *See Fulgenzi*, 711 F.3d at 584 (finding no impossibility preemption because the generic manufacturer could—indeed was required to—comply with its federal duty to update its labeling to match the brand-name manufacturer's labeling). The Tennessee Supreme Court has not yet had an opportunity to discuss *Wyeth* and *Mensing* in the context of a state-law claim that a brand-name drug manufacturer failed to warn consumers adequately about the dangers of its drug, a warning that federal law requires the generic manufacturer to replicate. *See Fulgenzi*, 711 F.3d at 584. Therefore, it is too early to speculate, as the majority does,

about whether the Tennessee Supreme Court would limit the liability of brand-name manufacturers to injuries caused by their "products," and not their "warnings."

The majority opinion reaches the conclusion that the brand-name manufacturers can only be held liable if patients ingest brand-name Reglan by relying on our previous opinion in *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011), decided under Kentucky products liability law. *Smith* included claims against the manufacturers of Reglan and the manufacturers of generic metoclopramide. The case was decided very shortly after *Mensing*, which included only a claim against the generic drug manufacturer. *Smith* followed *Mensing* to reject the claim against the maker of the generic drug on federal preemption grounds. *Id.* at 423. *Smith* went further, however, and rejected the claim against the brand-name manufacturer because adopting the plaintiffs' "theory of liability would require the court to attribute any deficiency in a name-brand manufacturer's labeling and marketing of its products to products manufactured by its generic competitors." *Id. Smith* further stated: "The plaintiffs' argument—that the name-brand defendants' liability stems from the fact that the regulatory structure governing name-brand and generic drugs makes it foreseeable that patients and their physicians will rely on the name-brand labels to use and prescribe generic drugs—has been rejected by all but one of the courts that have considered it." *Id.* at 423–24. For this latter proposition, *Smith* cited the "leading case" of *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994), "in which the court held that the manufacturer of a name-brand drug has no duty to patients who ingested only a generic version of the drug manufactured by the name-brand drug company's competitors." *Id.* at 424.

This part of *Foster* rested on the Fourth Circuit's understanding in 1994 that a generic drug manufacturer could use the federal CBE regulation to strengthen its own product labeling, independently of the brand-name manufacturer. *Foster*, 29 F.3d at 169–70. With generic manufacturers in control of warning labels for their own products, courts understandably followed *Foster* to hold that brand-name drug manufacturers could not be held liable for injuries caused by generic medications. Some courts in other jurisdictions have continued to rely on *Foster* to hold that brand-name manufacturers of Reglan cannot be held liable for injury caused by metoclopramide manufactured by their generic competitors. *See e.g.*, *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1284–85 (10th Cir. 2013) (and cases cited therein); *Guarino v. Wyeth*, 719 F.3d 1245, 1252–53 (11th Cir. 2013) (same).

These courts, like our own in *Smith* and the majority here, fail to recognize that *Foster*'s foundation was "severely eroded" by the Supreme Court's recent decisions in *Mensing* and *Bartlett*.[1] *See Fullington*, 720 F.3d at 748 (Murphy, J., concurring). Under *Mensing* and *Bartlett*, a generic manufacturer no longer retains independent control to strengthen its own label to disclose known risks of using the drug. The brand-name manufacturers control the warning labels for their own *and* their generic competitors' products. *See Mensing*, 131 S. Ct. at 2578. "With the brand manufacturers solely responsible for the content and updating of a generic's labels, it can no longer be credibly argued that communications regarding the risks of their product are not also

[1]The majority recasts my argument to be that "the basis for insulating brand-name manufacturers from suit has been 'severely eroded' since this court decided *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011)." That is not correct. My point is that *Foster* was "severely eroded" by *Mensing* and *Bartlett*. *See Fullington*, 720 F.3d at 748 (Murphy, J., concurring).

directed at consumers of the generic bioequivalents." *Fullington*, 720 F.3d at 748 (Murphy, J., concurring).

The majority criticizes my reliance on Judge Murphy's concurrence in *Fullington* because in that case the Eighth Circuit affirmed a summary judgment in favor of brand-name manufacturers, relying on *Bell v. Pfizer, Inc.*, 716 F.3d 1087 (8th Cir. 2013). But *Bell*, too, rested on the disintegrating *Foster* analysis, *see id.* at 1092, and that is precisely the point Judge Murphy made in her *Fullington* concurrence and that I make here. The majority also adheres to *Smith* on the ground that one panel may not overrule the decision of another panel. I have no disagreement with that general proposition. The majority concedes, however, that an inconsistent Supreme Court opinion can require modification of our decision. *See Salmi v. Sec'y of Health & Human Servs.*, 774 F.2d 685, 689 (6th Cir. 1985). Thus so here—*Mensing* precluded the reliance we placed on *Foster* in the *Smith* decision. We should not now repeat the same mistake in our analysis of Tennessee law.

Consumers—who do not have the knowledge required to weigh the benefits of a medication against its risks—rely on the superior expertise of the manufacturer charged with the duty to provide label warnings. Those in need of medicine rightly expect that the manufacturer will disclose a medication's potential to cause them physical harm. Thus, the plaintiffs' state-law causes of action against the brand-name drug manufacturers are predicated on the lack of an adequate warning from the entity charged with providing that warning, not on whether the plaintiffs ingested Reglan or a generic competitor's product. Once this distinction is realized and the flaw in reliance

on *Foster* recognized, section II.C. of the majority's analysis lacks sufficient grounding to deny the plaintiffs the right to proceed on their state-law claims.

For all of these reasons, I would hold that the plaintiffs may pursue their state-law tort claims against the brand-name manufacturers and their *Fulgenzi* claim against the generic manufacturers. Accordingly, I dissent from the majority's conclusions otherwise. I concur with the majority's conclusion that plaintiffs cannot pursue other state-law tort claims against generic drug manufacturers under the law as it presently exists.