

United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 08-3850

Gladys Mensing, *

Plaintiff - Appellant, *

v. *

Wyeth, Inc., doing business as Wyeth; *
Pliva, Inc.; Teva Pharmaceuticals, *
USA, Inc.; Alparma, Inc., doing *
business as Alparma Pharmaceuticals; *
UDL Laboratories, Inc.; Actavis *
Elizabeth, LLC; Schwarz Pharma, Inc.; *
Purepac Pharmaceutical Company, and *
the following fictitious party defendants *
(whether singular or plural, individual *
or corporate): No. 1, that entity which *
originally obtained permission from the *
U.S. Food and Drug Administration to *
market the drug branded Reglan No. 2, *
that entity which obtained permission *
from the FDA to market the Reglan, *
metoclopramide and/or metoclopramide *
HCI ingested by Gladys Mensing No. 3, *
that entity which originally *
manufactured and sold any Reglan *
which was ultimately ingested by *
Gladys Mensing No. 4, that entity *
which originally manufactured and sold *
any Reglan, metoclopramide and/or *
metoclopramide HCI which was *
ultimately ingested by Gladys Mensing *
No. 5, that entity which marketed *

Appeal from the United States
District Court for the
District of Minnesota.

Reglan or generic metoclopramide *
and/or metoclopramide HCl, jointly *
and individually, *
*
Defendants - Appellees. *

Submitted: October 20, 2009
Filed: November 27, 2009

Before WOLLMAN, MURPHY, and BYE, Circuit Judges.

MURPHY, Circuit Judge.

Gladys Mensing brought this failure to warn and misrepresentation case against a number of manufacturers of Reglan and its generic form, alleging that the medication she had taken caused her to develop tardive dyskinesia, a severe neurological movement disorder. The manufacturers moved for summary judgment and dismissal. The district court dismissed her claims against the generic defendants on the basis of federal preemption and against the name brand manufacturers on the basis that she had not taken their products. Mensing appeals, and we affirm the judgment in favor of the name brand manufacturers but reverse as to the generic manufacturers.

I.

In March 2001 Gladys Mensing's doctor prescribed Reglan to treat her diabetic gastroparesis, and her pharmacist filled her prescription with its generic bioequivalent, metoclopramide. Minn. Stat. § 151.21. After four years of ingesting metoclopramide, Mensing developed tardive dyskinesia. Mensing sued the manufacturers and/or distributors of generic metoclopramide (generic defendants). Mensing's complaint

includes a variety of claims, but she has not challenged the district court's characterization that "at the core" they all assert failure to warn. Mensing v. Wyeth, Inc., 562 F.Supp.2d 1056, 1058 (D.Minn. 2008). Mensing argues that despite mounting evidence that long term metoclopramide use carries a risk of tardive dyskinesia far greater than indicated on the label, no metoclopramide manufacturer took steps to change the label warnings. According to her allegations, metoclopramide manufacturers in fact promoted the drug for long term use. Although she never ingested the name brand drug, Mensing also sued the manufacturers of Reglan (name brand defendants) for fraud and negligent misrepresentation on the theory that her doctor relied on Reglan's label when assessing the risks and proper use of metoclopramide.

All defendants filed motions to dismiss or for summary judgment. The district court granted the motions to dismiss by generic defendants Actavis Elizabeth and Pliva and motions for summary judgment by generic defendants Teva, Wyeth, and UDL Laboratories on the ground of federal preemption. The court concluded that Mensing's failure to warn claims created an impermissible conflict with federal law because they would require generic manufacturers to deviate from the name brand drug label; they were therefore preempted. The court also granted summary judgment to name brand defendants Schwarz and Wyeth,¹ holding that they owed Mensing no duty of care under Minnesota law because she never ingested their product.

Grants of motions to dismiss and for summary judgment are subject to de novo review. We affirm a dismissal if, taking all the plaintiff's allegations as true, they "state a claim to relief that is plausible on its face." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007). On review of summary judgment, we "view the evidence in the light most favorable to the nonmoving party" and affirm only when "there are

¹Wyeth manufactured both Reglan and generic metoclopramide. It joined in the summary judgment motions of both the generic and name brand defendants.

no genuine issues of material fact[.]” Takele v. Mayo Clinic, 576 F.3d 834, 838 (8th Cir. 2009) (quotations omitted).

II.

We first address the generic defendants' argument that federal law preempts state failure to warn claims against them. Since a purely legal issue of statutory interpretation is raised, the generic defendants' motions for summary judgment and dismissal will be considered together.

A.

All prescription drugs require approval by the Food and Drug Administration (FDA) before they may be marketed. Manufacturers of new drugs submit a new drug application (NDA) to the FDA. 21 U.S.C. § 355(a)-(b). An NDA must include information about the drug's safety and efficiency gleaned from clinical trials. *Id.* at §§ 355(b), (d). It must also propose a label reflecting appropriate use, warnings, precautions, and adverse reactions. 21 C.F.R. § 201.56.

Recognizing a need to bring more affordable generic drugs to market as quickly as possible after the patents of name brand drugs expire, Congress passed the Drug Price Competition and Patent Term Restoration Act in 1984. This statute amended the Food, Drug, and Cosmetic Act (FDCA) and is therefore referred to as the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments provided an abbreviated new drug application (ANDA) procedure for generic manufacturers. 21 U.S.C. § 355(j). Generic manufacturers do not need to repeat the clinical trials conducted by name brand manufacturers. ANDA's are approved based on the initial safety profile of the name brand drug, as well as any postmarketing surveillance. See Bartlett v. Mutual Pharmaceutical Co., Inc., --- F.Supp.2d ---, No. 08-cv-358-JL, 2009 WL 3126305, at *2-*6 (D.N.H. Sept. 30, 2009) (detailing

requirements and history of ANDA procedure). As a result, ANDA applicants must show the FDA that their drug is essentially the same as the name brand drug and that their proposed label is in relevant part identical to the name brand drug label. 21 C.F.R. § 314.94(a)(8).

Drug labels are subject to change. New risks may become apparent only after the drug has been used more widely and for longer periods. When a manufacturer has "reasonable evidence of an association of a serious hazard with a drug[,]" the drug's label must be revised; "a causal relationship need not have been proved." 21 C.F.R. § 201.57(e) (redesignated as 21 C.F.R. § 201.80(e) in 2006, after the conduct at issue here). Manufacturers cannot distribute a "misbranded" drug, 21 U.S.C. §§ 331(a)-(b), including a drug whose "labeling is false or misleading in any particular." *Id.* at § 352(a). The FDA has several enforcement mechanisms to ensure that drugs with misleading labels are taken off the market. *See, e.g., id.* at § 333, 355(e).

There are several procedures in 21 C.F.R. § 314.70 by which a manufacturer may supplement its application and propose changes to the drug or its label. "Major changes" require the FDA's prior approval through a prior approval supplement. 21 C.F.R. § 314.70(b). Manufacturers may implement "moderate changes," including changing a label to strengthen a warning based on newly acquired information, through a Changes Being Effected (CBE) supplement. 21 C.F.R. § 314.70(c)(6)(iii)(A)-(D). Manufacturers may implement CBE changes before the FDA formally approves them.

The FDA approved Reglan in 1980. Manufacturers began seeking approval for generic versions of metoclopramide five years later. The generic metoclopramide labels have always been in relevant part the same as the Reglan label. The label warnings about tardive dyskinesia, and other similar but less severe extrapyramidal symptoms, did not change from 1985 through the time Mensing stopped ingesting the drug in 2005. Mensing alleges that despite mounting evidence that long term

metoclopramide users were at a much greater risk of movement disorders than indicated by the drug's label, no manufacturer took any step to enhance the warnings.² Moreover, Mensing asserts that defendants promoted metoclopramide for long term use even though the FDA had approved the drug only for use up to 12 weeks.

Acting on its own initiative pursuant to the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (FDAAA), the FDA ordered manufacturers of Reglan and generic metoclopramide on February 26, 2009 to add a boxed warning to their labels about the increased risks of tardive dyskinesia from long term metoclopramide usage.

B.

In considering a preemption defense we must be attuned to Congressional intent and the presumption against preemption. Wyeth v. Levine, 129 S.Ct. 1187, 1194-95 (2009) (quotation omitted) (courts must assume "that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."). In Wyeth, the Supreme Court ruled that failure to warn claims against name brand manufacturers are not preempted by the FDCA. The Court noted the historic coexistence of state tort remedies and federal regulation of prescription drugs:

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. But despite its 1976 enactment of an express pre-emption provision for medical devices, . . . Congress has not enacted such a provision for prescription drugs. . . . Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA

²Mensing notes that in July 2004 the FDA approved Schwarz's request to add a sentence to the Reglan label: "Therapy should not exceed 12 weeks in duration."

oversight to be the exclusive means of ensuring drug safety and effectiveness.

Id.

The Hatch-Waxman Amendments are part of this 70 year history and they do not explicitly preempt suits against generic manufacturers. Congress could have crafted a preemption provision for generic drugs in its 1984 amendments, having done so for medical devices less than 10 years earlier. It chose not to do that. Seven in ten prescriptions filled in this country are now for generic drugs. Susan Okie, *Multinational Medicines—Ensuring Drug Quality in an Era of Global Manufacturing*, 361 *New Eng. J. Med.* 737, 738 (2009). After Wyeth, 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.

The generic defendants distinguish Wyeth on the ground that it concerned claims against brand name manufacturers, but the decision carries important implications for their situation as well. *See, e.g., Wyeth*, 129 S. Ct. at 1197-98 ("[I]t has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate[.]"). The district court did not have the teachings of Wyeth available when it rendered its decision, but courts which have subsequently considered this issue have almost uniformly ruled that tort claims against generic manufacturers are not preempted. *See, e.g., Stacel v. Teva Pharmaceuticals, USA*, 620 F.Supp.2d 899, 906-907 (N.D. Ill. 2009); Schrock v. Wyeth, 601 F.Supp.2d 1262, 1265-66 (W.D.Okla.2009). The Fourth Circuit reached the same conclusion much earlier in considering whether a plaintiff injured by a generic drug can hold a name brand manufacturer liable. Foster v. American Home Products Corp., 29 F.3d 165, 170 (4th Cir. 1994) ("The statutory scheme governing premarketing approval for drugs simply does not evidence

Congressional intent to insulate generic drug manufacturers from liability for misrepresentations made regarding their products, or to otherwise alter state products liability law.").

Even when a federal law does not expressly preempt state law claims, a court may find that Congress impliedly preempted such claims by "conflict" if 1) compliance with both federal and state law is impossible, or 2) the claims would "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372-73 (2000) (quotation omitted). The district court concluded that each basis for conflict preemption was present. We disagree.

C.

The Supreme Court characterized "[i]mpossibility pre-emption [as] a demanding defense." Wyeth, 129 S.Ct. at 1199. To prevail on that defense, the generic defendants must show that compliance with both federal law and the state laws Mensing seeks to enforce is not merely difficult, but "a physical impossibility." Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153 (1982) (quotation omitted). The parties agree that generic labels must be substantively identical to the name brand label even after they enter the market. See, e.g., 21 C.F.R. § 314.150(b)(10) (FDA may withdraw approval of a generic drug if its label is "no longer consistent" with the name brand label); 57 Fed. Reg. at 17961, cmt. 39 (1992). Because of this requirement, the generic manufacturers argue they are prohibited from implementing a unilateral label change without prior FDA approval through the CBE process. Yet, 21 C.F.R. § 314.97 compels generic manufacturers to "comply with the requirements of §[] 314.70[.]" Section 314.70 includes the CBE process *and* the prior

approval supplement process.³ In this case we need not decide whether generic manufacturers may unilaterally enhance a label warning through the CBE procedure⁴ because the generic defendants could have at least *proposed* a label change that the FDA could receive and impose uniformly on all metoclopramide manufacturers if approved.

The regulatory framework makes clear that a generic manufacturer must take steps to warn its customers when it learns it may be marketing an unsafe drug. Generic manufacturers are subject to the requirement that their labeling "shall be revised as soon as there is reasonable evidence of an association of a serious hazard with a drug[.]" 21 C.F.R. § 201.57(e). The generic defendants argue that they comply with this statute by simply ensuring that their labels match the name brand label. Mensing alleges that the Reglan manufacturers did nothing to strengthen the label despite reasonable evidence of the drug's association with a serious hazard. In these circumstances, § 201.57(e) does not permit generic manufacturers passively to accept the inadequacy of their drug's label as they market and profit from it. See

³See supra sec. II-A for a discussion of these regulatory processes. If the defendants were correct that generic manufacturers can use the CBE process only to copy label changes initiated by the name brand manufacturer, it is curious that § 314.70(c) was never revised to distinguish between name brand and generic manufacturers.

⁴The district court relied heavily on two FDA statements that no longer carry the same weight after Wyeth. In light of Wyeth, the FDA formally withdrew its amicus briefs in Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514 (E.D.Pa. 2006); aff'd in part and rev'd in part, 521 F.3d 253 (3d Cir. 2008); vacated, 129 S.Ct. 1578 (2009). The other FDA statement appears in a footnote in the "Supplementary Information" section of a notice of proposed rule making for a regulation *not pertaining to generic drugs*. 73 Fed. Reg. 2848, 2849 n.1 (Jan. 16, 2008) ("CBE changes are not available for generic drugs."). Even the defendants admit that generic manufacturers can use the CBE process, § 314.97, to copy an updated name brand label. See also Demahy v. Wyeth, Inc., 586 F.Supp.2d 642, 655 (E.D.La. 2008), appeal docketed, No. 08-31204 (5th Cir. Dec. 16, 2008); Wyeth, 129 S.Ct. at 1201.

Wyeth, 129 S.Ct. at 1202 ("The FDA has limited resources to monitor the 11,000 drugs on the market[.] . . . [M]anufacturers, not the FDA, bear primary responsibility for their drug labeling[.]"). The statute itself empowers the FDA to withdraw approval for a drug that is "misbranded" due to an insufficient label. 21 U.S.C. §§ 331(a)-(b), 352(a).

Interpretive commentary outside the regulations supports the requirement that at a minimum a generic manufacturer should alert the agency to any new safety hazard associated with its product. In commentary published contemporaneously to the adoption of the Hatch-Waxman Amendments, the FDA stated: "After approval of an ANDA, if an ANDA holder [a generic manufacturer] believes that new safety information should be added, *it should provide adequate supporting information to FDA*, and FDA will determine whether the labeling for the generic and listed drugs should be revised." 57 Fed. Reg. 17950, 17961 cmt. 40 (Apr. 28, 1992) (emphasis supplied).

Further, 21 C.F.R. § 314.98 requires that generic manufacturers follow the same record keeping and reporting of adverse drug experiences post marketing that name brand manufacturers must undertake. In discussing this provision, the FDA noted that "ANDA applicants [must] submit a periodic report of adverse drug experiences even if the ANDA applicant has not received any adverse drug experience reports *or initiated any labeling changes*." 57 Fed. Rep. 17950, 17965 cmt 53 (Apr. 28, 1992) (emphasis supplied). See also CDER, Guidance for Industry, Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications 1-3 (Dec. 2001) (describing ANDA amendments addressing "labeling deficiencies" as "minor amendments" that the FDA will attempt to review within 60 days).

Implicit in these comments is the FDA's expectation that generic manufacturers will initiate label changes other than those made to mirror changes to the name brand label and that the agency will attempt to approve such proposals quickly. The

availability of one particular procedure (the CBE process, on which the district court expended the majority of its discussion) is immaterial to the preemption analysis in light of this clear directive to generic manufacturers and the availability of the prior approval process.

Because there is nothing in the FDCA or Hatch-Waxman Amendments that explicitly forbids them from proposing a label change through the prior approval process, the generic defendants cite regulatory language in § 314.70 to the effect that the prior approval procedure is for "major changes" while changes to enhance warnings are subject to the CBE procedure. Defendants' reading of § 314.70 is too restrictive. The section they cite establishes various methods of proposing changes to approved drugs. The more significant the change, the more notice the FDA needs prior to its implementation. The section repeatedly uses the nonrestrictive phrase "[t]hese changes include, but are not limited to" in order to describe the changes manufacturers can propose through each kind of supplement. §§ 314.70(b)(2), (c)(2), (d)(2). Section 314.70 does not evidence an FDA policy, let alone Congressional intent, to prevent generic manufacturers from proposing changes to a label's warning through the prior approval process. Indeed, manufacturers are *required* to use the prior approval process for "labeling changes" (with a few exceptions including permissive use of the CBE process for warning enhancements, § 314.70(b)(2)(v)(A)).

In addition to proposing a label change, the generic manufacturers could have suggested that the FDA send out a warning letter to health care professionals. When the FDA first adopted its labeling regulations, well before the Hatch-Waxman Amendments, it stated that the requirements "do not prohibit a manufacturer . . . from warning health care professionals whenever possibly harmful adverse effects associated with the use of the drug are discovered." 44 Fed. Reg. 37434, 37447 (June 26, 1979); see also CDER, Manual of Policies and Procedures (MAPP) 6020.10, NDAs: "Dear Health Care Professional" Letters (July 2, 2003) (guidance document

to name brand manufacturers stating that the letters may be ordered by the FDA or sent by manufacturers without FDA involvement).⁵

The generic defendants argue that they have no duty under the FDCA to propose stronger warnings, but the issue here is whether they have such a duty under state law. The question before this court is whether generic defendants can both fulfill a state law duty to warn and comply with the FDCA. Does federal law forbid them from taking steps to warn their customers? The district court concluded that generic drug manufacturers "may seek to add safety information to a drug label" through the prior approval process or by requesting that the FDA send "Dear Health Care Professional" letters, but it remained uncertain what the FDA might have done had they proposed a label change. It therefore hesitated to impose liability based on speculation.

Subsequently, the Supreme Court made it clear in Wyeth that uncertainty about the FDA's response to such measures makes federal preemption less likely. "[A]bsent clear evidence that the FDA would not have approved a change to [the drug's] label, we will not conclude that it was impossible for [the manufacturer] to comply with both federal and state requirements." Wyeth, 129 S.Ct. at 1198; see also Grand River Enterprises Six Nations, Ltd. v. Beebe, 574 F.3d 929, 936 (8th Cir. 2009) ("[A] hypothetical or potential conflict is insufficient to warrant the pre-emption of the state

⁵Mensing argues that the generic defendants themselves could have warned their customers of the risk of tardive dyskinesia through such letters. The letters are considered regulated labeling, 21 C.F.R. §§ 202.1(1)(1), (2), and under the FDAAA, the FDA sends the letters out on behalf of ANDA holders if it determines that such a letter is a necessary part of a risk evaluation and mitigation strategy. 21 U.S.C. § 355-1(i)(2). Although the FDAAA was not in effect when Mensing took metoclopramide, it provides support for the defendants' contention that Congress did not intend that generic manufacturers send out "Dear Healthcare Provider" letters uncoordinated with other manufacturers of the drug.

statute."), citing Rice v. Norman Williams Co., 458 U.S. 654, 659 (1982).⁶ To support preemption the generic defendants must show the likelihood of FDA *inaction*. The record contains nothing, let alone "clear evidence," to suggest the FDA would have rejected a labeling proposal from any of them. In fact, earlier this year the FDA mandated that metoclopramide manufacturers enhance the label's warning of the risks of tardive dyskinesia. See Letter from Joyce Korvick, CDER (Feb. 26, 2009), available at <http://www.fda.gov/downloads/Drugs/DrugSafety/.../UCM111376.pdf>.

The generic defendants attempt to minimize the significance of Wyeth by focusing on Justice Breyer's one paragraph concurring opinion, in which he emphasized the majority's point that an agency could preempt state law through "lawful specific regulations[.]" Wyeth, 129 S.Ct. at 1204 (Breyer, J. concurring). The defendants cite no regulations specifically mandating preemption like those posed as examples in Wyeth, however. Id. at 1201, n.9. On the face of the regulations in effect, generic manufacturers must comply with the CBE procedure and maintain adequate warnings. 21 C.F.R. §§ 314.97, 201.57(e). As Judge William K. Sessions

⁶The generic defendants argue that they would risk rescindment of their ANDA by implementing a unilateral label change through the CBE procedure without prior FDA approval. 21 C.F.R. § 314.150(b)(10). FDA commentary to § 314.150 makes clear that the section's purpose is to enforce the undisputed requirement that generic manufacturers change their label to match a name brand change. 57 Fed. Reg. 17950, 17970 cmt. 78 (Apr. 28, 1992). The issue of preemption does not rest on the availability of the CBE procedure, and hypothetical conflicts are not favored.

In Wyeth, the Supreme Court found it "difficult to accept" that "the FDA would bring an enforcement action against a manufacturer for strengthening a warning pursuant to the CBE regulation." Wyeth, 129 S.Ct. at 1197. The defendants have not cited a single instance in which the FDA even threatened an enforcement action against a generic manufacturer for unilaterally enhancing its label warnings. Moreover, "[t]he FDCA does not provide that a drug is misbranded simply because the manufacturer has altered an FDA-approved label;" the misbranding provisions focus on the accuracy of the label's substance, including the adequacy of its warnings. Id.; see also 21 U.S.C. §§ 355(e); id. at 352.

III has observed, Justice Breyer's concurrence "does not come close to a hint that an unofficial FDA interpretation at odds with the plain language of a regulation will have preemptive effect." Kellogg v. Wyeth, 612 F.Supp.2d 437, 442 (D.Vt. 2009) (concluding that Wyeth undermines preemption claims of generic manufacturers).

The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product. Instead, they are alleged to have placed a drug with inadequate labeling on the market and profited from its sales. If Mensing's injuries resulted from their failure to take steps to warn their customers sufficiently of the risks from taking their drugs, they may be held liable.

D.

Even if compliance with state and federal law is not impossible, state claims could still be preempted if they would obstruct the purposes and objectives of federal law. The generic defendants argue that proposing a label change would necessitate expensive clinical studies, thwarting the goal of the Hatch-Waxman Amendments to bring low cost generic drugs to market quickly. Yet the FDA did not conduct its own studies when it mandated an enhanced warning for metoclopramide. It simply referenced studies published elsewhere. Requests for label changes must be supported by scientific substantiation,⁷ but there is nothing to indicate that the information must be acquired through a manufacturer's own clinical tests. As a matter of fact, the Supreme Court concluded in Wyeth that multiple reports of an adverse experience with a drug provided the scientific substantiation to justify a manufacturer's request to change a label. Wyeth, 129 S.Ct. at 1197. Generic manufacturers are already required to collect and report adverse drug experiences with their products. 21 C.F.R.

⁷Section 314.70(c)(6)(iii)(A) addresses CBE labeling changes to strengthen warnings; the applicable version during the period when Mensing took metoclopramide did not specify an evidentiary standard.

§ 314.98, referencing 21 C.F.R. § 314. 80. Mensing alleges that if the generic manufacturers had merely taken note of the accumulation of adverse drug experiences reports and the published medical studies about metoclopramide, they would have had sufficient substantiation to warrant a label change.

The obligation Mensing seeks to impose upon generic manufacturers does not obstruct the purposes and objectives of the Hatch-Waxman Amendments in any way. On the contrary, "[f]ailure-to-warn actions," like Mensing's, "lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." Wyeth, 129 S.Ct. at 1202. The generic defendants argue that the Hatch-Waxman Amendments supply the relevant statutory framework, rather than the whole FDCA. Yet additions to the statute like the Hatch-Waxman Amendments must be considered part and parcel of the FDCA. These amendments provided for cheaper, expedited approval of generic drugs, not relief from the fundamental requirement of the FDCA that all marketed drugs remain safe. Congress and the FDA have long viewed state tort law as complementing, not obstructing, the goals of the FDCA. Wyeth, 129 S.Ct. at 1199-1200 (Congress "determined that widely available state rights of action provided appropriate relief for injured [drug] consumers" and that "state-law remedies further consumer protection by motivating manufacturers . . . to give adequate warnings."); id. at 1197 ("[T]he statute contemplates that federal juries will resolve most misbranding claims[.]").

"If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005). Like the Fourth Circuit in Foster, 29 F.3d at 170, we decline to assume that Congress intended to shield from tort liability the manufacturers of the majority of the prescription drugs consumed in this country and leave injured parties like Mensing no legal remedy.

III.

We turn next to Mensing's claims against the name brand manufacturers. Traditional products liability requires a plaintiff to show that she actually consumed the defendant's product. See, e.g., Bixler by Bixler v. Avondale Mills, 405 N.W.2d 428 (Minn. App. 1987). Although she never ingested name brand Reglan, Mensing claims that the name brand manufacturers are liable for various common law torts including negligent representation and fraud for misrepresenting the risks of tardive dyskinesia associated with metoclopramide.

Mensing's theory was rejected in Foster. There, the plaintiffs argued that "because generic drugs are required by federal law to be equivalent to their name brand counterparts," the name brand defendant should be responsible for representations or omissions on the generic manufacturer's label. Foster, 29 F.3d at 169. The Fourth Circuit's response was that the plaintiffs were reframing products liability claims which they could not prove. Id. at 168. Presuming that generic manufacturers were responsible for altering their own labels when postapproval safety concerns arose, the court found no legal precedent to hold the name brand manufacturers liable for injuries caused by their competitors. Id. at 170. Subsequently, the overwhelming majority of courts considering this issue has reached the same conclusion.⁸

The Minnesota Court of Appeals is one of these courts. In Flynn v. American Home Products Corp., 627 N.W.2d 342 (Minn. App. 2001), a plaintiff like Mensing sought to hold name brand manufacturers liable for the harm caused by ingesting a generic equivalent. The court declined to recognize the "fraud on the FDA" claim essentially based on the name brand defendant's misrepresentations to the FDA about

⁸Thirty two courts applying the laws of at least seventeen states, according to the defendants.

the drug's safety, and it also rejected an alternative argument based on Minnesota tort law. Id. at 350-52. Mensing argues that, unlike the Flynn plaintiffs, she did allege that the name brand defendants' representations "were relied upon by her physician when issuing the prescription." Id. at 349-50. Mensing cites only one court since Foster to have found such a factor determinative. Conte v. Wyeth, 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008).

Whatever the merits of Conte under California law, the Flynn court concluded that "central" to a fraudulent misrepresentation claim under Minnesota law is "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." Flynn, 627 N.W.2d at 350 (quotations omitted). In other words, regardless of whether her doctor relied upon the Reglan label, Mensing must show that the name brand manufacturers owed *her* a duty of care. Duty is a threshold requirement for all of the tort claims Mensing asserts.⁹ See, e.g., Noble Systems Corp. v. Alorica Central, LLC, 543 F.3d 978, 985 (8th Cir. 2008) (finding that under Minnesota law negligent misrepresentation requires the plaintiff to "prove some relationship that is sufficient to create a duty owed by the defendant to the plaintiff").

Such a duty of care does not extend to all potential Reglan consumers. "Minnesota common law . . . requires a stronger relationship and a direct communication." Flynn, 627 N.W.2d at 350. Since Mensing "did not purchase or use [the name brand defendants'] product, . . . there was no direct relationship between

⁹Mensing's attempt to characterize her fraud claim as a type requiring no proof of a duty of care is unavailing. A plaintiff claiming fraud in Minnesota must show that the defendant intended to induce another to act in reliance on its fraudulent statement. Specialized Tours, Inc. v. Hagen, 392 N.W.2d 520, 532 (Minn. 1986). Mensing's relationship with the Reglan manufacturers is too attenuated, and she has cited no Minnesota case in which the court imposed liability for fraud on a defendant who did not intend to communicate with the plaintiff. The Reglan manufacturers intended to communicate with their customers, not the customers of their competitors.

them, let alone a fiduciary relationship that gave rise to a duty." Id. at 350. Mensing focuses on the foreseeability of harm from the defendants' action. Like the Fourth Circuit, we conclude that holding name brand manufacturers liable for harm caused by generic manufacturers "stretch[es] the concept of foreseeability too far." Foster, 29 F.3d at 171. As for Mensing's negligent misrepresentation claim, "the Minnesota Supreme Court has recognized negligent misrepresentation involving damages only for pecuniary loss[.]" Flynn, 627 N.W.2d at 350, citing Smith v. Brutger Cos., 569 N.W.2d 408, 414 (Minn. 1997). We find it unlikely the Minnesota Supreme Court would extend the doctrine to misrepresentation involving the risk of physical harm in these circumstances. We conclude that under Minnesota law Mensing has not shown that the name brand manufacturers owed her a duty of care necessary to trigger liability.

IV.

In sum, we conclude that Mensing has stated a viable claim against the generic metoclopramide manufacturers. Far from prohibiting them from taking steps to warn their customers of new safety hazards, federal law requires such action. For the reasons stated we reverse the judgment in favor of the generic manufacturers but affirm the judgment as to the name brand manufacturers.
