

08-3850

IN THE
United States Court of Appeals
FOR THE EIGHTH CIRCUIT

GLADYS MENSING,

Plaintiff-Appellant,

v.

WYETH, INC., D/B/A WYETH; SCHWARZ PHARMA, INC.; PLIVA, INC.; TEVA
PHARMACEUTICALS, USA, INC.; UDL LABORATORIES, INC.; AND
ACTAVIS ELIZABETH, LLC,

Defendants-Appellees.

*On Appeal from the United States District Court
for the District of Minnesota*

BRIEF FOR DEFENDANT-APPELLEE SCHWARZ PHARMA, INC.

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CORPORATE DISCLOSURE STATEMENT

Appellee Schwarz Pharma, Inc. is 100% owned by UCB, Inc., a privately held Delaware corporation. UCB, Inc. is 100% owned by UCB Holdings, Inc., a privately held Delaware corporation. UCB Holdings, Inc. is 100% owned by UCB S.A., a Belgian corporation whose shares are publicly traded on the Euronext Brussels Stock Exchange.

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PRELIMINARY STATEMENT

From 2001 until 2008, Schwarz Pharma, Inc. manufactured and sold the prescription drug Reglan. It is undisputed that the plaintiff, Gladys Mensing, never purchased or consumed Schwarz's product. Instead, for four years, she took generic metoclopramide, which was manufactured by other defendants in this case. She alleges that she was injured by that generic metoclopramide, and not by Schwarz's Reglan. Nonetheless, she seeks to hold Schwarz liable based on supposedly misleading statements on the Reglan label, which was copied by the generic manufacturers.

Plaintiff conceded below that she cannot recover against Schwarz on a traditional products liability theory. Minnesota law, like the law of every other jurisdiction, simply does not permit a plaintiff to recover for products liability unless she proves that the defendant manufactured or sold the product that caused her injury. To get around this obstacle, plaintiff attempts to shift the focus of her lawsuit against Schwarz away from products liability altogether, to negligent misrepresentation and fraud. Her theory appears to be that Schwarz may be held liable to people supposedly injured by other manufacturers' products because by issuing warnings to its own customers, it inadvertently induces its competitors' customers to rely on those warnings, to their detriment. By describing her claims in this

manner, plaintiff argues that she is relieved of the obligation to prove that Schwarz manufactured or sold the product that caused her injury.

As the district court correctly recognized, this end-run around standard principles of products liability law cannot succeed. Regardless of what name she gives to her claims, plaintiff cannot recover from Schwarz for injuries caused by another manufacturer's product. Indeed, in 2001, the Minnesota Court of Appeals rejected these *precise* claims, holding that a consumer of a generic drug cannot bring claims for negligent misrepresentation or fraud against the manufacturer of the name-brand version of that drug. The reason is simple: under Minnesota law, a plaintiff cannot recover for negligent misrepresentation or fraudulent omission without proving that the defendant owed her, and breached, a *duty* of full and non-negligent disclosure. Likewise, to prove fraudulent misrepresentation, a plaintiff must prove that the defendant assumed such a duty by intentionally speaking to *her*, with the intent to induce *her* reliance. No Minnesota case has ever held that a defendant owes such a duty or is otherwise liable to a third party with whom it has no fiduciary, transactional, or other special relationship.

Minnesota courts are not alone in this holding. Since 1994, 28 federal and state courts, applying the laws of 17 different states, have *also* rejected these identical claims. Only one court (an intermediate appellate court in California) has held to the contrary. This virtual unanimity is understandable: if name-brand man-

ufacturers could be held liable for injuries allegedly caused by the ingestion of generic drugs, they would essentially become insurers against all risks created by entire product lines. Not only would such a system create perverse incentives and unnecessarily punish companies like Schwarz for torts allegedly committed by their direct competitors, but it would also be very difficult to limit the principle to the prescription drug industry. Under plaintiff's theory, the manufacturer of any well-known product susceptible of imitation could be liable for failure to warn of dangers lurking in competing products. This is not the way the law works in Minnesota or anywhere else.

The district court correctly granted judgment for Schwarz; the decision should be affirmed.

COUNTERSTATEMENT OF THE ISSUES

1. Does the manufacturer of a name-brand drug owe a duty of care to every consumer of the generic equivalent of that drug, absent any sort of transactional, fiduciary, or other special relationship between the consumer and the manufacturer?

Flynn v. Am. Home Prods. Corp., 627 N.W. 2d 342 (Minn. Ct. App. 2001)

Foster v. Am. Home Prods Corp., 29 F.3d 165 (4th Cir. 1994)

Smith v. Brutger Cos., 569 N.W.2d 408 (Minn. 1997)

Noble Systems Corp. v. Alorica Central, LLC, 543 F.3d 978 (8th Cir. 2008)

2. Can allegedly misleading statements on the label for a name-brand drug create fraud liability in favor of a consumer of the generic equivalent of that drug, if the consumer does not allege that the name-brand manufacturer intentionally directed any communication to its competitors' customers?

Flynn v. Am. Home Prods. Corp., 627 N.W. 2d 342 (Minn. Ct. App. 2001)

Foster v. Am. Home Prods Corp., 29 F.3d 165 (4th Cir. 1994)

Specialized Tours, Inc. v. Hagen, 392 N.W.2d 520 (Minn. 1986)

Richfield Bank & Trust Co. v. Sjogren, 244 N.W.2d 648 (1976)

COUNTERSTATEMENT OF THE FACTS

Metoclopramide is a prescription drug used primarily as short-term treatment for persistent gastroesophageal reflux and diabetic gastroparesis (characterized by nausea, vomiting, heartburn, persistent fullness after meals, and anorexia). Pl. App. 261a; Sch. App. 1-15.¹ It has been available by prescription under the brand name “Reglan” since 1979. Since the mid-1980s, it has also been available in generic form. The generic version is manufactured and sold by a number of companies, including several who are defendants in this lawsuit. The name-brand version, originally manufactured by a company called A. H. Robins Company,

¹ References to “Sch. App.” refer to Schwarz’s Appendix. “Pl. App.” refers to the plaintiff’s appendix. In an effort to provide the Court with a legible copy of the product label, Schwarz App. 1a-15a contains (1) an identical yet cleaner copy of the product label reproduced at Pl. App. 260a-262a, and (2) an enlarged copy of the identically-worded A. H. Robins’s label, which was also before the district court.

Inc., was manufactured and sold by Schwarz from December 2001 until February 2008.² Pl. App. 220a.

Plaintiff alleges that in 2001, her doctor prescribed metoclopramide to treat her diabetic gastroparesis. According to the complaint, plaintiff's original prescription was for "Reglan." Pl. App. 29a. However, plaintiff never purchased or ingested Reglan. When she took the prescription to her local pharmacy, the pharmacist filled it with generic metoclopramide, a cheaper but recognized equivalent version of Reglan. This was not an accident: pharmacists are required under Minnesota law to dispense generic equivalents for name-brand drugs, unless the prescribing physician writes "dispense as written" or "DAW" on the prescription form itself. See M.S.A. § 151.21(3).

Despite package-label warnings directing that metoclopramide be taken for no longer than 12 weeks, plaintiff took generic metoclopramide for over four years. Pl. App. 29a-30a. In March 2005, she stopped taking the drug after developing symptoms of tardive dyskinesia, a neurological disorder that is a known side effect of metoclopramide use and that was characterized in her case by involuntary facial movements. Pl. App. 30a.

² A. H. Robins was the original holder of the Reglan New Drug Applications ("NDAs"), the first of which was approved by the FDA in 1979. In late 1989, defendant-appellee Wyeth acquired a number of products, including Reglan, through the A. H. Robins bankruptcy proceedings. In December 2001, Schwarz acquired the NDA for Reglan tablets from Wyeth. That NDA was sold in 2008.

On “information and belief,” and nothing more, plaintiff alleges that her doctor prescribed metoclopramide for long-term use because he relied on the package label for Reglan, rather than the identical label on the generic products. See 30a.; Br. 4 (“In prescribing metoclopramide for Ms. Mensing, her physician relied on the labeling for Reglan.”). Among other warnings, the Reglan label (as well as the labels for generic metoclopramide) contained the following information:

First, the label explicitly described metoclopramide as a “short-term” treatment, to be used no longer than 12 weeks. Second, the label specifically disclaimed any recommendation for long-term use: in the section detailing “dosage and administration,” the label noted that “[t]herapy longer than 12 weeks has not been evaluated and cannot be recommended.” Third, the label warned doctors that some patients taking metoclopramide might develop tardive dyskinesia, the syndrome afflicting plaintiff. According to the label, “[b]oth the risk of developing the syndrome and the likelihood that it will become irreversible are believed to increase with the duration of treatment and the total cumulative dose.” See Pl. App. 260a-262a; Sch. App. 1-15. The labels for generic metoclopramide included the same information.

The heart of plaintiff’s suit is an allegation that the risk of tardive dyskinesia among long-term users of metoclopramide is considerably higher than the short-term risk described on the package label, and that all the defendants, including

Schwarz, knew this to be true. Pl. App. 31a-32a. The defendants were also aware, according to the complaint, that many doctors prescribed metoclopramide for longer than recommended. Therefore, plaintiffs allege, the Reglan label (and the nearly identical labels issued by the manufacturers of generic metoclopramide) failed to provide adequate warnings to doctors and patients about the true risk of metoclopramide use. Pl. App. 35a-37a. The label should have specified and otherwise emphasized, plaintiff argues, that long-term users were at higher risk than short-term users for developing tardive dyskinesia. Pl. App. 35a.

In September 2007, plaintiff filed this lawsuit, alleging a variety of products liability claims against Schwarz and the various companies that manufactured the generic metoclopramide she ingested. After discovery revealed that plaintiff had never ingested name-brand Reglan, Schwarz filed a motion for summary judgment, arguing that under Minnesota law, it could not be held liable for injuries allegedly caused by another manufacturer's generic product. Wyeth, which manufactured both Reglan and generic metoclopramide, later joined Schwarz's motion insofar as plaintiff alleged that Wyeth as the prior name-brand manufacturer was liable for injuries caused by generic metoclopramide.³ The district court granted the motion on October 30, 2008 and entered judgment on plaintiff's claims against Schwarz

³ In a separate filing, Wyeth has also joined and adopted the arguments in this brief insofar as plaintiff contends that Wyeth as the prior name-brand manufacturer is liable for injuries caused by generic metoclopramide that was not manufactured and distributed by Wyeth.

and Wyeth. Pl. App. 311a. In a separate order, the district court also dismissed the claims against the generic manufacturers. Pl. App. 282a. Those claims, the court held, were preempted by federal law. This appeal followed.

SUMMARY OF ARGUMENT

There is no dispute that in order to prove her claim for negligent misrepresentation, plaintiff must establish that Schwarz owed a duty of care to warn about the risk of its competitors' generic drugs. She cannot do that. Plaintiff argues that Schwarz assumes such a duty to any person who may "foreseeably" choose to rely on the Reglan label – even those persons with whom Schwarz has no relationship. That is not the law in Minnesota. The creation of a legal duty to reveal material facts under Minnesota law requires a conscious relationship between the plaintiff and the defendant. Schwarz has no such relationship with this plaintiff, who chose to purchase generic drugs manufactured by Schwarz's competitors.

As for fraud, the law is no different. Plaintiff cannot prove her claim without a showing that Schwarz assumed a duty by intentionally speaking to *her*, and that the communication involved an affirmative misstatement. Plaintiff can prove neither element. Schwarz's Reglan label was a communication to its own customers, not its competitors'. In any event, her complaint alleges misleading *omissions*, rather than affirmative misrepresentations.

The rule plaintiff advocates is contrary to Minnesota law and public policy, and it has been rejected by over two dozen courts throughout the country – three within the last two months. This court should reject it as well and should resist the invitation to disregard or modify Minnesota law.

ARGUMENT

I. THE MANUFACTURER OF A NAME-BRAND DRUG CANNOT BE HELD LIABLE FOR INJURIES CAUSED BY A GENERIC DRUG.

As the district court recognized, it is nearly axiomatic that a manufacturer has no duty to warn about another manufacturer's product. More specifically, in the context of prescription drugs, 28 different federal and state courts, applying the laws of 17 states, have concluded that name-brand drug manufacturers cannot be held liable for injuries caused by generic substitutes, whether the plaintiff chooses to call her claim failure to warn, fraud, or negligent misrepresentation. Minnesota is no different.

The leading case on this subject, as the district court noted, is *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994), in which the Fourth Circuit held that Wyeth, in that case as the manufacturer of a name-brand drug called "Phenergan," had no duty to the customers of its competitor, which marketed a generic equivalent of Phenergan, called "Promethazine." Just as in this case, the plaintiffs in *Foster* argued that "because generic drugs are required by federal law to be equivalent to their name brand counterparts, any representations

Wyeth makes when advertising Phenergan also apply to generic promethazine.” *Id.* at 169. The *Foster* plaintiffs also argued, as does this plaintiff, that “name brand manufacturers *** know that generic manufacturers rely on their studies and duplicate their labeling, and that if the name brand manufacturer does not issue a warning, it will simply not be made.” *Id.* Therefore, especially because Wyeth was “aware that when Phenergan is prescribed, the patient may actually receive generic promethazine,” *id.*, it owed a duty to all users of the generic drug to speak non-negligently when formulating the package warnings for the name-brand product. The Fourth Circuit rejected the claims, for three reasons.

First, the *Foster* court concluded that the plaintiffs were improperly attempting to disguise products liability claims as claims for misrepresentation in order to avoid the necessity of demonstrating that Wyeth manufactured the allegedly defective drug. “[A]ttempting to hold Wyeth liable for injuries caused by another manufacturer’s product,” the court held, was impermissible under Maryland law because it was an “effort to circumvent the necessity that a defendant be shown to have manufactured the product that caused an injury prior to being held liable for such injury.” *Id.* at 168.

Second, the *Foster* court concluded that no legal precedent or FDA regulation imposes liability on the name-brand manufacturer for injuries caused by the drug of its generic competitors. *Id.* at 170. The court recognized that “[n]ame

brand manufacturers undertake the expense of developing pioneer drugs, performing the studies necessary to obtain premarketing approval, and formulating labeling information.” *Id.* After reviewing FDA statutes and regulations, common law, and public policy implications, the court rejected plaintiffs’ theory of liability. “[U]sing a name brand manufacturer’s statements about its own product as a basis for liability for injuries caused by other manufacturers’ products,” the *Foster* court reasoned, “would be especially unfair when, as here, the generic reaps the benefits of the name brand manufacturer’s statements by copying the labels and riding on the coattails of its advertising.” *Id.*

Notably, the *Foster* court rejected the plaintiffs’ argument that name-brand manufacturers were the only parties responsible for the content of drug warning labels, noting that generic manufacturers have the same obligation as their name-brand counterparts to ensure the accuracy of product-label warnings. “Manufacturers of generic drugs,” the court wrote, “like all other manufacturers, are responsible for the representations they make regarding their products.” *Id.* at 170. Therefore, there was no reason to impose unconventional liability on name-brand manufacturers for injuries caused by generic drugs; the plaintiffs’ misrepresenta-

tion claim could properly be brought against the generic manufacturers without upsetting basic principles of product liability law.⁴

Third, the *Foster* court concluded that Wyeth did not owe a duty to the plaintiffs in that case to warn about risks associated with the generic equivalent of its product. The *Foster* plaintiffs had argued, just as plaintiff argues in this case, that it was “foreseeable to Wyeth that misrepresentations [on the name-brand label] could *** result in personal injury to users of *** generic equivalents.” *Id.* at 171. The court rejected this argument, concluding that “Wyeth is under no duty of care” to consumers of other companies’ generic drugs:

⁴ We note that this is exactly the argument plaintiff has advanced in the first two thirds of her brief to this Court. Challenging the district court’s conclusion that her claims against the generic manufacturers in this case are preempted by federal law, Plaintiff argues that federal law “requires all drug manufacturers,” including generics, “to update label warnings to reflect current knowledge about a drug’s risks.” See Br. 21-30. She argues more generally that generic manufacturers have a variety of other means at their disposal to warn patients of the risks of using their products. Br. 30-34. For those reasons, plaintiff argues, her claims against the manufacturers of generic metoclopramide should stand.

Schwarz takes no position on whether the district court was correct in concluding that federal law preempts plaintiff’s claims against the generic manufacturers. For present purposes, however, we simply note that the plaintiff cannot have it both ways. Plaintiff wants the benefit of *Foster*’s reasoning with respect to the liability of generic manufacturers, but she wishes to avoid the inevitable consequence of that benefit: that ordinary principles of products liability law need not be disturbed in order to accommodate her attenuated claim against name-brand manufacturers from whom she never purchased anything. Put simply, if plaintiff is correct that generic manufacturers have the ability to alter their labels as they see fit – and the duty to warn their own customers about the hazards of the drugs they produce – then liability for injuries caused by their products should be limited to them.

We think to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far. The duty required *** arises when there is such a relation that one party has the right to rely for information upon the other, and the other giving the information owes a duty to give it with care. There is no such relationship between the parties to this case, as Brandy Foster was injured by a product that Wyeth did not manufacture.

Id. (citation and internal quotation marks omitted).

Since *Foster* was decided in 1994, 27 other federal and state courts (including the district court below) have followed its reasoning and refused to extend liability to name-brand manufacturers for injuries caused by generic drugs. These courts have dismissed claims for both negligent misrepresentation and fraud under the laws of 16 different states beyond Maryland.⁵ Notably, as we discuss below

⁵ See *Moretti v. Wyeth*, 2009 WL 749532, at *3-*4 (D. Nev. Mar. 20, 2009); *Schrock v. Wyeth, Inc.*, 2009 WL 635415, at *4-*5 (W.D. Okla. Mar. 11, 2009); *Cousins v. Wyeth Pharma., Inc.*, 2009 WL 648703, at *2 (N.D. Tex. Mar. 10, 2009); *Smith v. Wyeth, Inc.*, 2008 WL 2677051, at *4 (W.D. Ky. June 30, 2008); *Wilson v. Wyeth, Inc.*, 2008 WL 2677049, at *4 (W.D. Ky. June 30, 2008); *Morris v. Wyeth, Inc.*, 2008 WL 2677048, at *4 (W.D. Ky. June 30, 2008); *Pustejovsky v. Wyeth, Inc.*, 2008 WL 1314902, at *2 (N.D. Tex. Apr. 3, 2008); *Swicegood v. Pli-va, Inc.*, 543 F. Supp. 2d 1351, 1358 (N.D. Ga. 2008); *Barnhill v. Teva Pharm. USA, Inc.*, No. Civ. A. 06-0282-CB M, Order at 4 (S.D. Ala. Apr. 24, 2007); *LeBlanc v. Wyeth, Inc.*, 2006 WL 2883030, at *6 (W.D. La. Oct. 5, 2006); *Goldych v. Eli Lilly & Co.*, 2006 WL 2038436, at *6 (N.D.N.Y. July 19, 2006); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 540-41 (E.D. Pa. 2006), aff'd in pertinent part and rev'd in other part, 521 F.3d 253 (3d Cir. 2008); *Tarver v. Wyeth*, 2005 WL 4052382, at *2 (W.D. La. June 7, 2005); *Block v. Wyeth, Inc.*, 2003 WL 203067, at *2 (N.D. Tex. Jan. 28, 2003); *Stanley v. Wyeth, Inc.*, 991 So. 2d 31, 34-35 (La. App. 1 Cir. 2008); *Sharp v. Leichus*, 2006 WL 515532, at *4 (Fla. Cir. Ct. Feb. 17, 2006), aff'd per curiam, 952 So. 2d 555 (Fla. 1st DCA 2007); *Huck v. Trimark Physicians Group*, No. LACV018947, Order at 1-2 (Iowa Dist. Ct. Feb. 27, 2009);

(see *infra* at 17-18, 28-30), Minnesota is among those states: the Minnesota Court of Appeals in 2001 rejected plaintiff's precise claims, holding that a name-brand manufacturer could not be held liable for negligent misrepresentation or fraud by a plaintiff who alleged that her injury was caused by a generic substitute. See *Flynn v. Am. Home Prods. Corp.*, 627 N.W. 2d 342 (Minn. Ct. App. 2001).

There is only one case rejecting the *Foster* analysis (*Conte v. Wyeth*, 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008)), and it is truly an outlier. Indeed, in the last two months alone, three federal courts have declined to follow *Conte's* reasoning. See *Moretti v. Wyeth*, 2009 WL 749532, at *4 (D. Nev. Mar. 20, 2009); *Schrock v. Wyeth, Inc.*, 2009 WL 635415, at *4-*5 (W.D. Okla. Mar. 11, 2009); *Cousins v. Wyeth Pharma., Inc.*, 2009 WL 648703, at *2 (N.D. Tex. Mar. 10, 2009). One of those courts explicitly rejected the decision and declined the plaintiff's invitation to extend its reach beyond California. See *Moretti*, 2009 WL 749532 at *4 ("[W]ith the exception of *Conte*, every other court that has considered this issue has rejected Plaintiff's arguments. Those courts have correctly held that name-brand manufac-

Buchanan v. Wyeth Pharm., Inc., CV-2007-900065, Order at 1 (Ala. Cir. Ct. Oct. 20, 2008); *Green v. Wyeth Pharm., Inc.*, CV-06-3917 ER, Order at 1 (Ala. Cir. Ct. May 15, 2007); *Kelly v. Wyeth*, 2005 WL 4056740, at *2 (Super. Ct. Mass. May 6, 2005); *Sheeks v. Am. Home Prods. Corp.*, 2004 WL 4056060, at *2 (Colo. Dist. Ct. Oct. 15, 2004); *Reynolds v. Anton*, 2004 WL 5000272, at *9 (Ga. Super. Ct. Oct. 28, 2004); *Westerlund v. Wyeth, Inc.*, No. MID L02174-05, slip op. at 3 (N.J. Super. Ct. Oct. 20, 2008); *Sloan v. Wyeth*, No. MRS-L-1183-04, slip op. at 5 (N.J. Super. Ct. Oct. 13, 2004); *Beutella v. A.H. Robins Co.*, 2001 WL 35669202, at *2 (Utah Dist. Ct. Dec. 10, 2001).

turers do not have a legal duty to warn about the risks associated with their competitors' generic drugs. Simply put, *Conte* stands alone and is contrary to Nevada law and public policy.”).

Conte is directly contrary to controlling Minnesota law and the law of every other jurisdiction to have considered these questions.⁶ Its reasoning has been rejected by every court to consider the question. *Foster*, on the other hand, has been followed by courts throughout this country, including courts in Minnesota. This Court should follow suit.

II. MINNESOTA LAW IS CONSISTENT WITH THE REST OF THE COUNTRY AND SQUARELY REJECTS PLAINTIFF’S THEORY.

Plaintiff attempts to avoid *Foster* and its near-unanimous progeny by asserting that her claims are proper under Minnesota common law for negligent misrepresentation and fraud. But Minnesota, like over a dozen other states, has adopted the *Foster* reasoning. In order to hold a defendant liable for misrepresentation or fraud under Minnesota law, a plaintiff must show that the defendant had a duty *to*

⁶ Indeed, *Conte* represents a departure even from *California* law, which has always held that a plaintiff cannot recover against the defendant absent proof that the defendant manufactured the product plaintiff was using at the time of her injury. See, e.g., *Sindell v. Abbott Labs.*, 607 P.2d 924 (Cal. 1980). The *Conte* court ignored this settled precedent and relied instead on a 40-year-old decision that upheld a verdict against a magazine that made misrepresentations in a public endorsement of a product. See *Hanberry v. Hearst Corp.*, 81 Cal. Rptr. 519 (Cal. Ct. App. 1969). Of course, by publishing warnings and instructions for its own products, drug manufacturers do not endorse, or encourage consumers to purchase, their competitors' products. Indeed, the defendant in *Hanberry*, “Good Housekeeping” magazine, was *paid* to endorse the product in question.

her – created either as a result of a direct and intentional communication or some other pre-existing relationship of trust or confidence. For this reason, Minnesota courts have already rejected plaintiff’s argument. This Court should not second guess those holdings.

A. Plaintiff’s Misrepresentation Claim Fails Because Schwarz Did Not Owe Her A Duty.

To begin, plaintiff cannot establish a negligent misrepresentation claim because, as the district court recognized, Schwarz owed her no duty to warn about the risks associated with its competitors’ generic metoclopramide or otherwise speak non-negligently. As various Minnesota courts and well over a dozen others throughout the country have held, a name-brand drug manufacturer has no duty to warn or otherwise communicate with the customers of its generic competitors.

There is no dispute about the elements of a negligent misrepresentation claim under Minnesota law. As the district court explained, in order to prove such a claim, a plaintiff must show:

- (1) a duty of reasonable care in conveying information;
- (2) breach of that duty by negligently giving false information;
- (3) reasonable reliance on the misrepresentation, which reliance is the proximate cause of physical injury;
- and (4) damages.

Pl. App. 318a-319a (citing *Smith v. Brutger Cos.*, 569 N.W.2d 408, 413 (Minn. 1997)). We note, of course, that Schwarz categorically denies that there was any “false” information on the Reglan package label. But putting that aside, plaintiff’s

claim fails regardless of the substance of Schwarz's warnings, because there is no way she can satisfy the first element of negligent misrepresentation. Simply put, Schwarz owed no *duty* to this plaintiff, with whom it had no relationship – transactional, fiduciary, or otherwise.

This issue has already been decided by the Minnesota courts. In *Flynn*, the plaintiff was prescribed generic “fen-phen,” a weight loss drug that was later found to cause heart disease. She sued, among others, the manufacturer of “Pondimin,” the name-brand version of fen-phen, claiming fraud and negligent misrepresentation for the alleged failure to reveal the drug's side effects to the FDA when seeking initial approval for the drug. As in this case, the plaintiff in *Flynn* alleged that her doctor, in deciding to prescribe fen-phen, relied upon the name-brand manufacturer's allegedly false assurances that the drug was safe. Reasoning that the defendant owed no duty of care to its competitors' customers, the trial court granted summary judgment to the defendant. The Minnesota Court of Appeals affirmed.

In the appellate court, the *Flynn* plaintiff argued, as this plaintiff does, that the defendant had a duty to disclose material information to her despite the fact that she had not purchased its product. The appellate court rejected that argument. “Although federal regulations required respondents to disclose product safety information to the FDA,” the Court reasoned, “respondents did not owe appellant, who did not purchase their product and with whom they had no relationship, the

same obligation.” *Flynn*, 627 N.W.2d at 350 (citing *In re Minnesota Breast Implant Litig.*, 36 F. Supp. 2d 863, 880 (D. Minn. 1998) (holding that under Minnesota’s fraudulent representation and fraudulent concealment law, a medical manufacturer does not have a duty to disclose to a plaintiff safety information concerning a product sold to the plaintiff by another manufacturer)).

Flynn is not alone in Minnesota. Various other Minnesota cases similarly hold that a speaker owes no duty of truthfulness and full disclosure to a third party who was not the intended recipient of its communications. The leading case outside the prescription drug context is *Richfield Bank & Trust Co. v. Sjogren*, 309 Minn. 362, 366 (1976), in which the Minnesota Supreme Court noted that the “general rule” is that a speaker “has no duty to disclose material facts” absent “[s]pecial circumstances.” Those circumstances are expressly limited to either (1) communications that are part of a “transaction” between the defendant and the plaintiff, or (2) communications between parties who have a “confidential or fiduciary relationship” with each other. *Id.*

It is undisputed that there is no relationship between this plaintiff and Schwarz. So, plaintiff invites this Court to invent a new exception to the general rule that a speaker owes no duty of care to third parties. This Court should reject the invitation to modify Minnesota law.

At the heart of plaintiff's argument is the assertion that a speaker owes a duty of care to every third party who might "foreseeably" choose to rely on the defendant's statements. Br. 46-47. No Minnesota court has ever so held. It is certainly true, as plaintiff notes, that foreseeability of injury is *relevant* to the question of duty, but it is not the sole determining factor. In misrepresentation cases, a plaintiff must show not only that the defendant's negligent statements were likely to cause harm, but also that the defendant had a *relationship* with the plaintiff sufficient to create a duty to speak non-negligently. Plaintiff has cited no cases, and we are aware of none, in which a Minnesota court has held a defendant liable for negligent misstatements when the plaintiff was not the intended audience for those statements. To the contrary, *Flynn* expressly holds the opposite.

This Court has explicitly and recently recognized the relationship requirement under Minnesota law. In *Noble Systems Corp. v. Alorica Central, LLC*, 543 F.3d 978 (8th Cir. 2008), this Court summarized the elements of negligent misrepresentation under Minnesota law as follows:

[i]n both intentional and negligent misrepresentation claims, the plaintiff must prove some relationship that is sufficient to create a duty owed by the defendant to the plaintiff, that the plaintiff relied on the defendant's misrepresentation, and that it thereby suffered harm.

Id. at 985 (citing *L&H Airco, Inc. v. Rapistan Corp.*, 446 N.W.2d 372, 380 (Minn. 1989); *Flynn*, 627 N.W.2d at 350). Affirming a dismissal in favor of the defen-

dant, and citing *Flynn*, this Court held that “Minnesota law does not appear to recognize any duty to disclose information to third parties with whom no relationship exists.” *Id.* at 985. Absent proof that the defendant intended its alleged misstatement to reach the plaintiff and expected the plaintiff to rely on it, this Court held that a claim for negligent misrepresentation could not stand.

Plaintiff does not cite any Minnesota law to the contrary. She cites two cases for the general proposition that the scope of a defendant’s duty to act non-negligently is determined by the foreseeability of the resulting injury. See *Molloy v. Meier*, 679 N.W.2d 711 (Minn. 2004); *Holthusen v. United States*, 498 F. Supp. 2d 1236 (D. Minn. 2007). But neither of these cases involved misrepresentations made to *strangers*. *Molloy* involved parties with a close relationship of trust; the case held that a child’s doctor owes a duty to his patient’s parents to accurately perform tests for genetic diseases, because it is foreseeable that the parents will rely on the doctor’s advice when deciding whether to conceive another child. And *Holthusen* had nothing to do with misrepresentations at all. That case was about a police officer’s duty to exercise due care when conducting a high-speed chase. Put simply, plaintiff cites no case in which a defendant was held liable for negligent *misrepresentation* under Minnesota law to someone to whom he never spoke or intended to speak, and with whom he had no fiduciary or other relationship of trust or confidence.

Indeed, all the misrepresentation cases plaintiff cites involve parties with direct and intentional relationships. *Florenzano v. Olson*, 387 N.W.2d 168 (Minn. 1986) and *Bonhiver v. Graff*, 248 N.W.2d 291 (Minn. 1976), both involved financial advisers who were either hired or otherwise relied upon by the plaintiffs and who gave bad advice. *Mulroy v. Wright*, 240 N.W. 116 (Minn. 1931) involved a city clerk who performed a real-estate assessment incorrectly. All these defendants were held liable for communications they made directly and intentionally to the plaintiffs who brought suit. Indeed, in all of these cases, the defendants were actually being paid (or attempting to be paid) by the plaintiffs for their services.

In short, Minnesota law is clear: in order to prove a duty of care, plaintiff must establish that she had a relationship with Schwarz. She cannot, because it is undisputed that this plaintiff was not Schwarz's customer. To get around this fact, plaintiff suggests that the warnings on Schwarz's Reglan label are intended by Schwarz to be read by every patient taking metoclopramide, or by their doctors. As a matter of law, this simply is not true.

When Schwarz publishes a label for one of its drugs, the warnings contained in that label are intended to be read and relied upon by consumers who purchase Schwarz's products. Most communications with patients take place through the filter of a doctor, who is a learned intermediary for the patient. See, e.g., *Mulder v. Parke Davis & Co.*, 181 N.W.2d 882, 885 (Minn. 1970). But whether a warning is

routed through a learned intermediary or made directly to a customer, it is still a communication between Schwarz and its own customers. A doctor may be the customer's agent for purposes of communicating with drug companies, but the law does not permit him unilaterally to expand Schwarz's audience to include patients who never took Schwarz's drugs. When Schwarz issues a label, it is not communicating with a community of doctors – and by extension, with every patient of every doctor in the world. It is communicating with its own customers, using those customers' doctors as the conduit.

The fact is, this plaintiff and her doctor made a *conscious choice* to buy metoclopramide from the generic defendants and not from Schwarz. As explained above, plaintiff's doctor had a choice when he wrote plaintiff's prescription. He could have instructed the pharmacy to fill her prescription with name-brand Reglan, and if he had, the pharmacy would have been required to do so. See M.S.A. § 151.21. But plaintiff's doctor did not make that choice. Instead, he left the "DAW" box blank – instructing the pharmacy to fill the prescription with generic metoclopramide. What's more, plaintiff *herself* consented to the substitution. Minnesota law requires pharmacists to specifically inform their patients that they have substituted generic equivalents for name-brand drugs. *Id.* There is no question that the decision to buy metoclopramide from the generic defendants – and not to buy Schwarz's Reglan – was intentional.

This plaintiff was not Schwarz's customer and was therefore not the intended recipient of the information printed on the Reglan label. For this reason, her claim for negligent misrepresentation fails; the district court properly granted judgment.

B. Plaintiff's Fraud Claim Fails Because Schwarz Did Not Intentionally Induce Her To Purchase Its Competitor's Product.

Plaintiff's claim for intentional fraud fares no better than her claim for negligence. A fraud plaintiff, just like a negligence plaintiff, must also show that she was the *intended* recipient of a misleading statement. And as we have already explained, plaintiff cannot make such a showing. In any event, plaintiff has not alleged that Schwarz made any affirmative misrepresentations to her. Generously construed, her complaint alleges misleading *omissions* on the Reglan package label. And as she acknowledges, claims for fraudulent omission require proof of exactly the same sort of *duty* necessary to prove negligent misrepresentation.

1. Plaintiff Has Waived This Claim.

To begin, plaintiff's fraud arguments are brand new at the appellate level, and for that reason alone, this Court should not consider them. In the proceedings below, plaintiff argued that all her claims against Schwarz (negligent misrepresentation, misrepresentation by omission, fraud by concealment, and constructive fraud) were "essentially contained" in her claim for negligent misrepresentation. Sch. App. 16-17. She conceded that in order to prove this claim, she needed to es-

tablish that Schwarz owed her a *duty* to provide complete and accurate information. The district court agreed with this characterization and analyzed the viability of plaintiff's claims as if they were all claims for negligent misrepresentation. See Pl. App. 318a (“Plaintiff asserts that she is pursuing only the above-mentioned claims and states that all of those claims are essentially contained within the elements of negligent misrepresentation.”).

On appeal, plaintiff now argues that her claims for “intentional fraud” stand apart from her negligence claims, and that these claims do *not* require proof of a duty of care. Plaintiff's argument is incorrect (and half-hearted: in her statement of the issues (Br. 2), plaintiff frames the question as she did below, asking “[w]hether name-brand prescription drug manufacturers owe a duty of care under Minnesota law to consumers of *** generic equivalents”). But regardless of merit, she has waived the right to present this new argument on appeal. It is well established that this Court does not consider arguments that were not offered first in the district court. See, e.g., *Cole v. Int'l Union, United Auto., Aerospace & Agricultural Implement Workers of Am.*, 533 F.3d 932, 936 (8th Cir. 2008) (“[T]his court will not consider arguments raised for the first time on appeal.”). Accordingly, this Court has repeatedly refused to reverse summary judgment orders on the basis of unpreserved arguments. See *Action Tapes, Inc. v. Mattson*, 462 F.3d 1010, 1014 (8th Cir. 2006) (“We do not reverse the grant of summary judgment on the basis of an

argument not presented below.”) (citing *Cronquist v. City of Minneapolis*, 237 F.3d 920, 924-25 (8th Cir. 2001)). Since plaintiff did raise this fraud argument in the district court, this Court should reject it here.

2. Plaintiff’s Argument Is Incorrect.

In any event, even if plaintiff had made this argument to the district court, it would have been rejected, as it has been repeatedly in Minnesota and throughout the country. If this Court chooses to consider plaintiff’s argument, it should do the same. In order to prove a claim for fraud without establishing the existence of a pre-existing relationship and consequent duty of care, a plaintiff must prove two things this plaintiff cannot: (1) that any alleged misrepresentation was *intentionally directed at her*; and (2) that the alleged misstatements were *affirmative misrepresentations*, rather than misleading omissions. Plaintiff can prove neither of these elements.

a. Fraud Requires Proof of Intentional Communication To The Plaintiff.

Plaintiff begins her discussion of fraud by stating that the elements of her claim are “intent, inducement, reliance, and damages.” Br. 42 (citing *Iverson v. Johnson Gas Appliance Co.*, 172 F.3d 524, 529 (8th Cir. 1999)). This shorthand description of the tort of fraud, cribbed from a decision of this court in which the relevant facts were very different from the ones at issue here, conveniently glosses a critical element of fraud. Under Minnesota law, a fraud plaintiff must plead and

eventually prove that the defendant's "intent" was to induce *the plaintiff's* reliance on an affirmative misrepresentation. As the Minnesota Supreme Court has explained,

[t]he required elements of a fraud action are: (1) there was a false representation by a party of a past or existing material fact susceptible of knowledge; (2) made with knowledge of the falsity of the representation or made as of the party's own knowledge without knowing whether it was true or false; (3) with the *intention to induce another* to act in reliance thereon; (4) that the representation *caused the other person to act* in reliance thereon; and (5) that the party suffer pecuniary damage as a result of the reliance.

Specialized Tours, Inc. v. Hagen, 392 N.W.2d 520, 532 (Minn. 1986) (citing *Burns v. Valene*, 214 N.W.2d 686, 689 (Minn. 1974) (emphasis added); *Davis v. Re-Trac Mfg. Corp.*, 149 N.W.2d 37 (Minn. 1967)) (emphases added). In other words, critical to a claim of fraud under Minnesota law is an allegation that the defendant made a false statement directly to the plaintiff (or to the plaintiff through an intermediary), and that the plaintiff justifiably relied on that false statement. There is absolutely no support for plaintiff's assertion that a third party – to whom the allegedly false statement was not made – can recover for fraud after having intercepted a communication not intended for her.

Plaintiff claims the law is different. Citing no Minnesota law at all, she asserts that a fraud defendant's liability is "not limited to those persons whose conduct the misrepresentation is intended to influence, or to harm received in the par-

ticular transaction which the misrepresentation was intended to induce.” Br. 43. The only support plaintiff offers for this statement is a quote from a comment to section 310 of the Restatement (Second) of Torts, and a recent Minnesota case that noted as a general matter that “Minnesota often looks to the Restatement for guidance.” Of course, plaintiff fails to note that this case went on to specify that the State relies on the Restatement “to guide our development of tort law *in areas that we have not previously had an opportunity to address.*” *Larson v. Wasemiller*, 738 N.W.2d 300, 306 (Minn. 2007) (emphasis added). This is not such an area. As detailed below, Minnesota has had numerous opportunities to decide whether fraud liability extends to third parties, and it has never chosen to do so.

To our knowledge, no Minnesota court has ever imposed fraud liability on a defendant who did not intentionally communicate with the plaintiff, and plaintiff here has cited no cases to the contrary. Indeed, *all* of the cases plaintiff cites in this section of her brief involved *direct and intentional communications* between a defendant and the party that ultimately brought the lawsuit. See *Gaetke v. Ebarr Co.*, 263 N.W. 448, 449, 452 (Minn. 1935) (salesman misrepresented terms of real-estate sale; court explains that fraud lies upon a showing of a misrepresentation made “with intention to induce *the person to whom it is made* to act in reliance upon it, or under such circumstances that *such person* is justified in acting in reliance”); *Richfield Bank & Trust Co. v. Sjogren*, 244 N.W.2d 648 (Minn. 1976)

(bank liable for fraudulent omission made directly to the plaintiff, and in which the bank's officer had a financial interest); *Busterud v. Farrington*, 31 N.W. 360 (Minn. 1887) (misrepresentation made directly to the plaintiff, with intent to make a sale to the plaintiff); *Lehman v. Hansord Pontiac Co.*, 74 N.W.2d 305 (Minn. 1955) (misrepresentation made directly to plaintiff to induce automobile sale).

b. Plaintiff Cannot Prove That Any Misstatements Were Intentionally Made To Her.

Without proof of a false statement made intentionally to *her*, plaintiff cannot prove her claim. For this reason, plaintiff's fraud claim is no more viable than her negligence claim.

Once again, *Flynn* is controlling and directly on point. Like this plaintiff, the *Flynn* plaintiff brought claims for fraud in addition to her negligent misrepresentation claim. And like this plaintiff, the *Flynn* plaintiff also asserted that she could recover without proof of an affirmative misstatement made directly and intentionally to her. The Minnesota Court of Appeal rejected that argument. After listing the five elements of fraud, including the two elements requiring intentional, affirmative misrepresentations to the plaintiff, the court explained that “[a]ppellant does not point to any affirmative representations made by respondents that were relied upon by her physician when issuing the prescription for fen-phen.” *Flynn*, 627 N.W.2d at 349. Without such allegations, the court held, the claim could not stand. “Appellant has not presented any Minnesota authority supporting an exten-

sion of this duty [of truthful disclosure] to third parties, and indeed, the authority we have found holds to the contrary.” *Id.* at 350 (citing *Karlstad State Bank v. Fritsche*, 392 N.W.2d 615, 618 (Minn. App. 1986)).

Plaintiff attempts to distinguish *Flynn* on this point by arguing that she *has* alleged an affirmative misrepresentation made directly to her doctor: the allegedly misleading Reglan package label, on which plaintiff claims her doctor relied when deciding to prescribe generic metoclopramide. Br. 45. This attempt fails, because as we discussed above, the alleged misstatements on the Reglan label were never intentionally directed at her. Instead, the label was directed to and intended to reach Schwarz’s *own customers*. Plaintiff was not the intended audience for the warnings on the Reglan label; she was a sale Schwarz *lost*.

Plaintiff barely confronts this argument, saying only that her claim is different from the claim in *Flynn* because she has alleged that her doctor actually read the Reglan label. But the communication here was no more direct than the one alleged in *Flynn*. The *Flynn* doctor was also alleged to have relied on the statements of the name-brand manufacturer to a third party (in that case, the FDA). In any event, the *Flynn* court addressed and dismissed plaintiff’s argument directly:

Appellant argues that respondents intended all consumers rely on their representations to the FDA and owed all consumers a duty to disclose material facts, but that contention conflicts with Minnesota common law, which requires a stronger relationship and a direct communication. Appellant did not purchase or use respondents’

product, and therefore, there was no direct relationship between them, let alone a fiduciary relationship that gave rise to a duty.

Flynn, 627 N.W.2d at 350.

In short, the undisputed facts preclude liability for fraud because the statements plaintiff claims were fraudulent were never intended to reach her in the first place. Minnesota law only imposes fraud liability on a defendant who speaks intentionally (and falsely) to the plaintiff.

c. Plaintiff Also Cannot Prove That The Reglan Label Contained Any Affirmative Misrepresentations.

There is a second reason plaintiff's fraud claim fails. Despite the characterizations in her brief, plaintiff has not actually alleged that Schwarz made any *affirmative misrepresentations* on the Reglan package label. Liberally construed, the complaint alleges detrimental reliance on misleading *omissions*, which simply are not actionable under Minnesota law unless they are made directly to the plaintiff, and under circumstances in which the defendant owes the plaintiff some special duty of trust, stemming from a pre-existing relationship. See *Richfield Bank*, 309 Minn. at 365.

The Reglan label states in three different places that the drug is intended for short-term use and that it is not recommended for use beyond 12 weeks. The label also contains a specific warning about the risk of developing tardive dyskinesia. Plaintiff's argument is not that these basic instructions were untrue; her claim is

that the warnings understated the risk for patients who took Reglan for considerably *longer* than recommended. But the label also stated that the risk of developing tardive dyskinesia increases “with the duration of treatment and the total cumulative dose,” and that “[t]herapy longer than 12 weeks has not been evaluated and cannot be recommended.” Pl. App. 260a-262a; Sch. App. 1-15.

This is why plaintiff’s long discussion of the supposedly inaccurate “1 in 500” claim is nothing more than a red herring. The package insert states that patients *who take Reglan as directed – for 12 weeks or less* – have a one in 500 chance of developing acute dystonic reactions – another neurological syndrome. Plaintiff alleges that this statement is untrue. Schwarz denies the assertion, but ultimately, it matters little. This plaintiff is not alleging that she took the drug as directed and thereby exposed herself to a higher risk of injury than what was disclosed on the package label. Instead, she alleges that she was injured as a result of *long-term* use of the drug, and that she would have avoided this fate if she had been warned that the risk of developing tardive dyskinesia was considerably higher than 1 in 500 for *long-term* users.

What plaintiff is really arguing is that there was a fraudulent *omission* from the package label. According to plaintiff, because Schwarz was aware that some doctors were prescribing metoclopramide for longer than 12 weeks, it should have added a warning to the Reglan label, specifying that the risk of developing tardive

dyskinesia was higher with long-term use than the relatively low risk described for short-term users. Schwarz denies that the package label was misleading in any way. But even if it were, fraudulent *omission* is not the same as fraudulent *misrepresentation*.

Perhaps this is why plaintiff conceded to the trial court (and to this Court in her statement of the issues) that she must establish a duty in order to prove her claim. As she acknowledges to this Court, fraudulent omission is actionable under Minnesota law only if the defendant has a duty – a pre-existing obligation to disclose material facts to the plaintiff, stemming from a fiduciary or other close relationship of trust or responsibility. As stated above, the leading case on fraudulent omission is *Richfield Bank & Trust Co. v. Sjogren*, which described the doctrine as follows:

[I]f a party conceals a fact material to [a] transaction, and peculiarly within his own knowledge, knowing that the other party acts on the presumption that no such fact exists, it is as much a fraud as if the existence of such fact were expressly denied, or the reverse of it expressly stated.

Before nondisclosure may constitute fraud, however, there must be a suppression of facts which one party is under a legal or equitable obligation to communicate to the other, and which the other party is entitled to have communicated to him.

Id., 309 Minn. at 365. As we have already established, there were no “[s]pecial circumstances” in this case that caused Schwarz to take on any duty to this plain-

tiff. Schwarz participated in no transactions with plaintiff, and it did not have any “confidential or fiduciary relationship” with her. At best, plaintiff claims to have intercepted a communication between this defendant and its own customers. Allegedly misleading omissions in such an attenuated communication are not actionable under Minnesota law.

For these reasons, plaintiff’s fraud claim cannot be sustained under Minnesota law. Had the district court been confronted with the new arguments plaintiff has offered on appeal, it would have rejected them. And if this Court chooses to entertain the arguments, it should reject them as well and affirm the dismissal of the fraud claims.

III. MINNESOTA’S LAW MAKES SENSE.

In the end, plaintiff’s real complaint is not that she has no claim against the name-brand manufacturers; it is that as a result of the district court’s preemption ruling, she apparently has no state-law claim against the companies that actually sold her the products she ingested. Someone, according to plaintiff, has to be responsible for her injuries.

As stated earlier, Schwarz takes no position on the correctness of the district court’s preemption ruling, except to say this: the nature of federal preemption is that state law remedies are disallowed in order to serve a congressional purpose – whether that purpose is national legal uniformity or some broader policy goal.

Every time a state law remedy is preempted by federal law, that remedy becomes unavailable to plaintiffs. The result, however, is not that state law gets altered in order to create a remedy against a different defendant in order to compensate for the federal alteration of state law. Minnesota law places the burden of compensating an injured products-liability plaintiff on the shoulders of the entity that manufactured or sold the product that caused her injury. If that cause of action is unavailable as a result of congressional lawmaking, the result is not that Minnesota must alter its law in order to create liability for some other entity that would ordinarily lack legal responsibility for the plaintiff's injury, or that this Court should presume to alter state law *for* Minnesota.

The fact is, limiting liability under state law to the manufacturer of a defective product is a rational and reasonable policy choice that Minnesota and nearly two dozen other states have made after careful consideration. There are good reasons for this rule, including but not limited to the fact that such defendants have control over the injury-causing product and thus are in the best position to make it safe. See, e.g., *Sharp v. Leichus*, 2006 WL 515532, at *7 (Fla. Cir. Ct. Feb. 17, 2006) (“[T]here is no allegation, nor could there be, that Wyeth or Schwarz were in a position to create or control the generic manufacturer’s making or distribution of the product that allegedly caused the injury. It would be manifestly unfair to hold a name brand manufacturer responsible for injuries that arise from a product that is

beyond its control.”); *Bocre Leasing Corp. v. Gen. Motors Corp.*, 84 N.Y.2d 685, 695 (1995) (Simons, J., concurring in part and dissenting in part) (“The duty of care is properly placed on the manufacturer *** because in today’s society the manufacturer is in the best position to recognize and cure defects in its product.”).

On the other hand, the opposite rule (advocated by plaintiff) would effectively create an insurance system in favor of generic drug manufacturers, who do not need one. Name-brand manufacturers already spend millions of dollars researching, testing, and securing regulatory approval of new products in exchange for short periods of exclusive sales. After that, drug lines often come to be dominated by generic manufacturers. But under plaintiff’s system, name-brand manufacturers would remain the insurers or guarantors of those drug lines in perpetuity, even long after their exclusive rights expire. See, e.g., *Foster*, 29 F.3d at 170 (observing that imposing unlimited liability on name-brand manufacturers would be “especially unfair” because “the generic manufacturer reaps the benefits of the name brand manufacturer’s statements by copying its labels and riding on the coat-tails of its advertising”). The inevitable result would be to chill the development of new products and make them considerably more expensive for consumers. See, e.g., *Sloan v. Wyeth*, MRS-L-1183-04, slip op. at 9 (N.J. Super. Ct. Oct. 13, 2004) (stating that “manufacturers would be less likely to develop new products if liabili-

ty were imposed upon these companies for injuries wrought by products of generic manufacturers”).

More than that, it is hard to imagine a limiting principle to the rule plaintiff advocates. If name-brand drug manufacturers are responsible for injuries caused by their competitors’ products on the basis of misleading warnings on their own labels, what is to prevent a plaintiff injured by some other product from suing not only the seller of the item she purchased, but also the manufacturer of a competing but similar product, claiming that she was induced to purchase a car, a boat, a jet-ski, or something else because she saw a commercial for the more well-known product, or read an old instruction manual? What prevents the plaintiff from suing researchers, academics, publishers, or anyone else who might be seen to have “endorsed” the offending product? Product liability law consciously places the burden of compensating injured plaintiffs on the manufacturers of those products; plaintiff should not be permitted to upset that policy election.

CONCLUSION

The judgment should be affirmed.

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April 24, 2009

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B)(i) because it contains 8959 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

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