IN THE SUPREME COURT OF IOWA

No. 12–0596

Filed July 11, 2014

THERESA HUCK,

Appellant,

vs.

WYETH, INC. d/b/a WYETH; **SCHWARZ PHARMA, INC.;** and **PLIVA, INC.,**

Appellees.

On review from the Iowa Court of Appeals.

Appeal from the Iowa District Court for Sac County, Gary L. McMinimee, Judge.

Plaintiff seeks further review of court of appeals decision affirming summary judgments dismissing her personal injury claims against pharmaceutical companies. **DECISION OF COURT OF APPEALS VACATED; DISTRICT COURT JUDGMENTS AFFIRMED IN PART, REVERSED IN PART, AND REMANDED WITH INSTRUCTIONS.**

Terrence J. Donahue Jr. of McGlynn Glisson & Mouton, Baton Rouge, Louisiana, and James R. Van Dyke of Eich, Van Dyke, Werden & Steger PC, Carroll, for appellant.

Henninger S. Bullock and Andrew J. Calica of Mayer Brown LLP, New York, New York, and Carl J. Summers of Mayer Brown LLP, Washington, DC, for appellee Schwarz Pharma, Inc.

Jeffrey F. Peck, Linda E. Maichl, Joseph P. Thomas of Ulmer & Berne LLP, Cincinnati, Ohio, and Gregory M. Lederer of Lederer Weston Craig PLC, Cedar Rapids, for appellee PLIVA, Inc.

Kevin C. Newsom and Lindsey C. Boney IV of Bradley Arant Boult Cummings LLP, Birmingham, Alabama, for appellee Wyeth, Inc.

Richard J. Sapp and Ryan G. Koopmans of Nyemaster, Goode, West, Hansell & O'Brien, P.C., Des Moines, for appellees Wyeth, Inc. and Schwarz Pharma, Inc.

WATERMAN, Justice.

This products liability action against pharmaceutical companies presents several issues involving the interplay between state tort law and federal prescription drug regulation. This case is one of many litigated in state and federal courts nationwide alleging severe side effects from prolonged use of metoclopramide, sold under the brand name Reglan and as a competing generic formulation. The plaintiff in this case used only the generic product. After developing a neurological disorder, she sued the manufacturer of the generic drug as well as the manufacturers of the branded formulation.

The district court dismissed all of plaintiff's claims in several summary judgment rulings. The district court, relying on *PLIVA, Inc. v. Mensing*, 564 U.S. ___, ___, 131 S. Ct. 2567, 2580–81, 180 L. Ed. 2d 580, 595 (2011), ruled plaintiff's claims against the generic manufacturer were preempted by federal law that requires conformity with the brand manufacturers' warning labels approved by the Food and Drug Administration (FDA). The district court granted summary judgment for the brand manufacturers based on *Mulcahy v. Eli Lilly & Co.*, which requires proof the defendant manufactured or supplied the product that caused plaintiff's injury. 386 N.W.2d 67, 76 (Iowa 1986). The court of appeals affirmed. We granted plaintiff's application for further review.

For the reasons explained below, we hold plaintiff's state common law tort claims against the generic manufacturer based on inadequate warnings are not preempted to the extent that the generic manufacturer failed to implement a stronger warning approved by the FDA in 2004. We decline, however, to alter long-standing Iowa products liability law to allow recovery against a manufacturer for injuries caused by use of its competitor's product. We thereby join the overwhelming majority of

courts, including every federal circuit court of appeals, in holding Reglan brand manufacturers are not liable to plaintiffs who consumed only the competing generic formulation. Accordingly, we vacate the decision of the court of appeals, affirm the district court's summary judgment for the brand manufacturers, reverse in part the summary judgment for the generic manufacturer, and remand for further proceedings against that defendant alone.

I. Background Facts and Proceedings.

We begin with a discussion of federal drug labeling regulation to provide the necessary context for the fighting issues. In 1984, Congress passed the Hatch-Waxman Amendments to the Food, Drug, and Cosmetics Act (FDCA) in order to expand access to affordable generic drugs by reducing barriers to generic market entry. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in relevant part at 21 U.S.C. § 355 (1988)); *see also Mensing*, 564 U.S. at ___, 131 S. Ct. at 2574, 180 L. Ed. 2d at 588. Prior federal law compelled virtually all companies to file a new drug application—requiring costly clinical trials—to receive FDA approval to market a drug. *Mensing*, 564 U.S. at ___, 131 S. Ct. at 2574, 180 L. Ed. 2d at 588. Hatch-Waxman eliminated this requirement for a generic drug applicant, instead requiring the applicant to demonstrate its product's chemical and biological equivalence to a previously approved drug—i.e., a brand manufacturer's drug. *See id.* at ___, 131 S. Ct. at 2574, 180 L. Ed. 2d at 588; *see also* 21 U.S.C. § 355(j)(2)(A) (2006).

When a brand manufacturer first files a new drug application, the FDA must approve the accuracy and adequacy of a drug's label. *See* 21 U.S.C. § 355(a), (b)(1), (d); *Wyeth v. Levine*, 555 U.S. 555, 566–67, 129 S. Ct. 1187, 1195, 173 L. Ed. 2d 51, 61 (2009). After the initial approval

of the new drug application, a brand manufacturer may update its label by filing an application with the FDA to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," but it need not wait for FDA approval. 21 C.F.R. § 314.70(c)(6)(iii)(A), (C) (2006); *see also Levine*, 555 U.S. at 567–68, 129 S. Ct. at 1196, 173 L. Ed. 2d at 62. The equivalence of brand-name and generic drugs is the foundation of the generic drug approval process, and accordingly, federal regulations "require that the warning labels of a brand-name drug and its generic copy must always be the same—thus, generic drug manufacturers have an ongoing federal duty of 'sameness.' " *Mensing*, 564 U.S. at ___, 131 S. Ct. at 2574–75, 180 L. Ed. 2d at 589; *see also, e.g.*, 21 U.S.C. § 355(j)(2)(A)(v), (4)(G); 21 C.F.R. §§ 314.94(a)(8), .127(a)(7); Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17950–01, 17961 (Apr. 28, 1992) ("[T]he [generic drug's] labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for [generic drug] approval."). The requirement that generic labeling mirrors that of the brand drug ensures generic manufacturers do not mislead consumers by "inaccurately imply[ing] a therapeutic difference between the brand and generic drugs." *Mensing*, 564 U.S. at ___, 131 S. Ct. at 2576, 180 L. Ed. 2d at 590. Manufacturers—both brand and generic—are required to propose stronger warning labels to the FDA if they believe such warnings are needed. *Id.* at ___, 131 S. Ct. at 2576, 180 L. Ed. 2d at 591.

The United States Supreme Court decisions of *Levine* and *Mensing* set parameters for when state-law failure-to-warn claims are preempted by federal prescription drug labeling regulations. First, *Levine* held that

federal drug regulations do not preempt state-law failure-to-warn claims against brand manufacturers because federal law allows brand manufacturers to unilaterally strengthen their warnings. 555 U.S. at 573, 129 S. Ct. at 1199, 173 L. Ed. 2d at 65 (concluding requiring brand drug manufacturers to comply with a state-law duty to warn would not obstruct the purposes and objectives of federal drug labeling regulation). "The Court did not find it significant that the FDA has authority to reject unilateral labeling changes . . . finding it 'difficult to accept' that the FDA would not have permitted a change to a stronger warning." *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 582 (6th Cir. 2013) (quoting *Levine*, 555 U.S. at 570, 129 S. Ct. at 1197, 173 L. Ed. 2d at 63). After *Levine*, some courts reasoned that generic drug manufacturers would then also be subject to state-law failure-to-warn claims. *See*, *e.g.*, *Demahy v. Actavis, Inc.*, 593 F.3d 428, 430 (5th Cir. 2010) ("[*Levine*] shadows our conclusion that the federal regulatory regime governing generics is also without preemptive effect."), *rev'd sub nom. Mensing*, 564 U.S. at ___, 131 S. Ct. at 2573, 180 L. Ed. 2d at 587); *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 607 (8th Cir. 2009) ("After [*Levine*], we must view with a questioning mind the generic defendants' argument that Congress silently intended to grant the manufacturers of most prescription drugs blanket immunity from state tort liability when they market inadequately labeled products."), *rev'd sub nom. Mensing*, 564 U.S. at ___, 131 S. Ct. at 2573, 180 L. Ed. 2d at 587.

But, the Supreme Court held otherwise in *Mensing*, a case involving generic manufacturers of metoclopramide. 564 U.S. at ___, 131 S. Ct. at 2572, 180 L. Ed. 2d at 586. The five-justice majority noted the FDA interprets its regulations "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 ___, 131 S. Ct. at 2575, 180 L. Ed. 2d at 590 (emphasis added). Otherwise, a generic manufacturer is obligated to copy the brand manufacturer's approved label. *See id.* at ___, 131 S. Ct. at 2575, 180 L. Ed. 2d at 590. Accordingly, the Court agreed with the FDA's interpretation of its regulations that "changes *unilaterally* made to strengthen a generic drug's warning label would violate the statutes and regulations requiring a generic drug's label to match its brand-name counterpart's." *Id.* at ___, ___, 131 S. Ct. at 2575, 2580, 180 L. Ed. 2d at 590, 595 (emphasis added) (highlighting that "[b]efore the Manufacturers could satisfy state law, the FDA—a federal agency—had to undertake special effort permitting them to do so"). Due to this conflict, the Court held federal law categorically preempts state-law failure-to-warn claims against generic manufacturers. *Id.* at ___, 131 S. Ct. at 2580–81, 180 L. Ed. 2d at 595. "The Court distinguished the situation in [*Levine*], which it characterized as holding that 'the possibility of *impossibility*' (i.e., possible FDA subsequent denial) was not enough for impossibility preemption from the case at hand, which concerned 'the possibility of *possibility*' (i.e., possible FDA prior approval)." *Fulgenzi*, 711 F.3d at 583 (quoting *Mensing*, 564 U.S. at ___ n.8, 131 S. Ct. at 2581 n.8, 180 L. Ed. 2d at 596 n.8). The *Mensing* Court acknowledged "the unfortunate hand that federal drug regulation has dealt" those whose pharmacies filled their prescriptions with generic metoclopramide instead of Reglan. *Mensing*, 564 U.S. at ___, 131 S. Ct. at 2581, 180 L. Ed. 2d at 596.

In response to *Mensing*, the FDA proposed a rule to amend generic labeling regulations. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67985–02 (proposed Nov. 13, 2013) [hereinafter Proposed Rule] (setting

deadline of January 13, 2014, for comments). The proposed rule "would create parity" between brand and generic manufacturers, granting both the ability to unilaterally improve labeling and then seek approval from the FDA. *Id.* at 67986.

Against this backdrop, we now turn to the facts of this case. In 1980, the FDA approved the new drug application for metoclopramide tablets, which are designed to treat digestive tract problems, including gastroesophageal reflux disease (acid reflux). This FDA approval allowed for the manufacture and distribution of a patented formulation of the drug, which was branded Reglan. Wyeth, Inc. came to own the Reglan brand in approximately 1989[1] and later sold the rights and liabilities associated with Reglan to Schwarz Pharma, Inc. in December 2001.[2] In addition to the Reglan tablets marketed by Wyeth and Schwarz [hereinafter referred to collectively as the brand defendants], a generic formulation of the drug was manufactured and distributed by PLIVA, Inc.

In February 2004, Theresa Huck's physician prescribed Reglan to treat her reflux. Her physician relied upon information published by the brand defendants in the Physician's Desk Reference, which contained the FDA-approved labeling for the drug. Huck's pharmacy filled this prescription with the PLIVA generic.

The FDA-approved labeling at the time Huck began taking metoclopramide stated "Therapy longer than 12 weeks has not been evaluated and cannot be recommended." The label also contained a warning about possible side effects, including tardive dyskinesia.

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[1]A.H. Robinson Company, Inc. obtained the original FDA approval for Reglan. Wyeth is the successor in interest to A.H. Robinson.

[2]Schwarz then manufactured and distributed Reglan until February 2008, when the brand was again sold.

Tardive dyskinesia is a severe, often irreversible neurological disorder resulting in involuntary and uncontrollable repetitive body movements of slow or belated onset. Symptoms include "grotesque facial grimacing and open-mouthed, uncontrollable tongue movements, tongue thrusting, [and] tongue chewing." *Fisher v. Pelstring*, 817 F. Supp. 2d 791, 802 (D.S.C. 2011). There is no known treatment or cure for tardive dyskinesia. The FDA-approved warning stated that tardive dyskinesia was expected to occur in one in every five hundred patients.

In July 2004, approximately five months after Huck began taking metoclopramide, the FDA approved additional label warning language requested by Schwarz. Printed in bold on the first line of both the "Indications and Usage" and "Dosage and Administration" sections of the label, the new language indicated, "**Therapy should not exceed 12 weeks in duration**." While this language appeared on the label for Reglan, it was not published in the Physicians' Desk Reference. Although required by federal regulations to mirror the brand defendant's label, PLIVA did not update its metoclopramide packaging to include the new warning approved in 2004. The record is silent as to why PLIVA failed to add that warning. Neither the brand defendants nor PLIVA communicated the new label information to Huck or her physician. Huck testified she never would have taken metoclopramide had she been warned its possible side effects included a neurological disorder.

Taking an average of 2.7 pills per day, Huck continued to refill her PLIVA generic prescription until March 2006. Though Huck had been experiencing symptoms of tardive dyskinesia for some time, she was not diagnosed with the disease until June 6, 2006.

Based on growing evidence that prolonged use of metoclopramide causes tardive dyskinesia, on February 26, 2009, the FDA imposed

heightened warnings for the drug's packaging. The FDA required the following black-box warning—its strongest—for metoclopramide:

> Chronic treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. The risk of developing tardive dyskinesia increases with the duration of treatment and the total cumulative dose. * * *
>
> There is no known treatment for tardive dyskinesia; however, in some patients symptoms may lessen or resolve after metoclopramide treatment is stopped. * * *
>
> Prolonged treatment (greater than 12 weeks) with metoclopramide should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risks to the patient of developing tardive dyskinesia.

On May 27, 2008, Huck filed suit against the brand defendants, PLIVA, and several other defendants no longer involved in the case.[3] Her petition did not distinguish between the brand defendants and PLIVA, instead referring to them collectively as "manufacturing defendants." In total, Huck pled thirteen claims against these manufacturing defendants: (1) strict products liability, (2) strict liability for a manufacturing defect, (3) strict liability for a design defect, (4) breach of express warranty, (5) breach of implied warranties (based on inadequate warnings), (6) negligence (based on inadequate warnings), (7) negligent misrepresentation, (8) breach of undertaking a special duty, (9) fraud and misrepresentation, (10) constructive fraud, (11) fraud by concealment, (12) violation of the Iowa Unfair Trade Practices Act, and (13) intentional infliction of emotional distress.

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[3]Huck's petition also named as defendants two of her physicians, Trimark Physicians Group, and Barr Laboratories (PLIVA's parent company). The district court granted summary judgment in favor of Barr Laboratories after Huck failed to serve the company with original notice. Huck's physicians and Trimark Physicians Group were later granted summary judgment based on Huck's failure to timely file expert designations. Huck did not appeal the summary judgments for those parties.

Huck filed a "Notice of Product Identification" on October 6 admitting she ingested only generic metoclopramide manufactured by PLIVA. In response, the brand defendants moved for summary judgment. Huck filed no resistance. On March 2, 2009, the district court granted the brand defendants' unresisted motion for summary judgment on all claims. The district court noted it was undisputed that the brand defendants "did not manufacture or sell the generic metoclopramide ingested by [Huck]" and, citing *Mulcahy*, concluded Huck's claims against the brand defendants therefore failed as a matter of law. Huck did not file a motion for reconsideration or immediately appeal the ruling.

For the next two and one-half years, Huck pursued her claims against PLIVA, the only remaining defendant. On February 26, 2010, PLIVA filed two motions for summary judgment, one arguing no genuine issues of material fact existed and the other arguing Huck's claims were preempted by federal law. On April 12, the district court ruled on PLIVA's motions. First, the district court rejected PLIVA's preemption argument. The district court also ruled that a factual dispute existed relating to whether Huck would not have ingested metoclopramide had she received (or, if the learned intermediary doctrine is applied, her physician received[4]) an adequate warning. The district court then dismissed several of Huck's claims,[5] but her common law claims for

[4]The learned intermediary doctrine is not at issue in this appeal.

[5]The district court dismissed the following claims: strict liability for failure to warn, strict liability for design defect, design defect, strict liability for manufacturing defect, breach of express warranty, breach of implied warranty (excluding breach of implied warranty of merchantability), fraud (to the extent they are not based on nondisclosure), breach of undertaking a special duty, the Unfair Trade Practice Act, intentional infliction of emotional distress. Huck does not appeal the dismissal of those claims.

breach of the implied warranty of merchantability, negligence (based on failure to warn), negligent misrepresentation, fraud and misrepresentation, constructive fraud, and fraud by concealment were allowed to proceed. Trial was set for February 7, 2011.

On December 14, 2010, PLIVA moved to stay all deadlines and continue the trial based on the United States Supreme Court's grant of certiorari in *Mensing*, which consolidated two lawsuits involving state tort-law claims against generic metoclopramide manufacturers. 564 U.S. ___, 131 S. Ct. 2572–73, 180 L. Ed. 2d 586–87. The district court granted the stay, acknowledging that two of the cases it had relied on in its denial of PLIVA's preemption motion were at issue in the *Mensing* appeal. *See id.* at ___, 131 S. Ct. at 2573, 180 L. Ed. 2d at 587.

After *Mensing* held federal preemption precluded plaintiffs' failure-to-warn claims, *see id.* at ___, 131 S. Ct. at 2580–81, 180 L. Ed. 2d at 595, PLIVA again moved to dismiss Huck's claims based on federal preemption. Additionally, on September 26, 2011, Huck filed a "Motion for Relief" from the 2009 summary judgment dismissing the brand defendants. Huck invoked the district court's "inherent power to correct interlocutory errors" and argued *Mensing*'s holding that generic manufacturers do not have the ability to unilaterally strengthen drug labels necessarily shifted responsibility for generic manufacturers' insufficient labeling to brand manufacturers, who *are* able to unilaterally strengthen labels. Asserting the *Mensing* decision overturned prior precedent, Huck asked the court to reinstate her claims against the brand defendants.

On January 9, 2012, the district court ruled on the pending motions. Regarding Huck's motion for relief, the district court highlighted that it granted the brand defendants' summary judgment

"based upon the rule in Iowa 'that a Plaintiff in a products liability action bears the burden of proving the Defendant manufactured or supplied the product that caused the injury.' *Mulcahy v. Eli Lilly & Co.*, 386 N.W.2d 67, 69 (Iowa 1986)." The court further concluded Huck's argument based on *Mensing* was meritless and denied the motion for relief as to the brand defendants. The district court granted PLIVA summary judgment on grounds of federal conflict preemption.

Huck appealed both the district court's grant of summary judgment in favor of PLIVA and its denial of her motion for relief against the brand defendants. We transferred the case to the court of appeals, which affirmed the district court's rulings. The court of appeals held Huck's claims against PLIVA "attack the adequacy of the labeling" and therefore are preempted because they "fall[] within *Mensing*'s sphere." The court of appeals specifically rejected Huck's argument that PLIVA can be held liable for failing to update its label to provide the additional bolded warning approved in 2004, reasoning federal law prohibits private attempts to enforce a generic manufacturer's obligation to match the brand manufacturer's label. As to the brand defendants, the court of appeals noted Huck failed to resist their motion for summary judgment, file a postjudgment motion, or immediately appeal the summary judgment. Consequently, the court of appeals concluded the only preserved issue relating to that summary judgment ruling is the issue explicitly decided by the district court: whether the brand defendants owed Huck a duty under Iowa law when she did not ingest a product manufactured or sold by them. The court of appeals held *Mensing* did not alter state-law principles requiring the dismissal of a claim brought against a defendant whose product plaintiff never used.

We granted Huck's application for further review.

II. Standard of Review.

We review rulings that grant summary judgment for correction of errors at law. *Parish v. Jumpking, Inc.*, 719 N.W.2d 540, 542 (Iowa 2006). Summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Iowa R. Civ. P. 1.981(3). "A fact is material if it will affect the outcome of the suit, given the applicable law." *Parish*, 719 N.W.2d at 543. "An issue of fact is 'genuine' if the evidence is such that a reasonable finder of fact could return a verdict or decision for the nonmoving party." *Id.* We view the evidence in the light most favorable to the nonmoving party. *Id.* Summary judgment is properly granted when the moving party shows "the nonmoving party has no evidence to support a determinative element of that party's claim." *Id.*

We may review the issues actually decided in a ruling granting an unresisted motion for summary judgment when the nonmoving party filed a postjudgment motion that gave the district court the opportunity to correct the alleged error. *See Cooksey v. Cargill Meat Solutions Corp.*, 831 N.W.2d 94, 98–99 (Iowa 2013); *id.* at 107 (Mansfield, J. dissenting); *Otterberg v. Farm Bureau Mut. Ins. Co.,* 696 N.W.2d 24, 28 (Iowa 2005) (noting the party moving for summary judgment has the burden "to show the district court that there was no genuine issue of material fact and that it was entitled to a judgment as a matter of law"); *Bill Grunder's Sons Constr., Inc. v. Ganzer,* 686 N.W.2d 193, 197–98 (Iowa 2004) ("[T]he nonmovant must at least preserve error by filing a motion following entry of [the unresisted summary] judgment, allowing the district court to consider the claim of deficiency.").

III. Analysis.

A. Whether Any of Huck's Claims Against PLIVA Survive *Mensing*. We must decide whether the district court correctly ruled that all of Huck's claims against PLIVA are preempted by *Mensing*. Applying *Mensing*, the district court ruled Huck's claims against PLIVA are preempted because it was impossible for PLIVA to alter its label. The court of appeals agreed. Huck argues *Mensing* preempts only claims that require the generic manufacturer to vary its labeling from that of the branded drug. She points out that PLIVA failed to update its label in 2004 to include the FDA-approved warning stating, "**Therapy should not exceed 12 weeks in duration.**" *Mensing* did not decide whether that claim is preempted. The Court of Appeals for the Sixth Circuit in *Fulgenzi,* however, recently adjudicated this very issue and squarely held *Mensing* does not preempt claims based on the generic manufacturer's failure to update its label warning with the language the FDA approved in 2004. *Fulgenzi*, 711 F.3d at 584. As the Sixth Circuit observed, "not only could PLIVA have independently updated its labeling to match [the warning added in 2004], it had a federal duty to do so." *Id.* (citation omitted). We find *Fulgenzi* persuasive and hold Huck's claims survive preemption to the extent they are based on PLIVA's failure to adopt the additional warning language approved by the FDA in 2004.

The federal preemption doctrine derives from the Supremacy Clause of the Federal Constitution. *See Ackerman v. Am. Cyanamid Co.*, 586 N.W.2d 208, 211 (Iowa 1998). Under the doctrine of conflict preemption, "[when] state and federal law directly conflict, state law must give way." *Mensing*, 564 U.S. at ___, 131 S. Ct. at 2577, 180 L. Ed. 2d at 592 (internal quotation marks omitted). But, "[t]here is a presumption against preemption which counsels a narrow construction of preemption

provisions." *Ackerman*, 586 N.W.2d at 213. We must evaluate each of Huck's surviving claims[6]—breach of the implied warranty of merchantability, negligence (based on failure to warn), negligent misrepresentation, fraud and misrepresentation, constructive fraud, and fraud by concealment—"to determine if it is impossible for PLIVA to comply with both the state-law duties underlying those claims and its federal labeling duties" or if state law "would obstruct the purposes and objectives of federal drug labeling regulation." *See Levine*, 555 U.S. at 568, 573, 129 S. Ct. at 1196, 1199, 173 L. Ed. 2d at 62, 65.

We will first evaluate her claims to determine if they make it impossible for PLIVA to comply with both state and federal law. Next, we will decide if her claims pose an obstacle to the purposes and objectives of Congress. Finally, we will consider PLIVA's argument that Huck's claims violate a federal law prohibiting private enforcement of the FDCA.[7]

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[6]PLIVA argues Huck preserved error only as to her failure-to-warn and breach-of-implied-warranty claims. When PLIVA moved for summary judgment in the wake of *Mensing*, Huck resisted this motion and argued her claims were still viable. On January 5, 2012, the district court dismissed all of Huck's remaining claims as preempted by *Mensing*. In her motion for reconsideration, Huck mentioned only her failure-to-warn claims and breach-of-implied-warranty claims. Nevertheless, we consider error preserved as to the additional claims because Huck resisted summary judgment and argues those claims on appeal.

[7]PLIVA argues that Huck cannot base her failure-to-warn claim on the 2004 label update because she has asserted the label was inadequate even *with* the additional language. The court of appeals agreed, concluding, "Iowa law does not provide a cause of action for failing to disseminate allegedly inadequate warnings." This mischaracterizes the issue. This argument—that "there is no such thing as a 'failure to *inadequately* warn' "—was rejected by the Sixth Circuit. *Fulgenzi*, 711 F.3d at 587–88. As that court observed:

> It may well be more difficult to prove proximate causation in a case where the warning that the defendant failed to provide was also legally inadequate. But there is no reason to believe that a severely inadequate warning would never cause an injury that a moderately inadequate warning would have prevented. A plaintiff need not prove that the alternative warning would have been objectively reasonable, only that it would most likely have prevented the injury in this case.

1. *Impossibility preemption*. We first consider Huck's negligence claim based on PLIVA's failure to warn. Huck concedes her failure-to-warn claim is preempted to the extent it required PLIVA to adopt a label different than that of the approved brand label, but argues she can base her common law negligence claim on PLIVA's failure to adopt the language approved in the 2004 warning against use of metoclopramide for longer than twelve weeks. We agree.

The facts of this case present a narrow path around *Mensing* preemption. Once the additional warning language was approved by the FDA in July 2004, PLIVA needed only to go through the "changes being effected" process to revise its label to match the updated brand-name

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> . . . [I]t is sufficiently plausible that the use of a neutral warning disavowing approval instead of a bold-faced warning affirmatively discouraging long-term use proximately caused [plaintiff's] injury. Whether in fact these allegations are true is a matter for further proceedings.

Id. We agree with the *Fulgenzi* court's reasoning.

The court of appeals also stated, "Huck has not argued these [2004 updated] warnings—providing what she argued is faulty information—would have prevented the harm she suffered." We do not find Huck has conceded that issue. To the contrary, Huck successfully resisted PLIVA's motion for summary judgment, in which PLIVA argued Huck was unable to prove that if she or her physician "had received an adequate warning, she would not have ingested the drug." The district court denied PLIVA's motion, finding that based on the record provided fact issues precluded summary judgment. *Cf. Clinkscales v. Nelson Sec., Inc.*, 697 N.W.2d 836, 841 (Iowa 2005) ("[W]e reiterate the well-settled maxim that questions of negligence or proximate cause are ordinarily for the jury—only in exceptional cases should they be decided as a matter of law."); *Lovick v. Wil-Rich*, 588 N.W.2d 688, 700 (Iowa 1999) (affirming denial of directed verdict on failure-to-warn claim; noting "proximate cause can be established by showing a warning would have altered the plaintiff's conduct so as to avoid injury"); *see also* Restatement (Third) of Torts: Prods. Liab. § 2 cmt. *i*, illus. 11, at 31 (1998) ("Whether the warning actually given was reasonable in the circumstances is to be decided by the trier of fact."); *cf. In re Prempro Prods. Liab. Litig.*, 586 F.3d 547, 569 (8th Cir. 2009) (" '[[T]]he vast majority of jurisdictions hold that where a warning is inadequate, the plaintiff is entitled to a rebuttable presumption that an adequate warning would have been heeded if one had been given.' " (quoting *Thom v. Bristol–Myers Squibb Co.*, 353 F.3d 848, 855 (10th Cir. 2003)). We decide today only the preemption issue as to Huck's claims against PLIVA and leave for further proceedings issues concerning the adequacy of PLIVA's warnings and whether an updated warning in 2004 would have reached Huck or her physicians and altered her behavior.

label. *See Mensing*, 564 U.S. at ___, 131 S. Ct. at 2575, 180 L. Ed. 2d at 589–90 (citing the FDA's interpretation of 21 C.F.R. § 314.94(a)(8)(iv))). This process allows manufacturers to update their label without waiting for FDA approval. *Id.* at ___, 131 S. Ct. at 2575, 180 L. Ed. 2d at 589. Though the FDA could have rejected PLIVA's request after the fact, such a rejection would have been unlikely. *Cf. Levine*, 555 U.S. at 571, 129 S. Ct. at 1198, 173 L. Ed. 2d at 64 ("[A]bsent clear evidence that the FDA would not have approved a change to [defendant's] label, we will not conclude that it was impossible for [defendant] to comply with both federal and state requirements."). Accordingly, it was not impossible for PLIVA to update its label and send informational letters consistent with the updated language, warning health care professionals and consumers that metoclopramide therapy should not exceed twelve weeks. To the contrary, PLIVA had a federal duty to match its label to Wyeth's. *See* 21 U.S.C. § 331(a) (prohibiting the introduction into interstate commerce any drug that is misbranded); 21 C.F.R. §§ 314.94(a)(8)(iii) (requiring generic applicant to match label of brand drug); 21 C.F.R. § 314.150(b)(10) (providing FDA may withdraw drug approval if the generic's label "is no longer consistent with that for [the brand-name]"); *see also Fulgenzi*, 711 F.3d at 584 ("[C]ompliance with federal and state duties was not just possible; it was required."). We therefore conclude Huck's state-law negligent failure-to-warn claim is not preempted by federal labeling regulations to the extent it is based on PLIVA's failure to adopt the additional warning language approved in 2004. A growing number of courts have reached the same conclusion.[8]

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[8]These courts include: *Neeley v. Wolters Kluwer Health, Inc.*, No. 4:11-CV-325 JAR, 2013 WL 3929059, at *9 (E.D. Mo. July 29, 2013); *Phelps v. Wyeth, Inc.*, 938 F. Supp. 2d 1055, 1061 (D. Or. 2013); *Johnson v. Teva Pharm. USA, Inc.*, No. 2: 10 CV 404, 2012 WL 1866839, at *3 (W.D. La. May 21, 2012); *Cooper v. Wyeth, Inc.*, No. 09–

Moving to Huck's remaining claims, we note at the outset that "there is no general, inherent conflict between federal pre-emption [sic] of state warning requirements and the continued vitality of state common-law damages actions." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 518, 112 S. Ct. 2608, 2618, 120 L. Ed. 2d 407, 424 (1992). "Of course any direct challenge to the adequacy of a label or warning is preempted." *Ackerman,* 586 N.W.2d at 213. But, "[w]e also examine whether a claim is merely another way of alleging the label or warning was inadequate. Such an indirect challenge is also preempted." *Id.* If Huck's claims against PLIVA do not require the company to change its labeling to differ from that of the approved label, they are not preempted. *See id.* ("[O]ur task remains to identify whether [plaintiff's] claims are predicated upon labeling and packaging requirements in addition to and different from those required by [federal law].").

Huck argues her claims for negligent testing and postmarket surveillance thus are not preempted. But, "merely to call something a design or testing claim does not automatically avoid [the] preemption clause." *Id.* at 214. The line between a claim for mislabeling and a claim for negligent testing is "razor thin." *See id.*

929–JJB, 2012 WL 733846, at *4 (M.D. La. Mar. 6, 2012); *Lyman v. Pfizer, Inc.*, No. 2:09-cv-262, 2012 WL 368675, at *5–6 (D. Vt. Feb. 3, 2012); *Couick v. Wyeth, Inc.*, No. 3:09–cv–210–RJC–DSC, 2012 WL 79670, at *5 (W.D.N.C. Jan. 11, 2012); *Del Valle v. PLIVA, Inc.*, No. B:11–113, 2011 WL 7168620, at *5 (S.D. Tex. Dec. 21, 2011); *Fisher*, 817 F. Supp. 2d at 805; *In re Reglan Litig.*, No. 289, 2012 WL 1613329 (N.J. Super. Ct. Law Div. May 4, 2012); *Hassett v. Dafoe*, 74 A.3d 202, 216 (Pa. Super. Ct. 2013); *see also Teva Pharm. USA, Inc. v. Super. Ct.*, 158 Cal. Rptr. 3d 150, 158 (Ct. App. 2013) (relying on *Fulgenzi* to hold failure-to-warn claim not preempted when generic manufacturers of alendronate sodium did not mirror the branded Fosamax label). In contrast, the Court of Appeals for the Fourth Circuit recently affirmed a summary judgment dismissing all claims against PLIVA based on *Mensing*'s impossibility or conflict preemption, while expressly noting the 2004 update theory was not timely made in that case. *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 474–76 (4th Cir. 2014).

> [T]he rule is that a claim based on negligent or inadequate testing will not be considered a disguised label-based challenge if adequate testing would have caused the manufacturer to alter the product itself. Conversely, the rule is that if defendant could remedy any problems with its product, that it learned about through adequate testing, by altering the product's label rather than by changing the product, then any challenge concerning negligent testing is preempted.

Wright v. Am. Cyanamid Co., 599 N.W.2d 668, 673 (Iowa 1999).

Federal drug regulation adds a wrinkle to the application of this rule: generic manufacturers are prohibited from altering the composition of a drug because they must mirror the formulation of the brand-manufacturer drug. *See, e.g.*, 21 U.S.C. § 355(j)(2)(A) (requiring bioequivalence); *id.* § 355(j)(2)(A)(ii), (iii) (requiring generic drug to have the same "active ingredients," "route of administration," "dosage form," and "strength" as its brand-name counterpart); *id.* § 355(j)(8)(B) (requiring the same "rate and extent of absorption"). Moreover, both generic and brand manufacturers are prohibited from making major changes to the "qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application" after their drug is approved. 21 C.F.R. § 314.70(b)(2)(i).

In light of these regulations, the only way for PLIVA to avoid liability for negligent testing would be to withdraw from the market. This issue is addressed by *Mutual Pharmacy Co. v. Bartlett*, 570 U.S. ___, ___ 133 S. Ct. 2466, 2477, 186 L. Ed. 2d 607, 622–23 (2013). In *Bartlett*, the Supreme Court rejected the "stop selling" argument because "if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption [sic] would be 'all but meaningless.' " *Id.* at ___, 133 S. Ct. at 2477–78, 186 L. Ed. 2d at 622 (quoting *Mensing*, 564 U.S. at ___, 131 S. Ct., at 2579, 180 L. Ed. 2d at 594) (noting "[j]ust as the prospect that

a regulated actor could avoid liability under both state and federal law by simply leaving the market did not undermine the impossibility analysis in [*Mensing*], so it is irrelevant to our analysis here"). But, as with her failure-to-warn claim, we conclude Huck's negligent-testing and postmarket-surveillance claims avoid preemption to the extent the claims are based on PLIVA's failure to adopt the 2004 label change. *Cf. Wright*, 599 N.W.2d at 675 (concluding negligent testing claim was "a disguised label-based claim" preempted by federal law).

Huck next argues her claim of breach of the implied warranty of merchantability based on warning defects escapes *Mensing* preemption because (1) metoclopramide was unfit "for the ordinary purposes for which such goods are used"—namely, for prolonged therapy; (2) PLIVA did not include the revised 2004 label limiting the duration of use to twelve weeks; and (3) metoclopramide did not conform to the statements of fact that appear on its label. *See* Iowa Code § 554.2314(*c*), (*e*), (*f*) (2005). Once more, we agree this claim may proceed if she is able to ground it on PLIVA's failure to adopt the 2004 additional approved warning. *See Fisher*, 817 F. Supp. 2d at 821 (denying PLIVA's motion for summary judgment on implied warranty of merchantability because "the Court does not find as a matter of law that long-term use was not an ordinary purpose for which metoclopramide was used"); *see also Wright v. Brooke Grp. Ltd.*, 652 N.W.2d 159, 182 (Iowa 2002) (citing the Restatement (Third) of Torts: Prods. Liab. § 2(b)–(c), at 14 (1998) as authority to allow breach of the implied warranty of merchantability claim based on inadequate warnings); *cf. Ackerman*, 586 N.W.2d at 213–14 (dismissing claim of breach of implied warranty of merchantability based on federal preemption).

Finally, Huck appeals the dismissal of her claims alleging fraud, misrepresentation, constructive fraud, and fraud by concealment. Our common law recognizes fraud claims by a consumer against a product manufacturer who "made misleading statements of fact intended to influence consumers" or "made true statements of fact designed to influence consumers and subsequently acquire[d] information rendering the prior statements untrue or misleading." *Brooke Grp. Ltd.*, 652 N.W.2d at 177 & n.4 (declining to decide whether such claims were preempted). We conclude her fraud and misrepresentation claims escape preemption to the extent they are based on the additional 2004 warning language PLIVA failed to adopt.

2. *Purposes and objectives analysis*. Next, we must consider whether state tort suits against generic manufacturers would frustrate the purposes and objectives of Congress, thus warranting preemption.[9] In *Levine*, the Court held suits against Reglan manufacturers would not obstruct the purposes and objectives of federal drug labeling regulation. *Levine*, 555 U.S. at 573, 129 S. Ct. at 1199, 173 L. Ed. 2d at 65. We reach the same conclusion with respect to Huck's claims against PLIVA.

Levine recognized that Congress has not provided a federal remedy for consumers harmed by prescription drugs and, as such, "state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Id.* at 574, 579, 129 S. Ct. at 1200, 1202, 173 L. Ed. 2d at 66, 69 (noting additionally that, "[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have

[9]Because defendants in *Mensing* argued only that it was impossible for a generic manufacturer to unilaterally strengthen its label without running afoul of federal law, the *Mensing* opinion did not consider the purposes and objectives prong of the conflict preemption analysis. 564 U.S. at ___, 131 S. Ct. at 2587, 180 L. Ed. 2d at 602–03 (Sotomayor, J., dissenting).

enacted an express pre-emption [sic] provision at some point during the FDCA's 70–year history"); *see also Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 451, 125 S. Ct. 1788, 1802, 161 L. Ed. 2d 687, 707 (2005) ("Private remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of [federal law]."). The *Levine* Court's reasoning on this issue applies to state tort claims against both generic and brand manufacturers:

> State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times.

555 U.S. at 579, 129 S. Ct. at 1202, 173 L. Ed. 2d at 68–69.

The Sixth Circuit's decision in *Fulgenzi* reinforces our conclusion that Huck's claims against PLIVA do not frustrate congressional goals. In *Fulgenzi*, the court considered the differences between brand and generic manufacturers, singling out the "promotion of generic drugs, and the attendant reduction in costs" as "[t]he most easily identifiable policy" of the FDCA. 711 F.3d at 585. "Permitting state tort actions to go forward against generic-drug manufacturers [as opposed to brand manufacturers], the argument goes, would increase costs and reduce usage." *Id.* Yet, the *Fulgenzi* court held this hypothetical difference does not justify preemption. *Id.* Citing the *Mensing* dissenters' observation that "the inability to sue for inadequate warnings may actually reduce consumer demand," *Fulgenzi* reasoned "[t]his is an empirical question, and we should not affirmatively answer on the basis of mere speculation about Congressional purposes." 711 F.3d at 585. The court concluded:

> It is hard to see how permitting state tort suits to go forward against sameness-violating generic defendants frustrates federal policies where permitting suits against FDA-*compliant* branded defendants does not. A vague policy of encouraging use of generic drugs, untethered from the structure of the Act, is not enough to support purposes-and-objectives preemption.

Id. at 586 (citation omitted). We agree with this analysis and hold Huck's claims survive impossibility preemption.

3. *Private right of action.* PLIVA argues Huck's claims are merely attempts to enforce the FDCA, which 21 U.S.C. § 337(a) disallows. The court of appeals and district court agreed. That section states: "[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). This provision ensures private suits do not "deprive the [FDA] of the ability to use its enforcement authority to achieve a delicate balance of statutory objectives." *Fulgenzi*, 711 F.3d at 586. PLIVA reads § 377(a) to mean "private litigants are barred from asserting claims involving violations of the FDCA or FDA's implementing regulations." We disagree and instead conclude Huck's claims—as limited by our decision today—are based on traditional state tort law principles that supplement federal requirements.

This case presents us with a "situation[] implicating 'federalism concerns and the historic primacy of state regulation of matters of health and safety,' " a situation governed by a presumption against preemption. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348, 121 S. Ct. 1012, 1017, 148 L. Ed. 2d 854, 861 (2001) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S. Ct. 2240, 2250, 135 L. Ed. 2d 700, 715 (1996)). "Where [a] claim is based on traditional state-tort-law principles, the lack of a private cause of action within a federal regulatory scheme will not preempt the claim for damages (even if state regulations might be

preempted)." *Fulgenzi.*, 711 F.3d at 586; *accord Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 255, 104 S. Ct. 615, 625, 78 L. Ed. 2d 443, 457 (1984) ("[T]raditional principles of state tort law . . . apply with full force unless they [are] expressly supplanted."). Likewise, an independent state law cause of action that parallels federal requirements is permissible. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330, 128 S. Ct. 999, 1011, 169 L. Ed. 2d 892, 906 (2008) ("[The express preemption provision in the Medical Device Amendments to the FDCA] does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements."); *Lohr,* 518 U.S. at 495, 116 S. Ct. at 2255, 135 L. Ed. 2d at 721 ("Nothing in [the statute] denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements."). "But if the claims 'exist solely by virtue of' the regulatory scheme, they are preempted." *Fulgenzi*, 711 F.3d at 586 (quoting *Buckman*, 531 U.S. at 353, 121 S. Ct. at 1020, 148 L. Ed. 2d at 864 (finding "fraud on the FDA" claim preempted because "the existence of . . . federal enactments is a critical element" of plaintiff's case)).

Huck's petition does not attempt to allege a prohibited private federal cause of action under the FDCA. Rather, she alleges state common law tort and warranty theories that exist regardless of whether the FDCA required a duty of sameness. Indeed, Huck could try her claims without reference to the FDCA. *Cf. Fulgenzi*, 711 F.3d at 588 (noting "the logic of *Buckman* would encourage exclusion of evidence of federal-law violations where possible"). Fundamentally, with variations on a theme, she asserts:

> (1) PLIVA had a duty to warn her that she should not take metoclopramide for longer than twelve weeks.[10]
>
> (2) PLIVA breached this duty.
>
> (3) Huck took metoclopramide for longer than twelve weeks because she was not instructed otherwise.
>
> (4) Huck suffered damages as a result of ingesting metoclopramide for more than twelve weeks.

Neither the federal duty of sameness nor the duty to report safety risks to the FDA are "critical element[s]" of her state law claims.[11] *See Buckman*, 531 U.S. at 353, 121 S. Ct. at 1020, 148 L. Ed. 2d at 864. Federal law has limited the way in which she can frame her claim: she cannot raise a claim based on labeling that would require PLIVA to unilaterally strengthen its label. She has managed to avoid that difficulty because PLIVA did not include the additional 2004 approved language. In sum, Huck's claims fit into a "narrow gap": she is suing for conduct that violates the FDCA, but she is not suing *because* the conduct violates the FDCA. *See In re Medtronic, Inc.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (internal quotation marks omitted).

B. The Brand Defendants. We next address whether the district court correctly entered summary judgment dismissing Huck's claims

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[10]This is distinct from the duty of label sameness imposed by federal law. If Huck premised her claim upon the duty of sameness, it would be preempted as an attempt to enforce federal law. *See Fulgenzi*, 711 F.3d at 588–89. Yet, we do not expect Huck to try her case without reference to the fact that the FDA approved a warning against prolonged use in 2004. We agree with the *Fulgenzi* court:

> Although federal-law violations here are not as relevant as they would be in a negligence per se case, references to federal law will inevitably arise. To avoid *Mensing* preemption, [plaintiff] must use the language of the 2004 FDA-approved label in her proximate-cause argument, not (or not merely) the fact of the failure to update. Federal standards are also likely to arise in determining the adequacy of PLIVA's warning, since FDA approval and industry practices may be relevant to the state duty of care.

Id.

[11]In contrast, "[f]ailure to update from one adequate warning to another would violate the FDCA, but not [state] law." *Fulgenzi*, 711 F.3d at 586–87.

against the brand defendants based on the undisputed fact that Huck consumed only the generic formulation sold by PLIVA—their competitor—and never used Reglan. The district court granted the brand defendants' unresisted motion for summary judgment, applying our decision in *Mulcahy*. The court of appeals affirmed, stating, "To the minimal extent Huck argues *Mulcahy* is either distinguishable or not applicable, we disagree and find the district court's application of *Mulcahy* is correct."

Mulcahy applied a well-settled requirement of Iowa law—the plaintiff must prove injury caused by a product sold or supplied by the defendant. 386 N.W.2d at 76. This long-standing requirement bars Huck's recovery from the manufacturers of a brand she never used.[12] Under Iowa law, manufacturers owe duties to those harmed by use of their products. We decline to change Iowa law to impose a new duty on manufacturers to those who never used their products and were instead harmed by use of a competitor's product. The FDA has responded to *Mensing* through a proposed rule to allow generic manufacturers to update their labeling on their own, regardless of the brand manufacturer labeling. *See* Proposed Rule, 78 Fed. Reg. at 67985. The rule change would vitiate the preemption defense of generic manufacturers. This is the appropriate way to address the unfairness resulting from *Mensing*, rather than turning Iowa tort law upside down.

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[12]Our preservation-of-error rules permit us to review issues the district court actually decided when granting an unresisted motion for summary judgment. *Otterberg*, 696 N.W.2d at 27–28. The brand defendants agree error is preserved to review whether the district court correctly entered summary judgment in their favor based on *Mulcahy*. Huck gave the district court the opportunity to revisit the issue in light of *Mensing* when she filed her motion for relief from judgment. *See Ganzer*, 686 N.W.2d at 197–98 (requiring postjudgment motion to preserve error for appellate review of unresisted summary judgment). Accordingly, we conclude error is preserved.

Huck argues we should reinstate her claims against the brand defendants because PLIVA was required to use the same warnings that accompanied Reglan. An overwhelming majority of courts adjudicating this issue have affirmed judgments or granted dispositive motions dismissing claims against the brand defendants when the plaintiff used only the generic formulation. *See, e.g.*, *In re Darvocet, Darvon and Propoxyphene Prods. Liab. Litig.*, ___ F.3d ___, ___, 2014 WL 2959271, *17–18 (6th Cir. June 27, 2014) (affirming dismissal of claims against brand defendants when plaintiffs consumed only generic painkiller; applying laws of twenty-two states in a multidistrict litigation action with sixty-eight lawsuits); *Moretti v. Wyeth, Inc.*, ___ Fed. Appx. ___, ___, 2014 WL 2726886, at *1 (9th Cir. June 17, 2014) (affirming summary judgment for brand defendants based on Nevada law); *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 476–78 (5th Cir. 2014) (affirming summary judgments for brand defendants because plaintiffs ingested only generic metoclopramide); *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 406 (6th Cir. 2013) (noting "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"); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1284–86 (10th Cir. 2013) (stating "the courts of other states have overwhelmingly rejected the very theory advanced by the Schrocks"); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1252 (11th Cir. 2013) ("[T]he overwhelming national consensus—including . . . the vast majority of district courts around the country to consider the question—is that a brand-name manufacturer cannot be liable for injuries caused by the ingestion of the generic form of a product."); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1092–94 (8th Cir. 2013) (affirming summary judgment for brand defendants because Bell never used Reglan and noting " '[a]n

overwhelming majority of courts considering this issue,' including the Eighth Circuit, have rejected Bell's theory of liability" (quoting *Mensing*, 588 F.3d at 613)); *Foster v. Am. Home Prods. Corp.,* 29 F.3d 165, 170 (4th Cir. 1994) ("There is no legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products, over whose production the name brand manufacturer had no control."). As the Sixth Circuit Court of Appeals summarized, "almost every court has . . . reason[ed] that a brand manufacturer does not owe a duty to a consumer unless the consumer actually used the brand manufacturer's product." *Darvocet* ___ F.3d at ___, 2014 WL 2959271, at *4 (citing Victor E. Schwartz, et. al., *Warning: Shifting Liability to Manufacturers of Brand–Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 Fordham L. Rev. 1835, 1857–58 (2013) [hereinafter Schwartz], which catalogs cases following the majority trend).

The Court of Appeals for the Tenth Circuit recently discussed three principal rationales used by courts, concluding "brand-name manufacturers are not liable to consumers of generic drugs":

> First, they based their view on traditional common law tort principles under which a manufacturer is liable for injuries caused by its own product. *See, e.g.*, *Mensing*, 588 F.3d at 604, 613 (holding name brand manufacturers liable for harm caused by generic manufacturers "stretches the concept of foreseeability too far" (quotation and alteration omitted)). Second, they reason that brand-name manufacturers' warnings and representations do not create a basis for liability to consumers of competitors' products because brand-name manufacturers only "intend[] to communicate with their customers, not the customers of their competitors." *Id.* at 613 n.9; *see also Stanley v. Wyeth, Inc.*, 991 So. 2d 31, 34 (La. Ct. App. 2008) ("A manufacturer cannot reasonably expect that consumers will rely on the information it provides when actually ingesting another company's drug."). Finally, they conclude that public policy

> considerations weigh against holding name-brand competitors liable for injuries caused by their generic competitor's drug. *See, e.g.*, *Foster*, 29 F.3d at 170 (citing the expense in development, research, and promotion undertaken by name-brand manufacturers not undertaken by generic manufacturers).

Schrock, 727 F.3d at 1285. We agree with each rationale.

In *Mulcahy,* we squarely held that "under Iowa common law a plaintiff in a products liability case must prove that the injury-causing product was a product manufactured or supplied by the defendant." 386 N.W.2d at 76. The brand defendants correctly argue this "product-identification requirement is decisive here because it is undisputed [Huck] did not use brand defendants' product, but instead used a generic equivalent product that was manufactured and sold by another company"—PLIVA—their competitor. We see no indication Congress intended to alter common law principles of causation to create liability for injuries caused by use of a competitor's product. *See Norfolk Redev. & Hous. Auth. v. Chesapeake & Potomac Tel. Co. of Va.*, 464 U.S. 30, 35, 104 S. Ct. 304, 307, 78 L. Ed. 2d 29, 34 (1983) ("It is a well-established principle of statutory construction that '[t]he common law . . . ought not to be deemed to be repealed, unless the language of a statute be clear and explicit for this purpose.' " (quoting *Fairfax's Devisee v. Hunter's Lessee*, 11 U.S. (7 Cranch) 603, 623, 3 L. Ed. 453, 459–60 (1812))). "Absent clearer indications, we cannot impute to Congress an intent to repeal, sub silentio, this deeply-rooted legal principle." *State Eng'r v. S. Fork Band of Te-Moak Tribe of W. Shoshone Indians of Nev.*, 339 F.3d 804, 814 (9th Cir. 2003) (citing *Norfolk*, 464 U.S. at 35–36, 104 S. Ct. at 307, 78 L. Ed. 2d at 34, and discussing common law doctrine of prior exclusive jurisdiction). We have never relaxed the product-identification causation requirement to impose liability for injuries caused by the use

of a competitor's product, and we decline to do so here. *Cf. Mulcahy*, 386 N.W.2d at 76 ("The imposition of liability upon a manufacturer for harm that it may not have caused . . . is an act more closely identified as a function assigned to the legislature under its power to enact laws.").

Huck contends the product-identification causation requirement does not apply to her negligent misrepresentation and fraud claims. We disagree. The plaintiffs in *Mulcahy* sued pharmaceutical companies for personal injuries resulting from the ingestion of DES, a synthetic estrogen compound. *Id.* at 69. The plaintiffs "set forth theories of recovery against the defendants based upon strict liability, *negligence, misrepresentation,* breach of warranties, alternate liability, enterprise liability, market share liability, and concert of action." *Id.* (emphasis added). We held the product-identification causation requirement applied " '[r]egardless of the theory which liability is predicated upon.' " *Id.* at 72–73 (quoting Annotation, *Products Liability: Necessity and Sufficiency of Identification of Defendant Manufacturer or Seller of Product Alleged to Have Caused Injury*, 51 A.L.R.3d 1344 § 2[a], at 1349 (1973)).

Moreover, the tort of negligent misrepresentation does not apply to sellers of products but rather is limited to those in the business or profession of supplying information for the guidance of others. *See Pitts v. Farm Bureau Life Ins. Co.*, 818 N.W.2d 91, 111–12 (Iowa 2012). "We have found accountants, appraisers, school guidance counselors and investment brokers all fall within this class of potential defendants." *Id.* at 112 (collecting cases). "However, we have refused to allow a suit for negligent misrepresentation where the defendant was a retailer in the business of selling and servicing merchandise . . . ." *Id.* Federal courts applying Iowa law likewise hold the tort of negligent misrepresentation does not apply to sellers of products:

> Even if Plaintiff's negligence actions were not barred by the contract's limitation of remedies, Defendant would be entitled to summary judgment on Plaintiffs' negligent misrepresentation claim. Plaintiffs concede that *Meier v. Alfa–Laval, Inc.*, 454 N.W.2d 576 (Iowa 1990) applies in this case. The *Meier* court held that liability based on the tort of negligent misrepresentation was limited to those persons in the business of supplying information versus persons who give information incidental to selling goods. *Id.* at 581. Clearly Defendant's business is more accurately described as selling goods than it is supplying information. In addition, even if Defendant were in the business of providing information, Plaintiffs' claim would fail in that Defendant did not supply "false information for the guidance of others in their business transactions." Restatement (Second) of Torts § 552(1) [(1965)]. Thus, summary judgment is appropriate as to Plaintiffs' negligent misrepresentation claim.

Nelson v. DeKalb Swine Breeders, Inc., 952 F. Supp. 622, 628 (N.D. Iowa 1996), *aff'd sub nom. Brunsman v. DeKalb Swine Breeders, Inc.*, 138 F.3d 358, 360 (8th Cir. 1998).

Courts in the Reglan litigation have applied the same limiting principles to dismiss negligent misrepresentation claims against brand name manufacturers when the plaintiff used only the generic product. *See, e.g.*, *Baymiller v. Ranbaxy Pharm., Inc.*, 894 F. Supp. 2d 1302, 1309–10 (D. Nev. 2012) (noting that Nevada law "limited the application" of section 552 to business transactions and concluding that because plaintiff did not purchase the brand-name product, there was no business transaction and section 552 did not apply); *Strayhorn v. Wyeth Pharm., Inc.*, 882 F. Supp. 2d 1020, 1030 (W.D. Tenn. 2012) (rejecting plaintiffs' claims of negligent and fraudulent representation against brand manufacturers when the Tennessee Supreme Court had declined to apply section 552 to fraudulent misrepresentation or in products liability actions previously), *aff'd*, 737 F.3d 378, 383 (6th Cir. 2013); *Mosley v. Wyeth, Inc.*, 719 F. Supp. 2d 1340, 1345–46 (S.D. Ala. 2010) (finding that section 552 did not apply in a products liability action

against brand manufacturers and stating, "Under the restatement, drug manufacturers cannot be classed, at least not in the same sense as accountants and real estate appraisers, as 'persons [who] make it a part of their business . . . to supply information for the guidance of others in their business transactions,' " and concluding, "under the facts of this case Wyeth and Schwarz did not engage in any business transaction with the Mosleys" (alternation in original) (citations omitted); *see also Darvocet,* ___ F.3d at ___, 2014 WL 2959271, at *16–18 ("After conducting a state-by-state *Erie* analysis, we conclude that the highest courts in each of the 22 implicated states would not recognize Plaintiffs' misrepresentation claims under their respective state laws."). We too decline to extend the tort of negligent misrepresentation to the brand defendants when Huck used only the generic drug sold by their competitor.

We did not retreat from the product-identification causation requirement for fraud cases in *Brooke Group Ltd.*, as Huck argues. Rather, we noted the general rule that "a manufacturer's failure to warn or to disclose material information does not give rise to a fraud claim." *Id.* at 177. We noted two exceptions: "where the manufacturer (1) has made misleading statements of fact intended to influence consumers, or (2) has made true statements of fact designed to influence consumers and subsequently acquires information rendering the prior statements untrue or misleading." *Id.* (citing Restatement (Second) of Torts § 551(2)(b)–(c), at 119 (1977)). But, the exceptions were expressly based on the existence of the relationship between the "customer/buyer and manufacturer," a relationship that created a duty. *Id.* We never held or suggested a fraud claim could be brought by a plaintiff against a manufacturer who owed the plaintiff no duty, as we conclude is the case

here. Our decision in *Brooke Group Ltd.* also forecloses another liability theory urged by Huck on appeal: "Good Samaritan" liability for a voluntary undertaking. *See id.* at 177–78 (holding marketing and advertising on the health effects of smoking are not an "undertaking" within the scope of Restatement (Second) of Torts section 323)).

Huck argues we should revisit *Mulcahy* in light of our adoption of section 7[13] of the Restatement (Third) of Torts: Liability for Physical and Emotional Harm, at 77 (2010) in *Thompson v. Kaczinski*, 774 N.W.2d 829, 835 (Iowa 2009). We disagree. *Thompson* was not a products liability case, and we have not applied section 7 of the Restatement (Third) of Torts in products liability actions. Rather, in products liability actions, we turn to the Products Restatement. *See Brooke Group Ltd.*, 652 N.W.2d at 167. Huck cannot evade the proof requirements of Iowa products liability law merely by labeling her claim as a common law negligent failure-to-warn theory. Her claims arise from injuries from her use of a product—PLIVA's generic metoclopramide. Products liability law broadly refers to the legal responsibility for injury resulting from the use of a product. *Bingham v. Marshall & Huschart Mach. Co.*, 485 N.W.2d 78, 79 (Iowa 1992). It encompasses the theories of negligence, strict liability and breach of warranty. *Id.* Although each is a separate and distinct theory of recovery, the same facts often give rise to all three claims. *See id.* "The underlying theories ordinarily concern improper design, *inadequate warnings*, or mistakes in manufacturing." *Smith v. Air Feeds,*

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[13]Section 7 provides:

> (a) An actor ordinarily has a duty to exercise reasonable care when the actor's conduct creates a risk of physical harm.
>
> (b) In exceptional cases, when an articulated countervailing principle or policy warrants denying or limiting liability in a particular class of cases, a court may decide that the defendant has no duty or that the ordinary duty of reasonable care requires modification.

Inc., 519 N.W.2d 827, 830 (Iowa Ct. App. 1994) (emphasis added). Thus, the Products Restatement applies to this case and its specific provisions control over general tort principles found in the Restatement (Third) of Torts provisions adopted in *Thompson.*

Moreover, section 7 of the Restatement (Third) of Torts addresses duty, not causation. *See* Restatement (Third) of Torts: Liab. for Physical Harm § 7, at 77. We have never applied section 7 to eliminate the requirement that the plaintiff prove her injuries were caused by a product sold or supplied by the defendant or to impose liability for injuries caused by a competitor's product. Nor has any other appellate court in the country. The product-identification requirement applied in *Mulcahy* remains good law. The Sixth Circuit Court of Appeals, applying Nebraska law, expressly rejected the argument that section 7 supported imposing liability on brand defendants for injuries of consumers of the generic competing product. *Darvocet,* ___ F.3d at ___, 2014 WL 2959271, at *27–28.

Huck points to no provision of the Products Restatement that would eliminate *Mulcahy*'s product-identification causation requirement or that would impose liability on a defendant whose product the plaintiff never used. We adopted sections 1 and 2 of the Products Restatement in *Brooke Group Ltd.*, 652 N.W.2d at 169. Those provisions require proof the defendant's product injured the plaintiff. Section 1 provides, "One . . . who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect." Restatement (Third) of Torts: Prods. Liab. § 1, at 5. Section 2 defines defect to include

inadequate warnings or instructions.[14] *Id.* § 2, at 14. Section 6 specifically addresses prescription drugs and imposes "liability for harm to persons caused by the defect." *Id.* § 6(a), at 144. Section 15 provides, "Whether a product defect caused harm to persons or property is determined by the prevailing rules and principles governing causation in tort." *Id.* § 15, at 231. The prevailing rule requires cause-in-fact causation. *See* Restatement (Third) of Torts: Liab. for Physical Harm § 26, at 346 ("Conduct is a factual cause of harm when the harm would not have occurred absent the conduct."). Cause-in-fact is lacking when the plaintiff used only a competitor's product, not the defendant's. *See Mulcahy*, 386 N.W.2d at 76. As noted above, the overwhelming majority of courts apply this product-identification causation requirement in Reglan litigation to reject claims against brand defendants for injuries caused by use of a competitor's generic drug.

We are not persuaded by the two outlier appellate decisions cited by Huck: *Wyeth, Inc. v. Weeks*, ___ So. 3d ___, ___, 2013 WL 135753, at *19, *reargument granted* (June 13, 2013) (Ala. Jan. 11, 2013) (applying Alabama law); *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 304–05 (Ct. App. 2008) (applying California law).[15] Both concluded the product-

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[14]Section 2(c) states:

> [A product] is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.

Restatement (Third) of Torts: Prods. Liab. § 2(c), at 14.

[15]Huck cites several unpublished trial court decisions allowing claims to proceed against brand defendants when plaintiffs used only the generic formulation, and one published district court decision, *Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010). *Kellogg* applied Vermont law that, unlike Iowa's, permits recovery for harm inflicted by a competitor's product. *See* 762 F. Supp. 2d at 708–09. *Kellogg* is at odds with *Mulcahy*. The unpublished decisions cited by Huck are similarly at odds with *Mulcahy* and lack

identification causation requirement for strict liability claims did not apply to fraud and negligent misrepresentation theories under the applicable state law. *Weeks*, ___ So. 3d at ___, 2013 WL 135753, at *19; *Conte*, 85 Cal. Rptr. 3d at 317–18. Iowa law differs. As we held in *Mulcahy,* a plaintiff seeking recovery for the side effects of a prescription who sues a pharmaceutical company under any theory, including misrepresentation, must prove she was injured by using the prescription drug manufactured or supplied by that defendant. 386 N.W.2d at 69, 72–73, 76. Additionally, the Alabama Supreme Court subsequently granted Wyeth's application for rehearing and reset *Weeks* for a second oral argument heard in September 2013. Lorelei Laird, *Generic drugs leave a bad taste for patients filing tort suits*, ABA Journal (Feb. 1, 2014), http://www.abajournal.com/magazine/article/generic_drugs_leave_a_bad_taste_for_patients_filing_tort_suits/. Judge Murdock, in his well-reasoned dissent from the initial decision, observed:

> [A]lmost every one of the 47 reported cases decided before the United States Supreme Court's decision in [*Mensing*], including cases decided by two United States Circuit Courts of Appeals, hold that a manufacturer of a brand-name drug has no duty to the consumer of a generic drug manufactured and sold by another company. (Only three courts, including the court certifying the question in this case, have held otherwise.) Since the Supreme Court's 2011 decision in PLIVA, every one of the 11 cases that have addressed the issue, including decisions by three United States Circuit Courts of Appeals, has reached this same conclusion.

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precedential value. A more recent Court of Appeals for the Seventh Circuit case, *In re GlaxoSmithKline LLC*, No. 14–2051, 2014 WL 2506461, at *1 (7th Cir. June 4, 2014), provided by Huck subsequent to oral argument is also unpersuasive. Though the plaintiff in that case ingested only a generic medication, the district court denied the brand manufacturer's motion for summary judgment. *Id.* The brand manufacturer petitioned the Seventh Circuit for a writ of mandamus to correct that ruling. *Id.* The Seventh Circuit acknowledged "that a majority of federal courts has ruled in favor of the [brand] manufacturer," but denied the brand manufacturer's petition for a writ of mandamus, reasoning that the legal issue could be resolved on appeal from a final judgment. *Id.*

> As these numbers indicate, the Supreme Court's holding in [*Mensing*]—that state-law claims against *generic*-drug manufacturers are preempted by the federal regulatory scheme—did nothing to undermine the essential rationale in the plethora of pre- and post-[*Mensing*] decisions holding that *brand-name* manufacturers are not liable for injuries caused by deficient labeling of generic drugs they neither manufactured nor sold. In fact, as discussed below, the opinion in [*Mensing*] expressly says as much, and opinions in post-[*Mensing*] cases are even more explicit in saying so.

Weeks, ___ So. 3d at ___, 2013 WL 135753, at *21 (Murdock, J. dissenting). It remains to be seen how the Alabama Supreme Court will ultimately decide whether brand defendants may be held liable under Alabama law to consumers who used only the generic formulation sold by a competitor.

Not only is Huck unable to satisfy *Mulcahy*'s causation requirement, she cannot establish that the brand defendants owed her a duty. *Cf. Hoyt v. Gutterz Bowl & Lounge L.L.C.*, 829 N.W.2d 772, 775 (Iowa 2013) ("[T]he determination of whether a duty is owed under particular circumstances is a matter of law for the court's determination."). We have made clear that our adoption of section 7 of the Restatement (Third) of Torts in *Thompson* did not supersede our precedent limiting liability based on the relationships between the parties. *McCormick v. Nikkel & Assocs.*, 819 N.W.2d 368, 374 (Iowa 2012) (noting general duty of care under section 7(a) is "subject to 'an articulated countervailing principle or policy' " in section 7(b), which " 'may be reflected in longstanding [sic] precedent' " (quoting Restatement (Third) of Torts: Liab. for Physical Harm § 7(b) & cmt. *a*, at 77–78)). In *McCormick*, we discussed how the law of duty remains intact in important ways after *Thompson*:

> Historically, the duty determination focused on three factors: the relationship between the parties, the foreseeability of harm, and public policy. [*Thompson,* 774

> N.W.2d] at 834. In *Thompson*, we said that foreseeability should not enter into the duty calculus but should be considered only in determining whether the defendant was negligent. *Id.* at 835. But we did not erase the remaining law of duty; rather, we reaffirmed it. *Id.* at 834–36. In short, a lack of duty may be found if either the relationship between the parties or public [policy] considerations warrants such a conclusion.

McCormick, 819 N.W. 2d at 371. We reiterated "our previous law of duty was otherwise still alive and well." *Id.* We affirmed summary judgment for the defendant electrical subcontractor under the control rule that predated *Thompson*. *McCormick*, 819 N.W.2d at 375; *see also Feld v. Borkowski*, 790 N.W.2d 72, 76–77 & n.1 (Iowa 2010) (applying contact-sports rule that predated *Thompson* to tort claim arising from injury to player during high school intramural softball game because the Restatement (Third) of Torts "expresses the notion that a reasonable-care duty applies in each case *unless* a special duty, like the contact-sports exception, is specifically recognized" (citing Restatement (Third) of Torts: Liab. for Physical Harm § 7 cmt. *a*, at 77)).

Due to the unique nature of the relationship between generic and brand manufacturers, a " 'countervailing principle or policy warrants denying liability in [this] particular class of cases.' " *Thompson*, 774 N.W.2d at 835 (quoting Restatement (Third) of Torts: Liab. for Physical Harm § 7(b), at 90) (Proposed Final Draft No. 1, 2005); *accord Kelly v. Wyeth*, No. Civ.A.MICV20003314B, 2005 WL 4056740, at *4 (Mass. Super. May 6, 2005) (concluding "strong social policy reasons" weigh against finding brand manufacturers owe a duty to generic consumers). As we concluded in *Mulcahy*, to expand tort liability to those who did not make or supply the injury-causing product used by the plaintiff involves policy choices and "social engineering more appropriately within the legislative domain." 386 N.W.2d at 76. Congress has created a

symbiotic relationship between brand and generic drug manufacturers. In this relationship,

> [n]ame brand manufacturers undertake the expense of developing pioneer drugs, performing the studies necessary to obtain premarketing approval, and formulating labeling information. Generic manufacturers avoid these expenses by duplicating successful pioneer drugs and their labels. Name brand advertising benefits generic competitors because generics are generally sold as substitutes for name brand drugs, so the more a name brand drug is prescribed, the more potential sales exist for its generic equivalents.

Foster, 29 F.3d at 170. The *Foster* court recognized that, as between these competing pharmaceutical companies, it would be "especially unfair" to find brand manufacturers have a duty to those who take generic drugs "when, as here, the generic manufacturer reaps the benefits of the name brand manufacturer's statements by copying its labels and riding on the coattails of its advertising." *Id.*; *see also Kelly*, 2005 WL 4056740, at *4 (highlighting that "[the drug] approval process can be a very time consuming and costly endeavor [for brand manufacturers], as the manufacturer bears the cost of research and development, as well as performing clinical studies of the drug's safety and effectiveness" while "[t]he makers of generic drugs, by contrast, do not have to expend the same amount of resources").

Through carefully crafted legislation, Congress has made policy choices that impact the economics of prescription drug sales to increase access to medication. Huck cites nothing in the text of the Hatch-Waxman Amendments or congressional record suggesting Congress intended to render brand defendants liable to consumers of generic products. To impose such liability would alter the relationship between generic and brand manufacturers. Specifically, extending liability to brand manufacturers for harm caused by generic competitors would

discourage investments necessary to develop new, beneficial drugs by increasing the downside risks. *See* Schwartz, 81 Fordham L. Rev. at 1870–72 (elaborating reasons why "expanding liability for a competitor's product is not sound health policy").

Economic and public policy analyses strongly disfavor imposing tort liability on brand manufacturers for harm caused by generic competitors. *See generally* Richard A. Epstein, *What Tort Theory Tells Us About Federal Preemption: The Tragic Saga of* Wyeth v. Levine, 65 N.Y.U. Ann. Surv. Am. L. 485 (2010) [hereinafter Epstein]. As Professor Epstein observed:

> The powerful influence of common law decisions creates gratuitous expense and uncertainty that feed their way back into the cycle of drug development, testing, and marketing. Properly understood, the entire duty-to-warn apparatus has become a tax on drugs, which, in some instances, may drive both old and new products off the market and, in most instances, will increase drug cost and reduce the levels of beneficial patient use.

Id. at 514. Professor Epstein further noted:

> The judicial failure to understand the historical arc of the law of torts leads to a second set of unsound judgments on matters of institutional competence . . . . There is nothing that erratic and expensive juries can do to make accurate scientific judgments that will allow people to plan their conduct in advance. Stability of expectations is indispensable in marketing dangerous compounds, and, for all its manifest failings, the FDA is better at this task than juries.

Id. at 522. As Professor Epstein elaborated:

> The FDA, for all its flaws, does have one advantage over a system of tort liability: It makes its judgments on the overall effects of drug use, not on the particulars of individual cases where the question of proper warning is compromised in a number of ways.

Id. at 488 (footnote omitted).[16]

Huck fails to articulate any persuasive case that public health and safety would be advanced through imposing tort liability on brand defendants for injuries caused by generic products sold by competitors. We agree with Professor Epstein that courts are not institutionally qualified to balance the complex, interrelated, and divergent policy considerations in determining labeling and liability obligations of brand and generic pharmaceuticals. Courts deal ad hoc with the record made by private litigants. By contrast, the FDA, with its four billion dollar budget, engages in public rulemaking allowing transparent input from all interest groups, guided by its own staff of qualified scientists.

Fundamental tort principles of risk apportionment further support a no-duty holding in this case. Liability generally follows control in our tort law. *Cf. McCormick*, 819 N.W.2d at 374 (noting the party in control "is best positioned to take precautions to identify risks and take measures to improve safety"). But, the brand defendants "d[id] not place [the generic product] in commerce, ha[d] no ability to control the quality of the product or the conformance of the product with its design, and d[id] not have the opportunity to treat the risk of producing the product as a cost of production against which liability insurance can be obtained." *See* Am. L. Prod. Liab. 3d § 5:10 (noting that, under these circumstances, "the defendant has not undertaken and assumed [a] special responsibility toward the consuming public"). Accordingly, the brand defendants cannot be classified as the sellers of the generic

[16]Epstein favors preemption of state law failure-to-warn claims against brand defendants brought by consumers of Reglan, Epstein, 65 N.Y.U. Ann. Surv. Am. L. 485, a view rejected in *Levine*. *See Levine*, 555 U.S. at 581, 129 S Ct. at 1204, 173 L. Ed. 2d at 70. Yet his policy arguments apply with greater force to efforts to extend state tort liability to brand defendants for injuries to consumers who used only the competing generic drug.

metoclopramide Huck ingested. *See* Restatement (Third) of Torts: Prods. Liab. § 1, at 5.

A brand manufacturer cannot ensure that a generic manufacturer complies with federal law—the two are, after all, *competitors*. The brand defendants had no control over whether PLIVA used their improved warning language approved by the FDA in 2004. Indeed, in this case PLIVA failed to update its label to conform to the improved warnings by the brand defendants approved by the FDA in 2004. Huck will have her day in court against PLIVA. We adopted products liability to place responsibility for the harm caused by a product on the party who profits from its manufacture and sale. *See Brooke Grp. Ltd.*, 652 N.W.2d at 164 (noting our purpose in adopting principles of products liability was to ensure " 'that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market' ") (quoting *Hawkeye-Sec. Ins. Co. v. Ford Motor Co.*, 174 N.W.2d 672, 683 (Iowa 1970))). PLIVA, not the brand defendants, profited from its sale of the generic formulation that harmed Huck.

We reject Huck's argument based on *Bredberg v. PepsiCo, Inc.,* 551 N.W.2d 321 (Iowa 1996). Huck relies on *Bredberg* to argue Iowa law permits liability on a party who designs, but does not manufacture or sell, the product that injured the plaintiff. In *Bredberg*, plaintiff was injured by an exploding glass bottle of Diet Mountain Dew. *Id.* at 323. He sued the retailer, PepsiCo, Inc. (which made and sold the Diet Mountain Dew concentrate), as well as Pepsi Cola General Bottlers, Inc. (which bottled and distributed the soft drink under a license agreement). *Id.* at 323 & n.1. The bottler was "required to mix the concentrate pursuant to a formula provided by PepsiCo." *Id.* at 323 n.1. The defendants moved for a directed verdict on grounds the evidence was

insufficient to prove the bottle was defective. *Id.* at 324. Importantly for present purposes, PepsiCo did not move for a directed verdict on grounds it did not manufacture or sell the bottle. The jury returned a verdict for plaintiff and allocated fault fifty percent to plaintiff, five percent to the retailer, twenty-five percent to the bottler, and twenty percent to PepsiCo. *Id.* at 325. The district court entered judgment for half the damages, and PepsiCo and the bottler appealed. *Id.* at 325. We transferred the case to the court of appeals, which reversed. *Id.* We granted Bredberg's application for further review. *Id.* at 326. In a footnote, we stated "PepsiCo contends that its licensing agreement with [the bottler] Pepsi Cola is not sufficient to impute liability on it as a manufacturer." *Id.* at 326 n.4. We declined to follow a case based on a Georgia statute because it "says nothing about whether PepsiCo could be held liable as a product 'designer,' as alleged by plaintiff against PepsiCo in the present case." *Id.* We went on to review the evidence and conclude it was sufficient to support the verdict that the bottle was defective. *Id.* at 326–29. We held the district court correctly denied defendants' posttrial motions and affirmed the judgment for plaintiff on that basis. *Id.* at 329.

The fighting issue in *Bredberg* was whether there was substantial evidence the bottle that exploded was defective. *See id.* at 327–28. That was the basis of the rulings on the directed verdict motion and the motion for JNOV, rulings our holding affirmed. *Id.* at 324–25. PepsiCo supplied the concentrate and, therefore, was a component parts supplier of the completed product—the full bottle of carbonated soft drink. *See id.* at 323 n.1. PepsiCo essentially outsourced the manufacture of the glass bottle and distribution of the finished product to its licensee, the bottler. PepsiCo controlled part of the manufacturing (mixing) process for the very product that injured plaintiff. *See id.* PepsiCo was thus in

the chain of distribution of the injury-causing product, with significant control over the process for which it profited. PepsiCo was held liable for injuries caused by the Pepsi™ product, consistent with *Mulcahy*—not for injuries from an exploding Coca-Cola bottle sold by a competitor.[17]

By contrast, the brand defendants control the brand label, but do not otherwise control PLIVA. As we noted, PLIVA failed to adopt the new warning language used by the brand defendants in 2004. And, the brand defendants, who incurred the costs to develop Reglan, do not profit from PLIVA's sale of the competing generic formulation.

Judge Murdock observed that limiting liability to the defendant that made the drug used by the plaintiff is consistent with "bedrock principles of tort law and of economic realities underlying those principles":

> From the beginning, what Alexander Hamilton referred to as "[t]he spirit of enterprise, which characterizes the commercial part of America," has animated Americans to work hard to produce innovative goods and services that have benefited not only themselves, but also their children, their communities, and America as a whole. An enterprising spirit alone, however, is not enough. The law must protect the fruits of enterprise and create a climate in which trade and business innovation can flourish. Concomitantly, the

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[17]Huck does not attempt to support her innovator liability theory against the brand defendants by relying on our court's professional malpractice decisions in which defective plans or specifications caused harm. *See, e.g.*, *Schiltz v. Cullen-Schiltz & Assocs., Inc.*, 228 N.W.2d 10, 12 (Iowa 1975). In *Schiltz*, a professional engineering firm was paid to design plans for the construction of a sewage treatment plant. *Id.* at 12. The general contractor built the facility in accordance with the engineer's design, which failed to provide for a dike for flood protection. *Id.* at 12–13. A nearby creek flooded and damaged the facility. *Id.* at 13. The contractor sued the engineering firm for negligently designing the facility without adequate flood protection, and the jury ultimately found for the plaintiff-contractor. *Id.* at 12–13. We affirmed the submission of the negligence theory. *Id.* at 18. *Schiltz* does not support imposing liability on brand defendants. The defendant engineer was hired and paid to design the facility built by the plaintiff. The engineer provided a service, not a product. *Schiltz* is not a case in which a different engineer copied and sold the design made by defendant for another project. There was no attempt in *Schiltz* to impose liability on a remote designer who was not retained and paid for the construction project at issue.

> law must justly allocate risks that are a function of that free trade and innovation.
>
> These dual needs have resulted in an economic and legal system that always has coupled the rewards from the sale of a good or service with the costs of tortious injury resulting from the same. Indeed, this and the corollary notion that parties are responsible for their own products, not those of others, are so organic to western economic and legal thought that they rarely find need of expression.

Weeks, ___ So. 3d at ___, 2013 WL 135753, at *20 (Murdock, J. dissenting) (alteration in original) (footnote omitted).

We adhere to these bedrock principles today, and join the multitude of courts that have concluded brand defendants owe no duty to consumers of generic drugs. *See*, *e.g.*, *Darvocet* ___ F.3d at ___, 2014 WL 2959271, at *17–18 (affirming dismissals of claims against brand defendants on no-duty grounds); *Lashley*, 750 F.3d at 476 ("[B]ecause Appellants did not ingest the brand manufacturers' products, these defendants have no common-law duty to them."); *Strayhorn*, 737 F.3d at 405 (acknowledging 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' " (quoting *Barnes v. Kerr Corp.*, 418 F.3d 583, 590 (6th Cir. 2005))); *Schrock*, 727 F.3d at 1282 (recognizing "[w]hether or not a duty exists depends on the relationship between the parties" and "brand-name manufacturers do not have any relationship" with the plaintiff who ingested a generic drug (alteration in original) (internal quotation marks omitted)); *Bell*, 716 F.3d at 1093 ("[N]othing in Arkansas law . . . supports extending such a duty of care to the customer of a competitor using a competing product."); *Foster*, 29 F.3d at 171 (concluding "Wyeth has no duty to the users of other manufacturers' products").

We are unwilling to make brand manufacturers the de facto insurers for competing generic manufacturers. *Cf.* Schwartz, 81 Fordham L. Rev. at 1871 ("Deep-pocket jurisprudence is law without principle.") It may well be foreseeable that competitors will mimic a product design or label. But, we decline Huck's invitation to step onto the slippery slope of imposing a form of innovator liability on manufacturers for harm caused by a competitor's product. Where would such liability stop? If a car seat manufacturer recognized as the industry leader designed a popular car seat, could it be sued for injuries sustained by a consumer using a competitor's seat that copied the design? Why not, under Huck's theory, if it is foreseeable others will copy the design?

In sum, we will not contort Iowa's tort law in order to create liability for brand manufacturers. The unfairness resulting from *Mensing* is best addressed by Congress or the FDA. *See Mensing*, 564 U.S. at ___, 131 S. Ct. at 2582, 180 L. Ed. 2d at 597 ("As always, Congress and the FDA retain the authority to change the law and regulations if they so desire."); Schwartz, 81 Fordham L. Rev. at 1875 ("Congress and the FDA . . . are the appropriate arms of government for making [drug liability] decisions in the context of fashioning the best health care policy for the country."); *see generally* Daniel Kazhdan, *Wyeth and PLIVA: The Law of Inadequate Drug Labeling*, 27 Berkeley Tech. L.J. 893 (2012) (discussing *Levine* and *Mensing* and "propos[ing] ways that drug companies, the FDA, Congress, and the states could remedy the harmful effects of the Court's distinction between brand-name drugs and generic drugs"). Indeed, the FDA's proposed rule allows generic manufacturers to unilaterally strengthen their labels. *See generally* Proposed Rule, 78 Fed. Reg. 67985–02. This rule would abrogate the *Mensing* holding,

permitting consumers of generic drugs to bring a claim against generic manufacturers consistent with the *Levine* analysis.

We will continue to apply the same long-standing causation rule applied in *Mulcahy*, which required Huck to prove the defendant manufactured or supplied the product that caused her injury, and we decline to extend the duty of product manufacturers to those injured by use of a competitor's product. We will not impose liability on the brand defendants for injuries to those using only the competing generic formulation. The district court correctly concluded the brand defendants were entitled to summary judgment in their favor.

IV. Disposition.

For the foregoing reasons, we vacate the decision of the court of appeals, reverse in part the district court's summary judgment for PLIVA and remand for further proceedings on Huck's claims against PLIVA based on its failure to adopt the 2004 warning language approved by the FDA for Reglan. We affirm the district court's summary judgments dismissing the other claims against PLIVA and dismissing Huck's claims against the brand defendants.

DECISION OF COURT OF APPEALS VACATED; DISTRICT COURT JUDGMENTS AFFIRMED IN PART, REVERSED IN PART, AND REMANDED WITH INSTRUCTIONS.

All justices concur except Cady, C.J., who concurs specially, and Hecht, Wiggins, and Appel, JJ., who concur in part and dissent in part.

CADY, Chief Justice (concurring specially).

I concur in the opinion of the majority on the claims by Huck against PLIVA, but otherwise concur in the result only. I agree with much of the dissent on the claims against the brand defendant, but decline at this time to conclude the public policy considerations that ultimately drive the decision in this case, on balance, support the imposition of a duty of care as suggested by Justice Hecht's opinion.

After the United States Supreme Court held in *PLIVA, Inc.* v. *Mensing*, 564 U.S. ___, ___, 131 S. Ct. 2567, 2580–81, 180 L. Ed. 2d 580, 595 (2011), that warning claims against a generic drug manufacturer were preempted, consumers of generic drugs harmed by its label had little avenue of relief except to turn to the brand drug manufacturer. A credible legal theory of recovery against the brand drug manufacturer has now been pieced together with the aid of our prior cases, but these efforts do not confront the existing congressional preemption into the broad area of brand and generic drugs. The law can stitch together legal theories into legal claims of action, but the underlying public policy ultimately drives the creation of a duty of care. Normally, courts are able to discern the public policy and apply it to reach an outcome; but in this case, the policies exist within an area fully occupied by Congress and which is still developing. The public policy considerations normally at play to impose a duty of care on manufacturers to protect product consumers are simply too general and attenuated to support the imposition of market-wide liability on the brand manufacturer, especially at a time when its market share is steadily being consumed by the generic drug manufacturer protected from liability.

Courts normally seek to find remedies for wrongs, but the complexity and sheer size of the particular area of inquiry and the role that has been assumed by Congress in regulating and navigating through the area should make courts more than cautious to step in to create legal liability for brand-name manufacturers. The policies at play are currently being developed and shaped by Congress and include policies that militate against court intervention at this time.

HECHT, Justice (concurring in part and dissenting in part).

I join the majority's analysis with respect to Huck's claims against PLIVA. As I believe the majority's[18] "product-identification causation requirement," however, has no application in a case where the product and warning allegedly responsible for injury have been identified, and because I believe our caselaw regarding duty and factual causation support the possibility of the brand defendants' liability here, I respectfully dissent from the majority's analysis and disposition of the claims against the brand defendants.

I. Iowa Products Liability Law and *Mulcahy*.

We have previously explained the law of products liability in Iowa "may involve causes of action stated in negligence, strict liability, or breach of warranty," among others. *Bingham v. Marshall & Huschart Mach. Co.*, 485 N.W.2d 78, 79 (Iowa 1992). We have noted these three theories are separate and distinct theories of recovery, and a single set of facts may give rise to any combination of the three. *Lovick v. Wil-Rich*, 588 N.W.2d 688, 698 (Iowa 1999). Typically, the underlying theories will involve claims of improper design, inadequate warnings, or defects in manufacturing. *Id.*

The imposition of liability for manufacturing defects has a long history in Iowa caselaw. *See, e.g., Hawkeye-Sec. Ins. Co. v. Ford Motor Co.*, 174 N.W.2d 672, 684 (Iowa 1970). In *Hawkeye*, we adopted the special, narrow principle of strict liability found in section 402A of the Restatement (Second) of Torts. *Id.* We explained that for various policy

[18]I will continue to refer to the analysis in Part III.B of the opinion by Justice Waterman as the "majority" for ease of reference only. As Chief Justice Cady's special concurrence makes clear, the analysis in Part III.B of Justice Waterman's opinion has the support of three justices, while Chief Justice Cady has concurred in the result only.

reasons, a commercial seller of a defectively manufactured product may be liable for harm caused by the defect regardless whether the plaintiff might establish negligence or breach of warranty by the seller. *Id.*; *see also* Restatement (Third) of Torts: Prods. Liab. § 1 cmt. *a*, at 7 (1998). While the facts in *Hawkeye* gave rise only to a claim of manufacturing defect, our explanation of strict liability principles suggested the strict liability theory might be applicable in cases involving allegations of design defect as well. *Hawkeye*, 174 N.W.2d at 684 (quoting authority applying strict liability when " 'the defect arose out of the design or manufacture' " of the product). We gave no indication whether the theory might also apply in a case giving rise to a claim of failure to warn, and it was not until many years later we concluded failure-to-warn claims typically invoke a reasonableness standard incompatible with a strict liability theory. *See Olson v. Prosoco, Inc.*, 522 N.W.2d 284, 289–90 (Iowa 1994); *see also* Restatement (Third) of Torts: Prods. Liab. § 1 cmt. *a*, at 6–7.

After setting forth the justifications for our adoption of the strict liability theory given the claim of manufacturing defect before us in *Hawkeye*, we took care to note analysis of any claim of negligence was "a different matter." *Hawkeye*, 174 N.W.2d at 685. We had no occasion to decide in *Hawkeye* how theories of negligence or strict liability might apply in cases not involving a manufacturer, because the special strict liability rule at issue there and elucidated in section 402A had no application to a party not engaged in the activity of making or selling a product as part of its business. *See* Restatement (Second) of Torts § 402A cmt. *f*, at 350–51 (1965). While it may often be deceptively simple to regard an actor's liability for injuries related to a product as "strict," we cautioned in *Hawkeye*, the Restatement (Second) did not preclude

liability based on the alternative ground of negligence when negligence could be proved—the special rule of section 402A often simply had no application to those claims. *Hawkeye*, 174 N.W.2d at 684–85; *see also Wright v. Brooke Grp. Ltd.*, 652 N.W.2d 159, 164 (Iowa 2002).

We more recently addressed the prospect of liability for injury caused by a product in *Wright*, a case presenting a claim of design defect. *Wright*, 652 N.W.2d at 169. We acknowledged our conclusion in *Olson* that cases involving claims of failure to warn should be analyzed under the rubric of negligence. *Wright*, 652 N.W.2d at 166. We noted the Restatement (Third) of Torts: Products Liability had, in addressing claims of design defect, abandoned the consumer-expectations test traditionally employed in strict liability analyses in favor of a risk–utility test typically found in negligence analyses. *Id.* at 169. We concluded we favored the Restatement's preference for avoiding doctrinal designation of design-defect claims as claims involving negligence or strict liability. *Id.* Like the drafters of the Restatement, we explained, we favored a functional risk–utility analysis for these claims without application of a doctrinal label. *Id.* We therefore adopted the framework for analyzing the liability of sellers and distributors of products for manufacturing defects, defective designs, and inadequate instructions and warnings found in sections 1 and 2 of the Restatement (Third) of Torts: Products Liability. *Wright*, 652 N.W.2d at 169; *see also* Restatement (Third) of Torts: Prods. Liab. §§ 1–2 at 5, 14. In so doing, we reiterated the Restatement's recognition that a traditional conception of strict liability may well be appropriate in manufacturing defect cases, but that negligence principles will often be more suitable in cases involving other types of claims. *Wright*, 652 N.W.2d at 168.

In the course of our analysis in *Wright*, we identified two principles further illuminating our examination of the brands' obligations here. First, we suggested that in certain instances, manufacturers and other parties may be liable in tort for damages suffered as a result of product defect, regardless whether the parties actually produce the specific object causing the damages. *See Wright*, 652 N.W.2d at 173 (examining civil conspiracy scenario where "manufacturers agree to suppress information about their product for the lawful purpose of facilitating the sale of their product, and in effectuating this plan subject themselves to liability for failure to warn of the risks of using their product"). Second, and more importantly for purposes of our analysis here, in examining a claim for failure to warn, we explained "what is really important is that the statements were made for the purpose of influencing the action of another," and these claims need not "involve[] a business transaction between the parties . . . ." *Id.* at 175–76. In *Wright* then, as in *Hawkeye*, we took care to establish that specific theories of products liability, whether strict liability or otherwise, did not displace other claims of negligence, and that each theory of liability must be analyzed in terms of the relevant facts and legal principles. *Wright*, 652 N.W.2d at 176; *Hawkeye*, 174 N.W.2d at 685.

Long before we made these analytical refinements to our law of products liability in *Wright*, we confronted certified questions from a federal case involving parents who had suffered damages as a result of the mother's ingestion of DES during pregnancy. *See Mulcahy v. Eli Lilly & Co.*, 386 N.W.2d 67, 69 (Iowa 1986). Unable to identify the manufacturer of the DES ingested by the mother, the parents brought suit against twenty-five drug companies who had manufactured or marketed DES during the period in which the mother had ingested it. *Id.*

The parents brought claims of strict liability, negligence, misrepresentation, and breach of warranty, among others. *Id.* We made no reference to whether specific claims of manufacturing defect, design defect, failure to warn, or any others had been advanced, but we gave no indication we had any occasion to consider the DES manufacturers' liability for claims of design defect or failure to warn.[19] *See id.* at 69–70.

Setting forth legal principles applicable for analyzing the parents' tort claims, we noted a "plaintiff in a products liability action must ordinarily prove that a manufacturer or supplier produced, provided or was in some way responsible for the particular product that caused the injury." *Id.* at 70. As authority for that proposition, we cited the Restatement (Second) of Torts section 402A—the strict liability provision having no application to negligence claims—and our earlier case of *Osborn v. Massey-Ferguson, Inc.*, 290 N.W.2d 893, 901 (Iowa 1980). *Mulcahy*, 386 N.W.2d at 70. In *Osborn*, we had similarly noted claims of strict liability for manufacturing defects typically involve a requirement of manufacture by the defendant, but we had distinguished the negligence claims at issue and noted those claims were to be analyzed in accordance with our standard negligence principles. *See Osborn*, 290 N.W.2d at 901; *see also Wright*, 652 N.W.2d at 168 (explaining principles underlying "strict liability [are] appropriate in manufacturing defect cases, but negligence principles are more suitable for other defective product cases"). We cited our earlier case of *Schiltz v. Cullen-Schiltz & Associates, Inc.*, 228 N.W.2d 10, 16–18 (Iowa 1975), as illustrative of the appropriate negligence analysis. *Osborn*, 290 N.W.2d at 901.

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[19]Our failure to address the theories of design defect and failure to warn might be attributable to the fact the DES manufacturers were manufacturers, and to the fact we had not often distinguished those claims from claims for manufacturing defect at that point. *See Mulcahy*, 386 N.W.2d at 69–70.

In *Schiltz*, we had encountered a claim alleging defective design of a sewage treatment facility. *Schiltz*, 228 N.W.2d at 17. We explained that to prevail on a claim of negligent design by the engineers, the claimant must prove the work fell short of the "degree of skill, care and learning ordinarily possessed and exercised" in the engineering profession and the substandard care resulted in the damage. *Id.* Notably, our negligence analysis in *Schiltz* imposed no requirement that the engineers had built or manufactured the defective sewage treatment facility. *See id.* Indeed, they had not, as they had merely provided plans and specifications for the facility's construction to an independent contractor, who had independent obligations to inspect the site and circumstances attending the project and to diligently pursue, supervise, and complete the construction. *Id.* at 12–13. Instead, for purposes of the negligence analysis, we made clear the important questions in *Schiltz* were whether the engineers had negligently designed the facility and whether that negligence had caused the damages suffered. *Id.* at 17; *see also McCarthy v. J.P. Cullen & Son Corp.*, 199 N.W.2d 362, 367–68 (Iowa 1972) (examining architects' duties with respect to plans and specifications and noting duty extended to protection of owners of adjacent properties from harms "which reasonably could be expected to flow from" the plans).

We acknowledged and employed the principles of these cases in *Mulcahy* neither to elide theories of strict liability and negligence, nor to suggest all products liability claims were to be treated as claims of manufacturing defect, but to ensure a "causal connection between the defendant's product and plaintiff's injury." *Mulcahy*, 386 N.W.2d at 70. Our general negligence principles, we noted, require a claimant to prove "the defendant caused the complained of harm or injury." *Id.* at 72. In a

case involving so many apparent manufacturers of DES, some of which had not been named as defendants, we explained, the claimants could not prove any of the named defendants "was in some way responsible for," or had actually "caused the injury to" the plaintiff. *Id.* at 70, 72. In a case involving fewer manufacturers, we noted, the plaintiff might not have run up against the same causation problem—if, for instance, the "plaintiff established that only two manufacturers' DES products were sold at a certain pharmacy, and [she] bought her DES only at that pharmacy but c[ould not] identify which brand she purchased." *Id.* at 73. Other theories of liability, such as enterprise liability, might also have "avoid[ed] the legal causation problem that arises from an inability to identify the manufacturer of the specific injury-causing product" in cases involving so many possible responsible parties, but we found those theories inapplicable given the facts before us. *Id.* at 72. Instead, given the sheer number of possibly responsible parties, we declined to adopt the special liability theories advanced by the plaintiffs and concluded we would not impose "liability upon a manufacturer for harm it may not have caused." *Id.* at 76.

Based on our products liability principles, and based on the specific problem at issue in *Mulcahy*, I believe our *Mulcahy* analysis provides useful but limited guidance for our resolution of the case before us. We are not faced here with a claim of strict liability for manufacturing defect on behalf of the brands, and thus the strict liability causation requirement that the manufacturer be responsible for the manufacturing defect, set forth in cases like *Hawkeye* and *Osborn* and imported in *Mulcahy*, is inapplicable here. *See Mulcahy*, 386 N.W.2d at 70; *Osborn*, 290 N.W.2d at 901; *Hawkeye*, 174 N.W.2d at 684; *see also Wright*, 652 N.W.2d at 164. More importantly for purposes of our

analysis with respect to the claims of negligence here, we are not faced with a case involving numerous possibly responsible defendants or involving the possibility an unnamed party might actually be responsible for the harm suffered in lieu of any named defendant. *See Mulcahy*, 386 N.W.2d at 71–72. Instead, by contrast, the parties here have stipulated to the relevant facts: the brands designed and manufactured branded Reglan; PLIVA manufactured the generic product actually ingested; and federal laws and regulations establish various obligations for PLIVA and the brand defendants. The causation problem we identified in *Mulcahy* therefore does not present itself here, and although our exposition of general negligence principles has application here, *Mulcahy* gives us no specific guidance as to how to resolve the negligence claims in scenarios like this one where all relevant actors have been identified. Instead, the negligence principles we have set forth in numerous cases like *Schiltz* must guide our resolution here, and those cases have never required an actor who has breached an obligation of care be a manufacturer for purposes of tort liability. *See Schiltz*, 228 N.W.2d at 17–18; *see also Bredberg v. PepsiCo, Inc.*, 551 N.W.2d 321, 327 (Iowa 1996) (noting product designers are also subject to strict liability claims).

Moreover, the brands have not offered any explanation as to why we must treat them as manufacturers for purposes of our negligence analysis. In fact, all parties involved have stipulated the brands were *not* manufacturers of generic metoclopramide at the time of Huck's ingestion. As noted, we have in numerous prior products liability cases held an actor need not be a manufacturer for purposes of analyzing liability, regardless whether the claim is one of negligence or strict liability. *See Weyerhaeuser v. Thermogas Co.*, 620 N.W.2d 819, 825 (Iowa 2000) (noting several justifications for holding an assembler liable in both

negligence and strict liability for the failure of a component it did not manufacture); *Bredberg*, 551 N.W.2d at 327; *Schiltz*, 228 N.W.2d at 18; *cf*. *Wright*, 652 N.W.2d at 169 (adopting sections 1 and 2 of the Restatement (Third) of Torts: Products Liability); *Clark v. McDaniel*, 546 N.W.2d 590, 592–94 (Iowa 1996) (holding used-car dealer liable for misrepresentation of car quality). Our negligence cases have always required a negligent act or omission on the part of an actor, causation, and damages within the actor's scope of liability. *See, e.g.*, *Thompson v. Kaczinski*, 774 N.W.2d 829, 834 (Iowa 2009); *Stotts v. Eveleth*, 688 N.W.2d 803, 807 (Iowa 2004); *Van Essen v. McCormick Enters. Co.*, 599 N.W.2d 716, 718 (Iowa 1999). As we have taken great care to emphasize in our products liability cases, no principle of products liability law displaces that framework. *See Wright*, 652 N.W.2d at 164; *Hawkeye*, 174 N.W.2d at 685.

Courts from numerous jurisdictions have recognized these principles and declined to dismiss claims against brand defendants given similar factual circumstances. *See, e.g.*, *Dolin v. SmithKline Beecham Corp.*, No. C6403, 2014 WL 804458, at *6 (N.D. Ill. Feb. 28, 2014) ("[T]hese parties stood in a relationship to one another that, while clearly not 'direct,' was sufficient for the law to impose a duty of reasonable conduct upon GSK for the benefit of Plaintiff."); *Chatman v. Pfizer, Inc.*, 960 F. Supp. 2d 641, 654 (S.D. Miss. 2013) ("Chatman may pursue her common-law claims under 'old' state law theories of liability, even though she may have been injured by a product manufactured by another."); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 704 (D. Vt. 2010) ("To date, however, Vermont has not eliminated common law actions for negligence or fraud merely because they involve products."); *Easter v. Aventis Pasteur, Inc.*, No. 5:03-CV-141 (TJW), 2004 WL 3104610, at *9 (E.D. Tex.

Feb. 11, 2004) ("Lilly, as a designer, has a duty to develop a safe design for thimerosal. Also, Lilly's design of and intimate knowledge about thimerosal also gives rise to a duty to inform users of hazards associated with the use of thimerosal. Therefore, the Court finds that the plaintiffs have adequately stated a design defect claim against Lilly."); *Wyeth, Inc. v. Weeks*, ___ So.3d ___, ___, 2013 WL 135753, at 19 (Ala. Jan. 11, 2013), *reargument granted* (June 13, 2013) ("Under Alabama law, a brand-name drug company may be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture of a brand-name prescription drug, by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company."); *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 320–21 (Ct. App. 2008) ("We hold that Wyeth's common-law duty to use due care in formulating its product warnings extends to patients whose doctors foreseeably rely on its product information when prescribing metoclopramide, whether the prescription is written for and/or filled with Reglan or its generic equivalent."); *Lance v. Wyeth*, 85 A.3d 434, 461 (Pa. 2014) ("There has been no supported presentation here which would persuade us to immunize companies from the responsibility to respond in damages for such a lack of due care resulting in personal injury or death."); *Clark v. Pfizer, Inc.*, No. 1819, 2008 Phila. Ct. Com. Pl. LEXIS 74, *29 (Ct. Com. Pl. 2008) ("[T]he relationship between the purchasers of generic Gabapentin and these defendant [brand] manufacturers herein is that of purchaser of drugs which never would have been purchased but for defendants' [conduct]."). *See generally* Allen Rostron, *Prescription for Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers*, 60 Duke L.J. 1123, 1160 (2011) [hereinafter Rostron] (noting courts have recognized "[n]egligence and strict products

liability are separate and distinct bases for liability" and "do not automatically collapse into each other merely because there are some situations in which a plaintiff might be able to assert both types of claims" (internal quotation marks omitted)).

Several courts have recognized that given the obligations created by the Hatch-Waxman Act, the causation problem we identified in *Mulcahy* is inapplicable here, because "whether a consumer ingests the name-brand or generic version of a given drug is immaterial as to the likelihood that negligence in the design or warning label of that drug will cause injury." *Dolin,* 2014 WL 804458, at *5; *see also, e.g., Schedin v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F. Supp. 2d 1125, 1131 (D. Minn. 2011) ("[u]nder the pre-2007 statutory framework . . . a brand-name manufacturer was the only entity in the trifecta of actors (the FDA, the brand-name manufacturer, and the generic) that could strengthen an inadequate label."), *aff'd in part, rev'd in part on other grounds*, 700 F.3d 1161 (8th Cir. 2012); *Kellogg*, 762 F. Supp. 2d at 702 ("A reasonable jury could conclude that inadequate, misleading and inaccurate information provided by the [brand defendants] was a . . . cause of her injury."); *Weeks*, 2013 WL 135753, at *19 ("In short, the patient must show that, but for the false representation made in the warning, the prescribing physician would not have prescribed the medication to his patient."); Rostron, 60 Duke L.J. at 1164 ("Throughout the long line of precedent that flowed out of *Foster*, courts have repeatedly made the same mistake, dwelling on the irrelevant concept of liability being imposed on multiple manufacturers because of uncertainty about who made a product and conflating that concept with the separate and distinct issue of whether a manufacturer can be liable for wrongdoing other than making and selling the product the plaintiff received."). Several courts have reasoned "case

law, commonsense and fairness dictates" the brands cannot both avoid claims of strict products liability on the ground they *were not* manufacturers of the generic version of the drug, and avoid claims of negligence on the ground they *were* manufacturers of some other drug. *Chatman*, 960 F.Supp.2d at 653 ("[T]hey cannot have it both ways."); *see also Dolin*, 2014 WL 804458, at *4 ("GSK has not shown why Plaintiff should be precluded from claiming at common law that GSK, independent of its capacity as a manufacturer . . . was negligent in connection with its [other responsibilities] . . . .").

Many courts have recognized proper resolution of negligence claims turns not on a question of whether a product is somehow involved, but on an analysis of traditional negligence principles. *See, e.g., Dolin,* 2014 WL 804458, at *4–5 (rejecting defense of manufacturer immunity and applying Illinois negligence law to claims against brand defendants); *Easter*, 2004 WL 3104610, at *9 (rejecting defense of manufacturer immunity and applying Texas negligence law to claims against brand defendants); *Lance*, 85 A.3d at 458–60 (rejecting defense of manufacturer immunity and applying Pennsylvania negligence law to claims against brand defendants); *see also Kolarik v. Corey Int'l Corp.*, 721 N.W.2d 159, 162–63, 166 (Iowa 2006) (noting olives were "products" for purposes of products liability and nevertheless allowing plaintiff to proceed on general negligence claim for failure to warn).

Finally, several courts have persuasively argued a decision to eviscerate an enormous segment of our negligence law and "immunize companies from the responsibility to respond in damages for such a lack of due care resulting in personal injury" is a "weighty and consequence-laden policymaking" judgment best left to Congress and the state legislatures—none of which have granted such immunity just yet. *Lance*,

85 A.3d at 461–62; *see also Chatman*, 960 F.Supp.2d at 654–55 (noting "the Mississippi legislature has abolished the requirement of privity 'in all causes of action for personal injury . . . brought on account of negligence' " (quoting Miss. Code Ann. § 11-7-20 (West, Westlaw through 2014 Regular (end) and First Extraordinary (end) Sess.)); *Kellogg*, 762 F.Supp.2d at 704 ("Neither the Vermont courts nor the Vermont legislature have collapsed negligence actions into strict liability actions where products are involved.").

I believe each of these principles is applicable in the case before us, and I believe both our law of products liability and our law of negligence dictate the brand defendants may be subject to liability here. As numerous authorities have noted, the causation problem the majority has identified in *Mulcahy* is irrelevant given the facts and claims before us. Instead, we must analyze the claims given our long-standing principles of negligence—a task I turn to now.

II. Duty.

We have often noted that while summary adjudication is rarely appropriate in negligence cases, the determination of whether a duty is owed under particular circumstances is a matter of law for the court's determination. *See*, e.g., *Hoyt v. Gutterz Bowl & Lounge L.L.C.*, 829 N.W.2d 772, 775 (Iowa 2013); *Thompson*, 774 N.W.2d at 834. In *Thompson*, we adopted the duty analysis of section 7 of the Restatement (Third) of Torts: Liability for Physical and Emotional Harm, and we concluded an actor generally has a duty to exercise reasonable care when the actor's conduct creates a risk of physical harm. *Thompson*, 774 N.W.2d at 835; *see also Feld v. Borkowski*, 790 N.W.2d 72, 75 (Iowa 2010) ("As a general rule, our law recognizes that every person owes a duty to exercise reasonable care to avoid causing injuries to others.").

We explained that in most cases, a court need not concern itself with the existence or content of the duty, and should instead proceed to analysis of the remaining elements of negligence liability. *Thompson*, 774 N.W.2d at 835; *see also Feld*, 790 N.W.2d at 76. In exceptional cases, we noted, an actor's general duty to exercise reasonable care might be displaced or modified based on countervailing policy considerations justifying limited or no liability in certain classes of cases—but those policy reasons were not to depend on the specific facts of any given case. *Thompson*, 774 N.W.2d at 835. In detailing this analysis more recently, we have noted we may look to the comments and principles of the current Restatement, the comments and principles of prior Restatements, and our prior caselaw in determining whether policy considerations dictate departure from our general recognition of a duty to exercise reasonable care in particular broadly drawn classes of cases. *See McCormick v. Nikkel & Assocs., Inc.*, 819 N.W.2d 368, 371–74 (Iowa 2012).

A. Applicable Duty Principles From Our Caselaw and the Restatements of the Law. The drafters of the Restatement (Third) have set forth several important duty principles to guide us in our analysis here. The drafters explain an actor's business operations may provide a fertile source for natural risks or third-party misconduct that creates risks that would not have occurred in the absence of the business. Restatement (Third) of Torts: Liab. for Physical & Emotional Harm § 37 cmt. *d*, at 5 (2012). Section 19, they note, specifically sets forth the standard of care for scenarios where an actor's conduct increases the risk of third-party conduct causing harm. *Id.* We adopted that reasoning in *Hoyt*, where we concluded the duty of care applies to all risks arising from a given course of conduct, even if also created in part

by a third party's conduct, regardless "whether innocent, negligent, or intentional." *Hoyt*, 829 N.W.2d at 779. In cases where business operations provide a source of risk, the drafters note, "the actor's conduct creates risks of its own and, therefore, is governed by the ordinary duty of reasonable care in [section] 7." Restatement (Third) of Torts: Liab. for Physical & Emotional Harm § 37 cmt. *d*, at 5.

The drafters also note section 315 of the Restatement (Second) of Torts has often led to pronouncements that "absent a special relationship an actor owes no duty to control third parties." *Id.* Section 315, however, addressed only affirmative duties to control third parties—it had nothing to say about "the ordinary duty of reasonable care with regard to conduct that might provide an occasion for a third party to cause harm." *Id.* The Restatement (Second) actually addressed that latter scenario in section 302B, the drafters explain, in providing for a duty of care when an actor's conduct " 'has created or exposed the other to a recognizable high degree of risk of harm through such [third-party] misconduct.' " Restatement (Third) of Torts: Liab. for Physical & Emotional Harm § 37, cmt. *d*, at 5 (quoting Restatement (Second) of Torts § 302B cmt. *e*, at 90). Thus, the drafters note, both the Restatement (Second) and the Restatement (Third) provide for liability when actors engage in conduct that increases the magnitude of natural or third-party risks. *Id.* § 37, cmt. *d*, at 4–5. Even when the actor and victim are complete strangers and have no relationship, the drafters explain, the basis for the ordinary duty of reasonable care under section 7 is conduct creating risk to another. *Id.* § 37 cmt. *b*, at 3; *see also West v. Broderick & Bascom Rope Co.*, 197 N.W.2d 202, 209 (Iowa 1972) (noting Iowa courts have "extricat[ed] themselves from the erroneous imposition of the privity requirement"). A relationship, in other words, does not typically

define the line between duty and no duty—instead, the line is drawn by conduct creating risk to another. Restatement (Third) of Torts: Liab. for Physical & Emotional Harm § 37 cmt. *b*, at 3; *see, e.g., Keller v. State*, 475 N.W.2d 174, 179 (Iowa 1991) ("[L]inking the existence of legal duty to a particular relationship between the parties is not an unwavering requirement for all negligence torts."); *see also Chatman*, 960 F. Supp. 2d at 654 ("As a general rule, in the context of negligence claims a relationship is *not* necessary for a duty to exist."); *Gipson v. Kasey*, 150 P.3d 228, 232 (Ariz. 2007) ("A special or direct relationship, however, is not essential in order for there to be a duty of care.").

Further, the Restatement (Third) devotes an entire section to conduct creating an ongoing risk of physical harm, in providing "[w]hen an actor's prior conduct, even though not tortious, creates a continuing risk of physical harm of a type characteristic of the conduct, the actor has a duty to exercise reasonable care to prevent or minimize the harm." Restatement (Third) of Torts: Liab. for Physical & Emotional Harm § 39, at 31. As the drafters make clear, the initial conduct need not be actionable or even tortious for a duty to arise under the section. *Id.* § 39 cmt. *c*, at 31. In addition, they explain that even in the rare case a court declines to apply the general section 7 duty we have recognized in our caselaw, an actor will nonetheless have an ongoing duty to use reasonable care to warn or otherwise mitigate risk under section 39. *Id.* § 39 cmt. *d* at 33–34.. Even if the actor does not *know* his or her conduct has created a risk of harm, the drafters point out, the duty provided in section 39 exists. *Id.* § 39 cmt. *d*, at 34. In that case, however, "[b]efore a *breach* of the duty occurs . . . an objectively foreseeable risk of harm must exist," and that question, the drafters note, "is a question of fact for the jury." *Id.* § 39 cmt. *d*, at 34–35. The

section 39 duty, the drafters explain, is justified both by an actor's creation of a risk, even if nontortiously, and by "the absence of the pragmatic and autonomy explanations" for the no-duty rule set forth in section 37.[20] *Id.* § 39 cmt. *c*, at 32. We have recognized the principles expressed in section 39 for many years. *See, e.g.*, *Lovick* 588 N.W.2d at 696 ("Our decision today confirms the existence of a post-sale duty for manufacturers to warn . . . ."); *see also Mercer v. Pittway Corp.*, 616 N.W.2d 602, 623–24 (Iowa 2000) ("[T]he inquiry is whether a reasonable manufacturer knew or should have known of the danger, in light of the generally recognized and prevailing best scientific knowledge, yet failed to provide adequate warning to users or customers.").

Section 552 of the Restatement (Second) of Torts provides additional insight. This section, setting forth requirements for the tort of negligent misrepresentation, provides that an actor supplying false information for the guidance of others may be liable for losses caused by justifiable reliance upon the information. *See* Restatement (Second) of Torts § 552, at 126–27. We have a long history of applying the section 552 principles in Iowa, and we have noted our caselaw ensures those liable are in a position to weigh potential uses of the information against

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[20]Section 37 of the Restatement (Third) provides the standard autonomy-based no-duty rule: "An actor whose conduct has not created a risk of physical or emotional harm to another has no duty of care to the other unless a court determines that one of the affirmative duties provided in §§ 38–44 is applicable." Restatement (Third) of Torts: Liab. for Physical & Emotional Harm § 37, at 2. The most common justification for this rule, the drafters note, "relies on the liberal tradition of individual freedom and autonomy" and places limits on "requiring affirmative conduct." *Id.* § 37 cmt. *e*, at 5. Tensions between the section 37 justification and our common "values about humanitarian conduct" is reflected in the numerous exceptions to the rule elsewhere in the Restatement. *Id.* § 37 cmt. *e*, at 6. The section 37 rule also has other less common pragmatic justifications, the drafters explain, such as the concern that an affirmative duty to aid others in peril might be confused with a general duty of self-sacrifice. *Id.* § 37 cmt. *e*, at 5–6. As the drafters note, the rule has no application in any case where "the entirety of the actor's conduct . . . [has] created a risk of harm." *Id.* § 37 cmt. *c*, at 3.

the potential magnitude and probability of loss if the information is inadequate or incorrect. *See Van Sickle Const. Co. v. Wachovia Commercial Mortg., Inc.*, 783 N.W.2d 684, 691–92 (Iowa 2010).

As the drafters of the Restatement (Second) recognized long ago, "[w]hen there is a public duty to supply the information in question . . . the maker of the negligent misrepresentation becomes subject to liability to any of the class of persons for whose benefit the duty is created." Restatement (Second) of Torts § 552 cmt. *k*, at 138. The rule, the drafters explained, applies to both public officers and private individuals or corporations required by law to file information for the benefit of the public. *Id.* § 552 cmt. *k*, at 139. In cases where the group to be protected by the filing requirement is a broad one, the drafters noted, a corporation might be liable to "any one who may reasonably be expected to rely on the information and suffer loss as a result." *Id.* As an illustration of the principle, the drafters offered the following example:

> A, a United States government food inspector, in the performance of his official duties, negligently stamps a quantity of B's beef as "Grade A." In fact the beef is of inferior quality. In reliance upon the stamps, C buys the beef from D, and suffers pecuniary loss as a result. A is subject to liability to C.

Restatement (Second) of Torts § 552 illus. 18, at 139; *see also id.* § 552 cmt. *i*, at 136 ("When a misrepresentation creates a risk of physical harm to the person, land or chattels of others, the liability of the maker extends, under the rules stated in §§ 310 and 311, to any person to whom he should expect physical harm to result through action taken in reliance upon it.").

We have applied reasoning presaging the drafters' section 552 analysis for more than a century here in Iowa. *See, e.g., Warfield v. Clark*, 118 Iowa 69, 72–73, 91 N.W. 833, 835 (1902) ("If the defendant in

fact falsely reported the financial condition of his company for the purpose of deceiving the public in relation to its responsibility as an insurer, it seems clear to us that we should not say as a matter of law that he only intended to wrong that particular class, and that those dealing in its stock were not his intended victims; for he knew that stock in such companies was often bought and sold, and that reliance might be placed upon his sworn statement by those dealing therein."). As a general proposition, we have long recognized and continue to recognize an actor may be liable to third parties who reasonably rely upon information prepared by the actor where the actor has reason to believe the information will be relied upon by the third party. *See, e.g.*, *Van Sickle,* 783 N.W.2d at 691; *Ryan v. Kanne*, 170 N.W.2d 395, 403 (Iowa 1969). The point of this discussion, of course, is not that a brand defendant must owe a duty to a consumer under section 552; the point, instead, is the tort of negligent misrepresentation is another illustration of the principle that an actor may create a risk of harm and thus owe a duty to another even in the absence of having sold or manufactured a product. Accordingly, the majority misses the mark in concluding the brand defendants owe no duty to Huck because they never sold her a product.

Similarly, just as we have applied the duty principles of the Restatement (Second) for many years, we have also applied the duty principles of the Restatement (Third) both before and after our adoption of the section 7 general duty in *Thompson*. *See, e.g., Bohan v. Hogan,* 567 N.W.2d 234, 237 (Iowa 1997) ("An act or omission may be negligent if the actor realizes or should realize that it involves an unreasonable risk of harm to another through the negligent or reckless conduct of the other or a third person." (quoting Restatement (Second) of Torts § 302A, at

86)); *Fiala v. Rains*, 519 N.W.2d 386, 389 (Iowa 1994) (same); *see also Mitchell v. Cedar Rapids Cmty. Sch. Dist.,* 832 N.W.2d 689, 702 (Iowa 2013) ("[W]e have adopted the duty principles of the Restatement (Third) . . . ."); *Hoyt*, 829 N.W.2d at 775–76, 776 n.4 (examining duty principles of Restatement (Third) sections 7, 19, 37, and 40).

Our analysis in *Bohan* is particularly illustrative of this point. *See Bohan,* 567 N.W.2d at 235–37. In *Bohan*, a group of investors brought negligence claims for losses suffered as a result of a deception by a securities broker. *Id.* at 235. The broker had secured funds from the investors by delivering them fictitious certificates of deposit purporting to have been issued by a Chicago bank. *Id.* At issue in the case were not the claims of the investors against the broker, but the investors' claims against a small Iowa printer who had printed the certificates, without knowledge of the deception, at the broker's request. *Id.* Despite the printer's lack of knowing involvement in the broker's scheme, and despite the lack of any special relationship between the printer and the investors, we reasoned the investors had stated a claim of the printer's "own active negligence in furnishing an instrumentality that caused harm to these claimants." *Id.* at 236. With the aid of the principles set forth in Restatement (Second) section 302B, and later in Restatement (Third) sections 7, 19, and 37, we concluded a duty to exercise reasonable care exists when an actor's conduct creates a risk of harm, even if the risk involves the negligent or reckless conduct of another. *See id.* at 236–37. No special relationship, we explained, was required between the parties to give rise to the duty. *Id.* at 237. We were thus "unable to conclude that there could be no set of facts proved that would support a claim of actionable negligence on the part of" the printer. *Id.* at 236.

Our cases following *Thompson* have applied the same principles. In *Feld*, we explained all actors owe a duty to exercise reasonable care to avoid causing injury to others, and the actor may be liable if the injury caused by the actor's conduct resulted from the risks rendering the actor's conduct negligent. *Feld*, 790 N.W.2d at 75–76; *see also* Restatement (Second) of Torts § 284(a), at 19 (providing negligent conduct includes acts "which the actor as a reasonable man should recognize as involving an unreasonable risk of causing an invasion of an interest of another"). We noted our long-standing contact-sports exception to the general duty to exercise reasonable care, and noted various policy reasons supported our modification of the general duty in the realm of slow-pitch high school softball. *Feld*, 790 N.W.2d at 76–78. We retained the general duty for that class of cases, but modified it such that actors in slow-pitch softball games now have a duty to avoid reckless disregard for the safety of others. *Id.* Similarly, in *McCormick*, we noted we had affirmed our law recognizing the general duty in *Thompson* and explained an actor generally has a duty to exercise reasonable care when the actor's conduct creates a risk of physical harm. *McCormick*, 819 N.W.2d at 371, 374. Concluding the subcontractor there owed no duty to a property owner's employee who had been electrocuted by a switchgear, we explained the subcontractor had not "create[d] a 'risk of physical harm,' " and thus our general negligence principles and the principles of the Restatement (Third) would not support liability. *Id.* at 374–75 (quoting Restatement (Third) of Torts: Liab. for Physical & Emotion Harm § 7(a), at 77). Finally, in *Hoyt*, we reiterated our long-standing rule that an actor has a duty to exercise reasonable care when his or her conduct creates a risk of harm, while explaining no-duty rulings should be limited to exceptional classes of

cases invoking specifically articulated countervailing policy considerations. *Hoyt*, 829 N.W.2d at 775.

Notably, we never invoked the duty question at all in *Bredberg* or *Mulcahy*. *See Bredberg*, 551 N.W.2d at 323–29; *Mulcahy*, 386 N.W.2d at 69–76. The majority appears to agree *Mulcahy* had nothing to say about duty—the court there was concerned with the majority's proposed "product-identification causation requirement," because the existence of a duty was never in question. The duty principle most prominently applicable in both *Mulcahy* and *Bredberg* was surely the long-standing strict products liability principle that "the seller, by marketing his product for use and consumption, has undertaken and assumed a special responsibility toward any member of the consuming public who may be injured by it." Restatement (Second) of Torts § 402A cmt. *c*, at 349; *see also Bredberg*, 551 N.W.2d at 326–27 (citing section 402A); *Mulcahy*, 386 N.W.2d at 70 (same); *see also Moore v. Vanderloo*, 386 N.W.2d 108, 117 (Iowa 1986) ("A drug manufacturer may be held liable for a defective product in a strict liability action.").

That strict liability principle, however, was not the *only* principle resolving the duty question in those cases or any other products liability cases, because as we have long noted, our long-standing general duty of reasonable care is also applicable in these cases. *See, e.g., Osborn*, 290 N.W.2d at 901 (citing cases examining "defective design of a product or project as negligence"); *see also Lovick,* 588 N.W.2d at 696 (confirming duty to exercise reasonable care in post-sale warning); *Cooley v. Quick Supply Co.*, 221 N.W.2d 763, 771 (Iowa 1974) (explaining question of whom should receive warning is "to be decided [by a jury] by standards of reasonable care."); *Hawkeye*, 174 N.W.2d at 685; *Bengford v. Carlem Corp.*, 156 N.W.2d 855, 864 (Iowa 1968) ("Applying these rules to the

evidence in this case it seems clear a jury could find defendant, Ford Motor Company, failed to follow these recognized standards of care and that as a proximate cause thereof plaintiff was injured."); *Wagner v. Larson*, 257 Iowa 1202, 1222, 136 N.W.2d 312, 324 (1965) ("If a manufacturer does everything necessary to make the machine function properly . . . then the manufacturer has satisfied the law's demands." (quoting *Campo v. Scofield*, 95 N.E.2d 802, 804 (N.Y. 1950))). As we have more recently explained, affirmative duties created as a result of a special relationship or undertaking, like the strict liability duty, may often overlap with the general duty, but the existence of an affirmative duty does not displace the general duty. *See, e.g., Hoyt*, 829 N.W.2d at 775–76; *see also Hawkeye*, 174 N.W.2d at 685; Restatement (Third) of Torts: Liab. for Physical & Emotional Harm § 6 cmt. *e*, at 68–69 (explaining special rules of law, "such as various rules of strict liability," may impose liability even in the absence of the general duty, and noting Restatement (Third) of Torts: Products Liability details those strict liability rules); *id.* § 40 cmt. *c*, at 40 (explaining relationship between general and affirmative duties); *id.* § 40 cmt. *h*, at 42–43 (same).

B. Application of Our Duty Principles. Applying our duty principles as we always have, the existence of a duty should not be controversial here. The brand defendants created risks in designing and manufacturing Reglan®, and created risks in developing its warning, which, by virtue of federal law, generics were required to mimic. Those risks gave rise to duties. These are not novel propositions in our caselaw. *See, e.g., Cooley*, 221 N.W.2d at 771 (requiring "reasonable assurance that the information will reach those whose safety depends upon their having it" (internal quotation marks omitted)); *West*, 197 N.W.2d at 209 (noting we recognize a duty of reasonable care "as to any

product which [an actor] can reasonably expect to be dangerous if he is negligent in its manufacture or sale"); *Tice v. Wilmington Chem. Corp.*, 259 Iowa 27, 43, 141 N.W.2d 616, 626 (1966) ("When a manufacturer, distributor, producer or retailer markets a product with representations as to its condition there should most certainly be imposed a strict accountability where the ultimate consumer relies upon those representations and suffers injury. . . ."); *see also PLIVA, Inc. v. Mensing*, 564 U.S. ___, ___, 131 S. Ct. 2567, 2585–86, 180 L. Ed. 2d 580, 600–01 (2011) (Sotomayor, J., dissenting) (noting FDA requires drug companies " 'to seek to revise their labeling and provide FDA with supporting information about risks' " and explaining it is "undisputed" that drug companies "have a duty under federal law to monitor the safety of their products"); Restatement (Third) of Torts: Prods. Liab. § 6(c), at 145 (establishing duty of care to balance risks and benefits of prescription drugs with respect to design); *id.* § 6(d), at 145 (establishing duty of care to balance risks and benefits of prescription drugs with respect to instruction and warning); *cf. Lamb v. Manitowoc Co.*, 570 N.W.2d 65, 68 (Iowa 1997) ("A duty to warn exists when a party reasonably foresee[s] a danger of injury or damage to one less knowledgeable unless an adequate warning is given." (Internal quotation marks omitted.)). Neither the majority nor the parties have suggested we depart from our long-standing recognition of both general and special duties when an actor's conduct creates a risk of physical harm, and I believe our recognition of those duties settles the question here. *See* Restatement (Third) of Torts: Liab. for Physical & Emotional Harm § 7, at 77; *see also Hoyt*, 829 N.W.2d at 776–77; *Feld*, 790 N.W.2d at 75–76; *Thompson*, 774 N.W.2d at 835; Restatement (Second) of Torts § 327, at 146 ("One who knows or has reason to know that a third person . . . is ready to give to another aid

necessary to prevent physical harm to him, and negligently prevents or disables the third person from giving such aid, is subject to liability for physical harm caused to the other by the absence of the aid which he has prevented the third person from giving."). Whether countervailing policy considerations may modify those duties is a separate question, and a question the parties do not address directly, but I will analyze it in turn.

Before tackling that question, however, I note even application of a relation-based conception of duty would establish duties on behalf of the brands, because federal law establishes the brands' responsibility for both the design of the drug and the warning in question here. *See, e.g., Dolin*, 2014 WL 804458, at *4 (explaining brand "was responsible for" generic's "design and warning label"); *see also Mulcahy*, 386 N.W.2d at 70 (explaining liability may attach when actor "was in some way responsible for the particular product that caused the injury"); *Lance*, 85 A.3d at 453 n.24 (explaining "*federal law* also imposes post-marketing duties on pharmaceutical companies, including the obligation to 'ensur[e] that [their] warnings remain adequate as long as the drug is on the market' "). With respect to design, federal law requires the generic version's chemical equivalence to the approved brand-name drug: it must have the same "active ingredient" or "active ingredients," "route of administration," "dosage form," and "strength" as its brand-name counterpart. 21 U.S.C. § 355(j)(2)(A)(ii)–(iii) (2012). The generic must also be "bioequivalent" and have the same "rate and extent of absorption" as the branded drug. *Id.* § 355(j)(2)(A)(iv), (8)(B). With respect to the warning, as the majority explains, the FDA must approve the accuracy and adequacy of the brands' labeling, and generic drug manufacturers are required, by law, to show "the labeling proposed for the new drug is

the same as the labeling approved for the [approved brand-name] drug." *Id.* § 355(a), (b)(1), (d), (2)(A)(v). And, after initial approval of the new drug application, a brand manufacturer may update its label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product" by filing an application with the FDA, but it need not wait for FDA approval, and the generic manufacturers are subject to an ongoing obligation of sameness. 21 C.F.R. § 314.70(c)(6)(iii)(A), (C) (2008); *id.* §§ 314.94(a)(8), .127(a)(7); Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17950–01, 17961 (Apr. 28, 1992) ("[T]he [generic drug's] labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for [generic drug] approval."). Moreover, every state now has a drug substitution law, which requires pharmacists filling prescriptions under most circumstances to substitute generic alternatives for branded drugs when available. *Dolin*, 2014 WL 804458, at *5 n.5; *see also, e.g.*, Iowa Code § 155A.32 (2013).

There can be no doubt, then, the brands understood other manufacturers were producing generic versions of the drug, those versions were required by law to use the brands' design and warning label, consumers were purchasing those versions, and the brands had the ability both initially and upon later investigation to remedy any defects in the drug's design or warning. *Dolin*, 2014 WL 804458, at *5–6; *see also Henkel v. R & S Bottling Co.*, 323 N.W.2d 185, 192 (Iowa 1982) ("A manufacturer must anticipate the nature of the environment in which the product [will] be used and [design against] the foreseeable risk attending the product's use in that setting."). A mountain of authority from other jurisdictions supports recognition of a duty on the part of a

brand manufacturer given these considerations. *See Dolin*, 2014 WL 804458, at *6 ("[T]hese parties stood in a relationship to one another that, while clearly not 'direct,' was sufficient for the law to impose a duty of reasonable conduct upon GSK for the benefit of Plaintiff."); *Schedin*, 808 F. Supp. 2d at 1136 ("[T]he jury had sufficient evidence from which to conclude [the brand] breached its duty to warn and that this breach caused [the generic consumer's] injuries."); *see also Chatman*, 960 F. Supp. 2d at 655 ("In an affirmative misrepresentation case, even though a defendant does not have a relationship with the plaintiff, it is still possible for the defendant to be liable for causing the plaintiff's physical injury if the plaintiff reasonably relies on false information provided by the defendant"); *Kellogg*, 762 F. Supp. 2d at 706 ("To recognize that a brand name drug manufacturer owes a duty to use reasonable care to avoid causing injury to consumers of the generic bioequivalents of its drugs does not 'recognize a new cause of action or enlarge an existing one' . . . ."); *Easter*, 2004 WL 3104610, at *9 ("Lilly's design of and intimate knowledge about thimerosal also gives rise to a duty to inform users of hazards associated with the use of thimerosal."); *Weeks*, 2013 WL 135753, at *19 ("[I]t is not fundamentally unfair to hold the brand-name manufacturer liable for warnings on a product it did not produce because the manufacturing process is irrelevant to misrepresentation theories based, not on manufacturing defects in the product itself, but on information and warning deficiencies, when those alleged misrepresentations were drafted by the brand-name manufacturer and merely repeated by the generic manufacturer."); *Conte*, 85 Cal. Rptr. 3d at 315 ("We hold that Wyeth's duty of care in disseminating product information extends to those patients who are injured by generic metoclopramide as a result of prescriptions written in

reliance on Wyeth's product information for Reglan."); *Lance,* 85 A.3d at 457 ("Wyeth—as the proponent of a contraction of existing tort law—has failed to persuade us that federal regulatory involvement warrants a departure from Pennsylvania's system of civil redress, where there is a demonstrated lack of due care in the face of an existing duty."); *Clark*, 2008 Phila. Ct. Com. Pl. LEXIS 74, at *28–32 (concluding brand manufacturer owed duty to generic purchaser).

Accordingly, I believe both relation-based and risk-based conceptions of duty compel our recognition of a duty here.

C. Countervailing Policy Considerations. As noted, we have recognized categorical principles or policy considerations may sometimes provide a basis for modifying or eliminating our long-standing general duty of care for certain broadly drawn classes of actors. *See, e.g., Feld*, 790 N.W.2d at 76. In the context of prescription drugs, the drafters of the Restatement (Third) have explained the general trend has *not* been to disembowel the long-standing duty to warn—instead, courts have typically recognized the duty, and modified it slightly such that the duty is generally to warn and provide instructions to the prescribing physician. *See* Restatement (Third) of Torts: Liab. for Physical & Emotional Harm § 7 cmt. *i*, at 82. Of course, as the drafters recognize, even that minor modification is subject to important exception, as courts have generally recognized the duty to warn extends even to patients when a drug company "knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm." *See* Restatement (Third) of Torts: Prods. Liab. § 6(d)(2), at 145. Neither the parties nor the majority has advanced a suggestion we discard duties to warn generally in the pharmaceutical industry, and I do not believe any

court from any jurisdiction or any policy principle would support that approach.

I do not discount the impact of litigation on the pharmaceutical industry. I would note, however, we have been presented with very little information for purposes of undertaking any reasoned comparison of that impact with the substantial social impact of filleting our long-standing law of fault-based liability in Iowa. We do know the brands have been granted significant advantages in exchange for the burdens of responsibility they bear for drug design and labeling. They are entitled to an initial period of government-protected monopoly privileges in the form of patent protection. *See* 35 U.S.C. § 154. They are entitled to an extension of those monopoly privileges when generic versions of their drugs receive FDA approval. *See id.* § 156 (patent-term extension)*;* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in relevant part at 21 U.S.C. § 355 (1988)) (pairing generic approval with patent-term extension). We know they enjoy "the fiscal rewards of name-brand recognition and the commensurate ability to charge a higher price . . . , even after [their] exclusive marketing period expires." *Conte*, 85 Cal. Rptr. 3d at 317. Moreover, we know our recognition of a duty does not subject the brands to any *new* obligation here—as all parties involved concede, the brands are already subject to these obligations with respect to the branded versions, and the design and warning must remain the same for the generic versions.

Perhaps most importantly, we know Congress weighed each of these considerations in enacting the Hatch-Waxman amendments to the FDCA, and notably, made no reference to elimination of the brands' fault-based legal obligations. *See* Drug Price Competition and Patent

Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984). Indeed, I believe both courts and legislatures have typically regarded the tort system as providing powerful incentives to engage in responsible, reasonable behavior to promote safety in numerous industries, including the pharmaceutical industry. *See generally Wyeth v. Levine*, 555 U.S. 555, 578, 129 S. Ct. 1187, 1202, 173 L. Ed. 2d 51, 68–69. Our general assembly codified that recognition shortly after the Hatch-Waxman amendments, in noting our general tort duties are applicable even in products liability actions, to actors well outside the direct stream of product distribution in both negligence and strict liability. *See, e.g.*, Iowa Code § 668.12 (1987) ("Nothing [contained in subsection providing state-of-the-art defense] shall diminish the duty of an assembler, designer, supplier of specifications, distributor, manufacturer, or seller to warn concerning subsequently acquired knowledge of a defect or dangerous condition that would render the product unreasonably dangerous for its foreseeable use or diminish the liability for failure to so warn."); *see also Lovick*, 588 N.W.2d at 693 (explaining "section 668.12 clearly established our legislature's understanding of the duty").

Furthermore, as I have noted, the Supreme Court has rejected the notion that negligence claims against brand defendants for failure to warn based on state tort law are preempted by federal law. *See Levine*, 555 U.S. at 581, 129 S. Ct. at 1204, 173 L. Ed. 2d at 70. Yet, the majority quotes at length from an article authored by Professor Epstein asserting the Supreme Court got it wrong on preemption. Repurposing Epstein's rejected policy arguments favoring preemption, the majority advances them in favor of a no-duty rule in this case. As they failed in furtherance of preemption, they must come up short here as well.

Epstein would place great reliance on the expertise of the FDA in assessing the risks posed by medications to consumers, allocating the duty to warn, and regulating the content of warnings. But there is another side of the story. As the Supreme Court noted in *Levine*, the resources of the FDA are limited while the volume of regulated medications is vast. *Levine*, 555 U.S. at 578–79, 129 S. Ct. at 1202, 173 L. Ed. 2d at 68 (noting the FDA has limited resources with which to regulate 11,000 medications). This reality has prompted a former FDA commissioner, along with a noted administrative law authority, to express reservations about the agency's ability to effectively monitor the safety of the consuming public, and to affirm the ameliorative purposes served by state tort law:

> Our second concern is that the FDA's pro-preemption arguments are based on what we see as an unrealistic assessment of the agency's practical ability—once it has approved the marketing of a drug—to detect unforeseen adverse effects of the drug and to take prompt and effective remedial action. After all, there are 11,000 FDA-regulated drugs on the market (including both prescription and over-the-counter drugs), with nearly one hundred more approved each year. The reality is that the FDA does not have the resources to perform the Herculean task of monitoring comprehensively the performance of every drug on the market. Recent regulatory failures, such as the agency's ineffectual response to Vioxx, have demonstrated the FDA's shortcomings in this regard. Given the FDA's inability to police drug safety effectively on its own, we question the wisdom of the FDA's efforts to restrict or eliminate the complimentary discipline placed on the market by failure-to-warn litigation.
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> The information-gathering tools lawyers have in litigation are, by any measure, more extensive than the FDA's.
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> Statutory gaps in the FDA's authority to gather information, especially post-approval, hamstring its ability to ensure the

> safety of drugs on the market. The FDA Amendments Act may help close those gaps somewhat, but they remain substantial. . . . . The benefits of this litigation should not be discarded lightly, and, as we have said, we see no benefit to the FDA or the public in finding failure-to-warn litigation pre-empted.

David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 Geo. L. J. 461, 465, 492, 495 (2008). If the reasons advanced by Kessler and Vladeck—and by the Supreme Court in *Levine*—for rejecting preemption of failure-to-warn claims are to be given any practical recognition, they must apply with equal, if not greater, force to the majority's contention the courthouse doors should be closed to consumers like Huck by a court-made no-duty rule. *See Levine*, 555 U.S. at 592, 129 S. Ct. at 1210, 173 L. Ed. 2d at 77 (Thomas, J., concurring) ("Initial approval of a label amounts to a finding by the FDA that the label is safe for purposes of gaining federal approval to market the drug. It does not represent a finding that the drug, as labeled, can never be deemed unsafe by later federal action, or as in this case, the application of state law.").

It is instructive, in my view, that Congress has not chosen to preempt failure-to-warn cases brought against brands. The policy choice against preemption maintained by Congress during the more than seven decades of the FDA's existence evidences that the legislative branch values the salutary effects of tort law in this area. Congress clearly knows how to prescribe preemption, as it did so in the medical device field in 1976. *See* 21 U.S.C. § 360k(a) (2012); *Levine*, 555 U.S. at 574, 129 S. Ct. at 1200; 173 L. Ed. 2d at 66. The choice by Congress in eschewing preemption for brand pharmaceuticals reveals faith in the beneficial impact of the civil justice system in augmenting the protections afforded by the FDA. *See Levine*, 555 U.S. at 574, 129 S. Ct. at 1200,

173 L. Ed. 2d at 66 ("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."); *see also id.* 555 U.S. at 574, 129 S. Ct. at 1199–1200, 173 L. Ed. 2d at 65–66 ("Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1938 statute or in any subsequent amendment. Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers. It may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." (Footnote omitted.)); Rostron, 60 Duke L.J. at 1191 ("The FDA's regulatory oversight repeatedly has proven insufficient to prevent unreasonably dangerous drugs from reaching consumers. Tort law provides vital incentives for drug makers to act with appropriate care. Courts should apply tort law in a manner that encourages drug companies to continue producing innovative products but to act reasonably to ensure that their products are safe and accompanied by adequate warnings and accurate information. Striking the right balance is a challenge, but it is one that courts must continue striving to meet. These issues can quite literally be matters of life and death." (Footnote omitted.)); *cf.* Allison Stoddart, *Missing after* Mensing*: A Remedy for Generic Drug Consumers*, 53 B.C. L. Rev. 1967, 1998 (2012) ("The tort system incentivizes manufacturers to strengthen warnings by allowing tort claims against manufacturers when the probability of harm from an inadequate warning is greater than the burden of enhancing the warning—that is, when the manufacturer is negligent.").

The majority's claim that the pharmaceutical industry will be substantially harmed by a rule imposing a duty on the brands, who

controlled the content of the warning PLIVA was legally required to use, is, in my view, speculative and overblown. *See* Steven Garber, *Economic Effects of Product Liability and Other Litigation Involving the Safety and Effectiveness of Pharmaceuticals*, Rand Institute for Civil Justice, at xv (2013), *available at* www.rand.org/pubs/monographs/mg1259.html (suggesting policymakers should be "wary of broad claims about economic effects of pharmaceutical liability, including generalizations based on anecdotes or examples").[21] The safety-based regulations promulgated by the FDA can comfortably coexist with the brands' duty to exercise reasonable care in warning consumers of grave health risks attending the use of pharmaceuticals.[22] *See, e.g.*, *Levine*, 555 U.S. at

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[21]Although interests advocating restriction of tort liability contend certain products have been either withdrawn or withheld from the market because of the costs associated with the civil justice system, there is scarce direct empirical evidence supporting these contentions. Even if we were to credit the contentions, however, our analysis would require examination of additional crucial questions: Were the products bad or dangerous? Was their withdrawal from the market in the public interest? *See, e.g.,* Gary T. Schwartz, *Reality in the Economic Analysis of Tort Law: Does Tort Law Really Deter?*, 42 UCLA L. Rev. 377, 410–13 (1994) [hereinafter Schwartz].

[22]Principles of federalism and practicality bolster this understanding. Numerous commentators and authorities have recognized states are independent sovereigns in the federal system, and play a historic and important role in the local regulation of health and safety. *See, e.g.*, Ernest A. Young, *Federal Preemption and State Autonomy, in Federal Preemption: States' Powers, National Interests* 249, 251–52 (Richard A. Epstein & Michael S. Greve eds., 2007) (noting preemption problematically limits regulatory diversity by constraining state autonomy). Similarly, numerous commentators have noted tort claims operate as an important check even in federally regulated fields. *See, e.g.,* Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DePaul L. Rev. 227, 230–33 (2007) (criticizing the Consumer Product Safety Commission's inclusion of an express preemption clause in its mattress flammability standards as "[r]emoving a significant incentive for industries to improve outside of meeting the federal standard" (internal quotation marks omitted)); *see also* Thomas O. McGarity, *The Preemption War: When Federal Bureaucracies Trump Local Juries* 236–38 (2008) (explaining common law reinforces incentives for compliance with federal regulations, fills gaps for unanticipated consequences of regulations, and provides protection while agencies take time to formulate responses to problems); Schwartz, 42 UCLA L. Rev. at 385 ("Likewise, tort suits can (first) uncover and (then) dramatize information in a way that can set in motion a regulatory response."). *See generally* Thomas H. Sosnowski, *Narrowing the Field: The Case Against Implied Field Preemption of State Product Liability Law*, 88 N.Y.U. L. Rev. 2286, 2293–94 (2013).

593, 129 S. Ct. at 1211, 173 L. Ed. 2d at 78 (Thomas, J., concurring) ("The federal statute and regulations neither prohibited the stronger warning label required by the state judgment, nor insulated Wyeth from the risk of state-law liability."). As Robert Rabin has explained,

> Tort duties do not "require" anything other than the payment of damages. If tort liability does lead a defendant to a private assessment in favor of greater future precautionary measures, then tort, of course, has had a regulatory effect. But tort itself dictates no particular change in a losing defendant's conduct.
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> [T]here is no inexorable principle that productivity gains from uniform national health and safety standards—a frequently invoked rationale for preemption—should be borne by injury victims in cases of residual harm. Moreover, once again, it is critical to underscore the dynamics of tort. Liability does not entail enforced departure from regulatory standards; it only compels payment of damage awards.
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> If the tort claim rests on an assertion that substantial post-approval new evidence of risk has come to light, and has neither been incorporated into a revised warning, nor rejected by the agency as insubstantial, *the foundational risk/benefit analysis on which agency certification was based is inapposite. Hence, the tort claim is not an effort to revisit and supersede the regulatory approval process.*
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> In proposing a framework for addressing these tensions, based on focused examination of whether the agency directive is grounded in the same evidence-based risk/benefit inquiry as the tort process would entail, I join those commentators who seek to forge a path that recognizes the distinct benefits that both regulation and tort have to offer.

Robert L. Rabin, *Territorial Claims in the Domain of Accidental Harm: Conflicting Conceptions of Tort Preemption*, 74 Brook. L. Rev. 987, 991, 993, 1002, 1009 (2009) (emphasis added).

Given these considerations, and taking account of the vast range of information that must be weighed when balancing the interests of the pharmaceutical industry and those of consumers, I do not believe we are adequately equipped to craft a bright-line no-duty rule here. I would leave that policymaking to our general assembly, which has continued to recognize duties in this realm. I would therefore continue to hew to the long-standing and widespread recognition of the brands' general and affirmative duties here.

III. Factual Causation.

In addition to establishing the existence of a duty or duties, we have often explained in both products liability and traditional negligence cases the plaintiff "must establish a causal relationship between the alleged negligence and injury." *Lovick,* 588 N.W.2d at 700 (products liability); *accord Thompson*, 774 N.W.2d 836–39 (negligence). In the context of failure to warn claims, we have noted factual causation is established by demonstrating "a warning would have altered the plaintiff's conduct so as to avoid injury." *Lovick*, 588 N.W.2d at 700. More generally, as the drafters of the Restatement (Third) have provided, "[c]onduct is a factual cause of harm when the harm would not have occurred absent the conduct." Restatement (Third) of Torts: Liab. for Physical & Emotional Harm § 26, at 346; *accord Thompson*, 774 N.W.2d at 837–39 (adopting Restatement (Third) factual causation and scope of liability principles); *see also Asher v. OB-Gyn Specialists, P.C.*, 846 N.W.2d 492, 500 (Iowa 2014). This is tort law's familiar "but-for" test, and both the First and Second Restatements of Torts endorsed this standard in providing "the harm would not have occurred had the actor not been negligent." *See, e.g.*, Restatement (Second) of Torts § 431 cmt.

a, at 429; *see also* Restatement (Third) of Torts: Liab. for Physical & Emotional Harm § 26 cmt. *b*, at 347.

Here, as the majority explains, Dr. Gyano relies upon information published by the brands—for purposes of covering both branded versions of drugs and their generic counterparts—in the Physician's Desk Reference in making prescription decisions generally, and she relied on this information in 2004 to prescribe branded Reglan for Huck. Dr. Gyano has explained the risk–benefit analysis she uses in making prescription decisions has changed as a result of her access to the brands' updated information and labeling. She now supplements the conversation she typically has with patients with this risk–benefit information before making prescription decisions. Further, she has noted she would have modified her treatment conversations and decisions in the same way had she received this information back in 2004, and the information would have had the same impact. Finally, Dr. Gyano and Huck have explained had this information been available sooner, and had they discussed the implications back then, Huck would never have taken metoclopramide, and would never have developed tardive dyskinesia. Applying our principles of factual causation in straightforward fashion, we may safely conclude Huck has advanced evidence sufficient to allow a jury to find her harm would not have occurred had the brands not allegedly failed to satisfy their obligation of reasonable care, and similarly, she has advanced evidence sufficient to allow a jury to find a warning would have altered her conduct such that she would have avoided injury. *See Lovick*, 588 N.W.2d at 700 ("[C]aus[ation] can be established by showing a warning would have altered the plaintiff's conduct so as to avoid injury.").

Although that analysis resolves the factual causation question simply and completely, I think it prudent to point out several general principles relevant to the factual causation analysis in both products liability cases in general and in the case we actually confront here. *Dolin*, 2014 WL 804458, at *7 (noting courts have often "conflate[d] two facially similar, but fundamentally distinct, tort liability problems"); Rostron, 60 Duke L.J. at 1164 ("[C]ourts have repeatedly made the same mistake, dwelling on the irrelevant concept of liability being imposed on multiple manufacturers because of uncertainty about who made a product and conflating that concept with the separate and distinct issue of whether a manufacturer can be liable for wrongdoing other than making and selling the product the plaintiff received.").

As I have already noted, the factual scenario we confront here is not the one we examined in *Mulcahy*, where we could not identify the actor allegedly responsible for harm. Instead, we face here a scenario where an injury occurred in connection with a given product and the plaintiff can demonstrate tortious conduct by someone other than the product's manufacturer had a causal role in producing the injury. This latter scenario is not a novel one in the field of products liability law. *See generally* Madden & Owen on Products Liability § 19:4, at 370–78 (3d ed. 2000) (collecting cases); Melissa Evans Bush, *Products Liability and Intellectual Property Licensors*, 22 Wm. Mitchell L. Rev. 299, 311–14 (2000) (collecting cases).

The scenario arises in numerous ways, and in each, courts have not hesitated in finding factual causation. Where an organization in the business of testing products and affixing labels certifying the results of its testing is negligent in its labeling, for example, courts have concluded the tester's negligence may be a factual cause of injuries when these

products fail to perform in accordance with the labeling. *See, e.g.*, *Hempstead v. Gen. Fire Extinguisher Corp.*, 269 F. Supp. 109, 118 (D. Del. 1967) ("If plaintiff succeeds in proving his charge that Underwriters was negligent in approving the design of a fire extinguisher which was imminently dangerous, and that plaintiff's injury was a result thereof, Underwriters must respond in damages."). When a publisher is in the business of placing an endorsement or seal of approval on products, and fails to exercise ordinary care in approving a particular product, courts have concluded the publisher's conduct may be a factual cause of damages when the product fails to perform in accordance with the publisher's representation. *See, e.g., Hanberry v. Hearst Corp.*, 81 Cal. Rptr. 519, 522 (Ct. App. 1969) ("[I]ts seal and certification tend to induce and encourage consumers to purchase products advertised in the magazine and which bear that seal and certification."). Likewise, courts have concluded nonmanufacturing seed certifiers constitute a nontrivial link "in the chain of distribution which [places] a [product] in the stream of commerce," and thus those certifiers may play a causal role in any damage suffered by third parties relying on those certifications. *Rottinghaus v. Howell*, 666 P.2d 899, 907 (Wash. Ct. App. 1983) ("MPIA's conduct in certifying the defective seed, issuing a blue tag stating such and representing the quality of the seed in the 1977 directory created an issue for the jury as to whether defendant was liable for negligence and negligent misrepresentation."). Similarly, a trade association or other organization setting insufficient safety standards for a product may factually cause harms flowing from the plaintiff's use of the product. *See Meneely v. S.R. Smith, Inc.*, 5 P.3d 49, 57 (Wash. Ct. App. 2000) ("We hold the evidence and the reasonable inferences therefrom support the jury's findings that NSPI negligently caused Mr. Meneely's injuries. . . .").

Perhaps more to the point, we recognized in both *Schiltz* and *McCarthy* designers and suppliers of specifications may have a causal role in damages resulting from the failure of structures built according to those designs or specifications. *See Schiltz*, 228 N.W.2d at 17; *McCarthy*, 199 N.W.2d at 367–68. In *Schiltz*, we explained the plaintiff had advanced substantial evidence an engineering firm had negligently designed protective dikes for a sewage treatment facility and substantial evidence the negligence was a factual and legal cause—using our old tort terminology—of the plaintiff's damage. *Schiltz*, 228 N.W.2d at 18. Similarly, in *McCarthy*, we recognized an architect's negligence in supplying plans and specifications for the construction of a school might constitute the factual cause of "improper collection and discharge of surface waters upon" a plaintiff's adjacent property. *McCarthy*, 199 N.W.2d at 367.

In addition to those propositions, I note products liability cases have never displaced our age-old torts principle that "an intervening act will not relieve a negligent defendant of liability if that act or force was a normal consequence of the defendant's conduct or was reasonably foreseeable by that defendant." *Iowa Elec. Light & Power Co. v. Gen. Elec. Co.*, 352 N.W.2d 231, 235 (Iowa 1984); *see also, e.g., Rossell v. Volkswagen of Am.,* 709 P.2d 517, 526 (Ariz. 1985) (explaining "an intervening force becomes a superseding cause only when its operation was both unforeseeable and when with the benefit of 'hindsight' it may be described as abnormal or extraordinary" and applying rule in case of negligent placement of car battery); *Larson Mach., Inc. v. Wallace*, 600 S.W.2d 1, 9 (Ark. 1980) (explaining "[t]he mere fact that other causes intervene between the original act of negligence and the injury for which recovery is sought is not sufficient to relieve the original actor of liability, if the injury is the natural and probable consequence of the original

negligent act or omission and is such as might reasonably have been foreseen" and applying rule in case of fertilizer spreader); *Weyerhaeuser*, 620 N.W.2d at 831 ("[T]he fire and resulting explosion were . . . foreseeable intervening causes [of product's defect] that did not supersede [defendant]'s responsibility."); *Zacher v. Budd Co.*, 396 N.W.2d 122, 135 (S.D. 1986) (explaining "even if a plaintiff is assumed contributorily negligent, whether that intervening force supersedes the defendant's negligence is for the jury to decide" and applying rule in case of wheel explosion).

In short, the universe of imaginable scenarios in which an actor who has not manufactured or sold a product may nevertheless both cause and be liable for damages caused is enormous. The majority's proposed "product-identification causation requirement" does no work to address the vast majority of these scenarios. *See Dolin*, 2014 WL 804458, at *8 ("Taken out of context, language in product identification cases . . . may well appear to support GSK's argument. In truth, the principles for which that line of cases stands are inapposite here."). The majority's invocation of the requirement here improvidently forsakes our clear and easily applied principles of factual causation. I would instead apply our traditional principles of factual causation in this case and conclude Huck has advanced evidence sufficient to allow a jury to find the brands' alleged negligence was a but-for cause of the harm she has suffered here. I would therefore reverse the district court's entry of summary judgment on Huck's claims with respect to the brands and remand for trial.

Wiggins and Appel, JJ., join this concurrence in part and dissent in part.