REL:08/15/2014

SUPREME COURT OF ALABAMA

SPECIAL TERM, 2014

1101397

Wyeth, Inc.,[1] et al.

v.

Danny Weeks and Vicki Weeks

Certified Question from the United States District Court for the Middle District of Alabama, Southern Division

(Case No. 1:10-cv-602)

On Application for Rehearing

BOLIN, Justice.

The opinion of January 11, 2013, is withdrawn, and the

---

[1]Although the style of the order certifying the question shows this entity as "Wyeth, Inc.," it is also referred to in the order, briefs, and other documents submitted to this Court as "Wyeth, LLC."

following is substituted therefor.

The United States District Court for the Middle District of Alabama, Southern Division ("the district court"), has certified to this Court the following question pursuant to Rule 18, Ala. R. App. P.:

> "Under Alabama law, may a drug company be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture or distribution of a brand-name drug, by a plaintiff claiming physical injury from a generic drug manufactured and distributed by a different company?"

Facts and Procedural History

In its certification to this Court, the district court provided the following background information:

> "Plaintiffs Danny and Vicki Weeks filed this action against five current and former drug manufacturers for injuries that Mr. Weeks allegedly suffered as a result of his long-term use of the prescription drug product metoclopramide, which is the generic form of the brand-name drug Reglan.® The Weekses claim that two companies -- Teva Pharmaceuticals USA and Actavis Elizabeth, LLC -- manufactured and sold the generic metoclopramide that Mr. Weeks ingested.
>
> "The Weekses concede that Mr. Weeks did not ingest any Reglan® manufactured by the three brand-name defendants, Wyeth LLC, Pfizer Inc., and Schwarz Pharma, Inc. The Weekses nonetheless assert that the brand-name defendants are liable for Mr. Weeks's harm on fraud, misrepresentation, and/or suppression

theories because they at different times manufactured or sold brand-name Reglan® and purportedly either misrepresented or failed adequately to warn Mr. Weeks or his physician about the risks of using Reglan® long-term. The brand-name defendants moved to dismiss the claims against them, arguing, among other things, (1) that the Weekses' claims, however pled, are in fact product liability claims that are barred for failure of 'product identification' and (2) that they had no duty to warn about the risks associated with ingestion of their competitors' generic products. The Weekses responded to the brand-name defendants' motion, and the defendants replied. On March 31, 2011, this Court granted in part and denied in part the brand-name defendants' motion, holding that the Weekses might be able to state a claim for relief under Alabama law if they could prove that the brand-name manufacturers had a duty to warn Mr. Weeks's physician about the risks associated with long-term use of brand-name Reglan® and, further, that the Weekses, as third parties, had a right to enforce an alleged breach of that duty.

"Within the last year alone, federal district courts in this State have issued four decisions addressing the question whether brand-name Reglan® manufacturers can be held liable on fraud, misrepresentation, and/or suppression theories for physical injuries allegedly caused by plaintiffs' ingestion of generic metoclopramide. The first two courts answered no; however, this Court held otherwise, thereby creating an intrastate split. Compare Simpson v. Wyeth, Inc., No. 7:10-CV-01771-HGD, ... (N.D. Ala. Dec. 9, 2010)[not reported in F. Supp. 2d], report and recommendation adopted (N.D. Ala. Jan. 4, 2011)[not reported in F. Supp. 2d] (holding that a brand-name manufacturer has no duty under Alabama law to warn of the risks associated with a competitor's generic product); Mosley v. Wyeth, Inc., 719 F. Supp. 2d 1340 (S.D. Ala. 2010)(same), with Weeks v. Wyeth, Inc., No. 1:10-cv-

602 (M.D. Ala. Mar. 31, 2011)[not reported in F. Supp. 2d](denying brand-name manufacturers' motion to dismiss on the ground that the plaintiffs there had pleaded a claim 'that defendants perpetrated a fraud on the physician'); see also Barnhill v. Teva Pharm. USA. Inc., No. Civ. 06-0282-CB-M (S.D. Ala. Apr. 24, 2007)[not reported in F. Supp. 2d](holding that a brand-name manufacturer of the drug Keflex® has no duty under Alabama law to warn of the risks associated with a competitor's generic product). Since this Court's decision, another district court in Alabama has followed the earlier decisions. See Overton v. Wyeth, Inc., No. CA 10-0491-KD-C (S.D. Ala. Mar. 15, 2011)[not reported in F. Supp. 2d], report and recommendation adopted (S.D. Ala. Apr. 7, 2011)[not reported in F. Supp. 2d].

"Certification is appropriate here to resolve the disagreement among the federal district courts within Alabama and to prevent both federal courts within the State and state courts around the country from having to 'mak[e] unnecessary Erie guesses' about unsettled questions of Alabama law. Tobin v. Michigan Mut. Ins. Co., 398 F.3d 1267, 1274 (11th Cir. 2005); see also, e.g., Lehman Bros. v. Schein, 416 U.S. 386, 391 (1974)(noting that certification often 'save[s] time, energy, and resources and helps build a cooperative judicial federalism'). 'Because the only authoritative voice on Alabama law is the Alabama Supreme Court, it is axiomatic that that court is the best one to decide issues of Alabama law.' Blue Cross & Blue Shield of Ala., Inc. v. Nielsen, 116 F.3d 1406, 1413 (11th Cir. 1997).

"The question framed ... satisfies the requirements of Ala. R. App. P. 18(a): first, it presents a pure question of Alabama law; second, it is 'determinative' of this case in the sense that a negative answer would require dismissal of the Weekses' claims against the brand-named defendants; and third, although two Alabama trial courts have addressed the question whether a brand-name

manufacturer can ever be held liable for physical harm caused by a generic product and answered it in the negative,[1] the Alabama Supreme Court has never considered or resolved either that question or the subsidiary question whether a plaintiff claiming physical injury can prevail on fraud, misrepresentation, and/or suppression theories under these facts.

"Considerations of judicial efficiency likewise counsel certification. During the last year, the number of Reglan®/metoclopramide cases nationwide ballooned from 250 to approximately 3500. Current estimates suggest that among the 3500 cases there are at least 250 Alabama-resident plaintiffs and that most (if not all) of these plaintiffs assert the fraud, misrepresentation, and/or suppression theories asserted here. The Alabama Supreme Court's definitive resolution of the question presented will therefore affect not only cases pending (or that might later arise) in this State, but also the scores of Alabama-resident cases pending in courts around the country -- particularly in large consolidated actions pending in California, New Jersey, and Pennsylvania. Moreover, the question's significance extends well beyond the Reglan® litigation -- and for that matter, even beyond pharmaceutical litigation. It is likely to recur any time a brand-name manufacturer (of any product) is sued on fraud, misrepresentation, and/or suppression theories by a plaintiff who claims to have been injured while using a generic-equivalent product.

"....

"[1]See Buchanan v. Wyeth Pharm., Inc., No. CV-2007-900065, Order at 1 (Ala. Cir. Ct. Oct. 20, 2008); Green v. Wyeth Pharm., Inc., No. CV-06-3917

ER (Ala. Cir. Ct. May 14, 2007)."

Discussion

At the outset, we limit the question posed to manufacturers of prescription drugs and not to any distributors thereof.[2] The Weekses' complaint alleges that three brand-name manufacturers, Wyeth, Pfizer, Inc., and Schwarz Pharma, Inc. (hereinafter collectively referred to as "Wyeth"), falsely and deceptively misrepresented or knowingly suppressed facts about Reglan or metoclopramide such that Danny Weeks's physician, when he prescribed the drug to Danny, was materially misinformed and misled about the likelihood that the drug would cause the movement disorder tardive dyskinesia and related movement disorders.[3] The Weekses contend that Wyeth had a duty to warn Danny's physician about

[2]We have agreed to answer the certified question, which impacts only the narrow field of prescription drugs, which is subject to stringent Food and Drug Administration regulations and oversight. This opinion does not plow new ground, nor does it create a heretofore unknown field of tort law that has been referred to as "innovator liability," as discussed infra. Instead, this opinion answers the question whether the Weekses may bring a fraudulent-misrepresentation claim under Alabama law.

[3]The Weekses also sued generic manufacturers of metoclopramide, Teva Pharmaceuticals USA and Actavis Elizabeth, LLC.

the risks associated with the long-term use of metoclopramide and that the Weekses, as third parties, have a right to hold Wyeth liable for the alleged breach of that duty.

A fraudulent-misrepresentation action is governed by § 6-5-101, Ala. Code 1975, which provides that "[m]isrepresentations of a material fact made willfully to deceive, or recklessly without knowledge, and acted on by the opposite party, or if made by mistake and innocently and acted on by the opposite party, constitute legal fraud." A claim of fraudulent misrepresentation comprises the following elements: "(1) a false representation (2) concerning a material fact (3) relied upon by the plaintiff (4) who was damaged as a proximate result." Fisher v. Comer Plantation, 772 So. 2d 455, 463 (Ala. 2000)(quoting Baker v. Bennett, 603 So. 2d 928, 935 (Ala. 1992)). "An essential element of fraudulent-misrepresentation and fraudulent-suppression claims is a duty to disclose." Nesbitt v. Frederick, 941 So. 2d 950, 955 (Ala. 2006).

We recognize that Wyeth argues that the Weekses' claims are, in essence, "products-liability" claims. In Atkins v. American Motors Corp., 335 So. 2d 134 (Ala. 1976), in

conjunction with Casrell v. Altec Industries, Inc., 335 So. 2d 128 (Ala. 1976), this Court adopted the Alabama Extended Manufacturer's Liability Doctrine ("AEMLD"). The AEMLD is "a judicially created accommodation of Alabama law to the doctrine of strict liability for damage or injuries caused by allegedly defective products." Keck v. Dryvit Sys., Inc., 830 So. 2d 1, 5 (Ala. 2002). This Court has explained that the AEMLD did not subsume a common-law negligence or wantonness claim. Tillman v. R.J. Reynolds Tobacco Co., 871 So. 2d 28 (Ala. 2003); Vesta Fire Ins. Corp. v. Milam & Co. Constr., 901 So. 2d 84 (Ala. 2004).

> "It must be remembered, ... that the AEMLD, as established in Casrell and Atkins, supra, is 'an example of judicial legislation,' not of legislative enactment. Keck v. Dryvit Sys., Inc., 830 So. 2d 1, 8 (Ala. 2002). This Court warned last year in Keck that '[j]udicial decision-making should not be seen as the opportunity to legislate.' 830 So. 2d at 8. Alabama remains a common-law state, and therefore common-law tort actions 'so far as [they are] not inconsistent with the Constitution, laws and institutions of this state ... shall continue in force, except as from time to time ... may be altered or repealed by the Legislature.' § 1-3-1, Ala. Code 1975. We will not presume to so define the boundaries of the judicially created AEMLD so that it subsumes the common-law tort actions of negligence and wantonness against the retailer defendants."

Tillman, 871 So. 2d at 34-35. We have also recognized that

fraudulent suppression is a claim separate from an AEMLD claim. Keck, supra. Accordingly, for purposes of this certified question, we will not treat the Weekses' claims as AEMLD claims governed by the principles of the AEMLD.

Wyeth argues, based on Pfizer, Inc. v. Farsian, 682 So. 2d 405 (Ala. 1996), that a plaintiff who in substance alleges physical injury caused by a product has a products-liability claim, no matter the label or labels he uses in his complaint, and that, in a products-liability claim, the plaintiff must prove that the defendant manufactured the product the plaintiff claims injured him or her. We recognize that in Farsian this Court contended that the plaintiff's claim was in substance a products-liability claim and not a fraud claim as he had asserted. In Farsian, a heart-valve recipient's valve had not malfunctioned, although the valves in some other patients who had received the valve made by the manufacturer had malfunctioned. The federal court where the action was filed certified the following question to this Court:

> "'Does a heart valve implantee have a valid cause of action for fraud under Alabama law if he asserts that the valve's manufacturer fraudulently induced him to have the valve implanted when the damages he asserts do not include an injury-producing malfunction of the product because the

valve has been and is working properly?'"

682 So. 2d at 406. The manufacturer argued that, although the plaintiff had alleged a risk of possible future malfunction of the valve, it was uncontroverted that his valve was and had been working properly. The manufacturer contended that the plaintiff was really asserting a products-liability claim and that, as such, the action did not accrue until there was an injury-producing malfunction. The manufacturer further argued that an allegation of fraud did not relieve the plaintiff from having to prove an injury-producing malfunction. The plaintiff argued that his fraud claim was not subsumed by products-liability law and that he could recover damages even if he could not prove that his valve was not yet malfunctioning.

In addressing the question, we stated:

> "The question certified to this Court concerns whether [the plaintiff] may maintain a fraud claim under Alabama law. We conclude that he may not.
>
> "Regardless of how [the plaintiff] pleads his claim, his claim is in substance a product liability/personal-injury claim -- [the plaintiff] seeks damages because of the risk that his heart valve may one day fail. Alabama courts have never allowed a recovery based on a product that, like [the plaintiff]'s valve, is and has been working properly. Each of our prior cases in which fraud or

> other intentional conduct was alleged has involved a failure, a malfunction, or an accident that involved the defendant's products and which injured the plaintiff. See Quality Homes Co. v. Sears, Roebuck & Co., 496 So. 2d 1 (Ala. 1986); Treadwell Ford, Inc. v. Campbell, 485 So. 2d 312, 313 (Ala. 1986), appeal dismissed, 486 U.S. 1028, 108 S.Ct. 2007, 100 L.Ed.2d 596 (1988)."

682 So. 2d at 407. Ultimately, we stated:

> "[The plaintiff]'s heart valve has not failed. Instead, it has been working properly and as intended by its manufacturer .... Although the parties see different theories of this case -- [the plaintiff] relying upon Alabama fraud law, while [the manufacturer] argues in the context of product liability law -- we conclude that the answer to the certified question, whether it is couched in terms of fraud law or in terms of product liability law, must be that [the plaintiff] does not now have a cause of action for damages, because the valve has not failed."

682 So. 2d at 408. Farsian is distinguishable. This Court's holding there was that, under either a fraud theory or a products-liability theory, the plaintiff did not have a valid cause of action because fear that the valve could fail in the future was not, without more, a legal injury sufficient to support his claim. In the present case, the Weekses are arguing that Wyeth fraudulently misrepresented or suppressed facts to Danny's physician regarding the dangers of the long-term use of Reglan and that, as a result, Danny was injured.

This is not a claim that the drug ingested by Danny was defective; instead, it is a claim that Wyeth fraudulently misrepresented or suppressed information about the manner in which (i.e., the duration) the drug was to be taken. In short, the Weekses' claim is based on what Wyeth said or did not say about Reglan and their assertion that those statements or omissions caused Danny's injuries. Farsian does not support a conclusion by this Court that the Weekses' claim is in substance a products-liability claim.

We note that Alabama's Pharmacy Act, § 34-23-1 et seq., Ala. Code 1975, permits a pharmacist to select in place of a brand-name drug a less expensive drug product that is the pharmaceutical and therapeutical equivalent of the brand-name drug and that contains the same active ingredient or ingredients and is the same dosage-form strength, unless the prescribing physician indicates otherwise on the prescription. § 34-23-8, Ala. Code 1975. In the present case, it appears that Danny's prescription did not prohibit the pharmacist from substituting a generic drug for the brand-name drug. "Currently all states have some form of generic substitution law." PLIVA, Inc. v. Mensing, 564 U.S. ___, __, 131 S.Ct.

2567, 2583 (2011)(Sotomayor, J., dissenting). That a pharmacist acted under § 34-23-8 and gave Danny a generic drug does not preclude Danny's ability to assert a fraudulent-misrepresentation claim against the brand-name manufacturer of the drug. Additionally, many insurance plans are structured to promote the use of generic drugs. PLIVA, 564 U.S. at ___ n.2, 131 S.Ct. at 2584 n.2. We now turn to the federal laws governing prescription drugs.

Prescription drugs are unique because of the extensive federal regulation of that product by the Food and Drug Administration ("the FDA"). "Congress has established a comprehensive regulatory scheme, administered by the FDA, to control the design and distribution of prescription drugs." Blackmon v. American Home Prods. Corp., 328 F. Supp. 2d 659, 665 (S.D. Tex. 2004)(citing 21 U.S.C. §§ 301-393). The FDA has the ultimate authority to determine whether a new prescription drug is safe and effective for use. 21 U.S.C. §§ 355(a) and (d)(prohibiting the distribution of a new drug without FDA approval of a new-drug application showing the drug to be safe and effective). The approval process begins with an investigational new-drug application ("IND") submitted

to the FDA, which includes information about the chemistry, manufacturing, pharmacology, and toxicology of the drug. See 21 U.S.C. § 355(b); 21 C.F.R. § 312.21. The IND also includes pre-clinical data (animal pharmacology and toxicology), and protocols for human testing must be detailed.[4]

After clinical trials on humans have been completed, the manufacturer may submit a new-drug application ("NDA") to the FDA. The manufacturer must present "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling." 21 U.S.C. § 355(d)(5). The NDA shall include: (1) reports of the clinical trials and testing done to determine the safety and effectiveness of the

[4]The clinical phase of testing on human subjects is divided into three phases: Phase one involves about 20 to 100 healthy, nominally paid volunteers and is designed to test for safety and tolerability (21 C.F.R. § 312.21(a)); phase two involves several hundred unpaid volunteers diagnosed with a particular condition and assesses the preliminary efficacy of the drug as well as safety and tolerability (21 C.F.R. § 312.21(b)); and phase three involves hundreds to several thousands of patients and is designed to evaluate the safety and efficacy of the drug on a larger segment of the population (21 C.F.R. § 312.21(c)). The FDA may require phase-four studies concurrent with market approval to conduct postmarketing reports in drugs intended to treat life-threatening and severely debilitating illnesses. 21 C.F.R § 312.95

drug; (2) the complete ingredients or components of the drug; (3) the composition of the drug; (4) a complete description of the manufacturing, processing, and packaging methods and controls; (5) samples of the drug and its components (if requested); and (6) samples of the proposed labeling. 21 U.S.C. § 355(b)(1). The NDA also must disclose all the investigators who worked in clinical trials of the drug, as well as their reports. Also, an NDA must include the patent number and expiration dates for any patents related to or impacted by the drug. 21 U.S.C. § 355(b)(1). The patent is generally good for 20 years, giving the manufacturer (drug developer) the exclusive right to make and sell the drug during that period. 35 U.S.C. § 154(a)(2). The manufacturer make seek a five-year extension of the patent under 35 U.S.C. § 156(g)(6)(A).

When the patent on a brand-name drug expires, generic manufacturers may seek to replicate a generic version. Generic versions of brand-name drugs contain the same active ingredient as the brand-name original. United States v. Generix Drug Corp., 460 U.S. 453 (1983). To expedite the approval process for generic drugs in order to bring

prescription-drug costs down while at the same time preserving patent protections for brand-name drugs, Congress adopted the Drug Price Competition and Patent Term Restoration Act of 1984. 21 U.S.C. § 355. This Act, also known as the Hatch-Waxman Act, provides for an abbreviated new-drug-application ("ANDA") process for the approval of generic versions of brand-name drugs. The ANDA relies on the FDA's previous determination that the brand-name drug is safe and effective. See Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 675 (1990)("The ANDA applicant can substitute bioequivalence data for the extensive animal and human studies of safety and effectiveness that must accompany a full new drug application."). This allows an applicant for a generic version of a drug to avoid the costly and time-consuming process associated with an NDA,[5] which allows the

[5]The marketing of brand-name drugs also adds to the expense of the brand-name drugs. "The prescription drug industry is subject to extensive federal regulation, including the now familiar requirement that prescription drugs be dispensed only upon a physician's prescription. In light of this requirement, pharmaceutical companies have long focused their direct marketing efforts not on the retail pharmacies that dispense prescription drugs but on the medical practitioners who possess the authority to prescribe the drugs in the first place. Pharmaceutical companies promote their products to physicians through a process called 'detailing' whereby employees known as 'detailers' or 'pharmaceutical

dissemination of low-cost generic drugs. See H.R. Rep. No. 98-857 (Part I) at 14 (June 21, 1984). A generic manufacturer is not entitled to all data in the master file controlled by the FDA because some data may constitute trade secrets belonging to the brand-name manufacturer. 21 C.F.R. § 314.430. At the same time, Congress sought to protect brand-name manufacturers whose patent rights could be threatened by the marketing of generic versions of their patented innovations. See American Bioscience, Inc. v. Thompson, 243 F.3d 579, 580 (D.C. Cir. 2001); Purepac Pharm. Co. v. Thompson, 238 F. Supp. 2d 191 (D. D.C. 2002).

Brand-name manufacturers have a duty to supply the FDA with "postmarketing reports," which include reports of any serious and unexpected adverse reactions suffered by a user of a drug. 21 C.F.R. § 314.80. The brand-name manufacturer must also submit annual reports to the FDA on significant information, including information that might affect the safety, effectiveness, or labeling of the product. 21 C.F.R.

---

sales representatives' provide information to physicians in the hopes of persuading them to write prescriptions for the products in appropriate cases." Christopher v. SmithKline Beecham Corp., ____ U.S. ____, ____, 132 S.Ct. 2156, 2163 (2012)(footnote omitted).

§ 314.81. A generic manufacturer is likewise required to submit these reports to the FDA. 21 C.F.R. § 314.98. However, brand-name manufacturers and generic manufacturers have different federal drug-labeling responsibilities.

> "A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. See, e.g., 21 U.S.C. §§ 355(b)(1), (d); Wyeth [v. Levine, 555 U.S. 555], 570-571 [(2009)]. A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's. See, e.g., § 355(j)(2)(A)(v); § 355(j)(4)(G); 21 CFR §§ 314.94(a)(8), 314.127(a)(7)."

PLIVA, 564 U.S. at ___, 131 S.Ct. at 2574. "Drug labels are subject to change. New risks may become apparent only after the drug has been used more widely and for longer periods." Mensing v. Wyeth, Inc., 588 F.3d 603, 606 (8th Cir. 2009), reversed on other grounds, PLIVA, supra. Under the "Changes Being Effected" or "CBE" rule, a brand-name manufacturer, upon discovering a clinically significant hazard, may modify its label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" without FDA approval. 21 C.F.R. § 314.70(c)(6)(iii)(A). Ultimately, the FDA will review any CBE modification to a label. 21 C.F.R. § 314.70(c)(7). If the FDA rejects the change, it may order the

manufacturer to cease distribution of the drug with the revised label. 21 C.F.R. § 314.70(c)(7).

A "label" is defined as "a display of written, printed, or graphic matter upon the immediate container of any article ...." 21 U.S.C. § 321(k). "'[L]abeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). The FDA interprets "labeling" broadly, to include:

> "Brochures, booklets, mailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the 'Physicians Desk Reference') for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug ...."

21 C.F.R. § 202.1(l)(2). The FDA includes in its interpretation of labeling "Dear Doctor" letters, PLIVA, 564 U.S. at ____, 131 S.Ct. at 2576, which are letters drug manufacturers send to health-care providers informing them of critical newly discovered risks or side effects of a medication.

The FDA has determined that a generic manufacturer cannot unilaterally strengthen a warning label for a generic drug or send a "Dear Doctor" letter under the CBE rule because doing so would violate the statutes and regulations requiring the label of a generic drug to match the brand-name manufacturer's label. PLIVA, 564 U.S. at ___, 131 S.Ct. at 2575.

> "Federal regulations applicable to generic drug manufacturers directly conflict with, and thus preempt, state laws that hold generic drug manufacturers liable for inadequate warning labels on their products. Mensing, 131 S.Ct. at 2578. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., a manufacturer seeking federal approval to market a new drug must prove that it is safe and effective and that the proposed label is accurate and adequate. 21 U.S.C. § 355(b)(1). By contrast, under the Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Amendments, generic drug formulations can gain FDA approval by showing bioequivalence to a reference-listed drug that has already been approved by the FDA. 21 U.S.C. § 355(j)(2)(A). A generic drug application must also show that 'the labeling proposed for the new drug is the same as the labeling approved for the listed drug.' 21 U.S.C. § 355(j)(2)(A)(v). Therefore, rather than a duty to warn, 'generic manufacturers have an ongoing federal duty of sameness' regarding their warning labels. Mensing, 131 S.Ct. at 2574. Under the same rules, generic drug manufacturers may not issue additional warnings through Dear Doctor letters, nor may they imply in any way that there is a therapeutic difference between their product and the name-brand drug. Id. at 2576."

Phelps v. Wyeth, Inc., 857 F. Supp. 2d 1114, 1133 (D. Or.

2012)(emphasis added). According to the FDA, if a generic manufacturer believes that stronger warnings are needed, then the manufacturer is required to propose such changes to the FDA, and, if the FDA agrees that such changes are necessary, the FDA will work with the brand-name manufacturer to create a new label for both the brand-name and generic drug. PLIVA, 564 U.S. at ___, 131 S.Ct. at 2576.

The Supreme Court, in two cases, has addressed the extent to which manufacturers may change their labels after FDA approval. We note that, because of the extensive federal regulations, both the manufacturers of brand-name drugs and generic drugs in those cases argued that the federal regulations preempted state-law claims. In Wyeth v. Levine, 555 U.S. 555 (2009), the plaintiff developed gangrene and her forearm had to be amputated when a physician's assistant injected her artery with the anti-nausea drug Phenergan by using the "IV push" method of intravenous injection. She sued Wyeth, the manufacturer of Phenergan, for failing to provide an adequate warning about the different risks involved with the various methods of administering the drug. She relied on common-law negligence and strict-liability theories. A jury

found that Wyeth had failed to provide an adequate warning about the risks involved when Phenergan is administered by the IV push method. On appeal, Wyeth argued that the plaintiff's failure-to-warn claims were preempted by federal regulations regarding drug labeling because it was impossible for a manufacturer to comply with both state laws and federal-labeling obligations. Wyeth also argued that recognition of state-law suits would undermine Congress's intent to entrust labeling to the expertise of the FDA. The Supreme Court rejected both contentions and held that there was no preemption. The Supreme Court concluded that Wyeth failed to demonstrate that it was impossible for it to comply with both federal and state requirements, and it noted that state-law claims are an important complement to the FDA's regulation of prescription drugs. The Supreme Court stated:

> "In keeping with Congress' decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation. The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured

> persons to come forward with information. Failure-to-warn actions, in particular, lend force to the [Federal Food, Drug, and Cosmetic Act]'s premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation."

555 U.S. at 578-79 (footnote omitted).

PLIVA, supra, also involved a preemption claim regarding labels, but the manufacturer there produced the generic version of a brand-name drug. "The question presented [was] whether federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus pre-empt, these state-law claims." 564 U.S. at ___, 131 S.Ct. at 2572. The FDA had issued a labeling requirement regarding Reglan, the brand name of metoclopramide, the generic drug at issue in the present case. The plaintiffs in PLIVA were prescribed Reglan but received the generic form of the drug, which contained the same labeling information the FDA had approved for the brand-name drug. According to the FDA, 57 Fed. Reg. 17961 (1992) requires a generic-drug manufacturer's labeling to be the same as the brand-name-drug manufacturer's labeling because the brand-name drug is the basis for the FDA's approval of the generic drug. 564 U.S. at ___, 131 S.Ct. at 2575. By 2009,

the FDA had ordered a "black box" warning for Reglan concerning the dangers associated with its long-term use. The plaintiffs had suffered severe neurological reactions from taking the generic form of the drug and had brought state-law tort claims against the manufacturers of the generic form of the drug for failing to warn them of such danger. The basis of the plaintiffs' claims was that the warning labels for the generic drug were inadequate and that the generic manufacturers had a duty to strengthen their warning labels under the FDA's CBE process. 564 U.S. at ___, 131 S.Ct. at 2575. The Supreme Court found that the FDA's federal-labeling requirement preempted the plaintiffs' state-law claims against the manufacturers of the generic drug because it would have been impossible for the generic manufacturers to change their warning labels without violating the federal requirement that the warning on a generic drug match the warning on its brand-name counterpart.

> "[B]rand-name and generic drug manufacturers have different federal drug labeling duties. A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. See, e.g., 21 U.S.C. §§ 355(b)(1), (d); Wyeth [v. Levine], [555 U.S. 555] at 570-571, 129 S.Ct. 1187 [(2009)]. A manufacturer seeking generic drug approval, on the other hand, is responsible for

> ensuring that its warning label is the same as the brand name's. See, e.g., § 355(j)(2)(A)(v); § 355(j)(4)(G); 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7)."

564 U.S. at ___, 131 S.Ct. at 2574. The Supreme Court held that because the FDA prevented the generic manufacturers from independently changing the safety label on their generic drugs, "it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same." 564 U.S. at ___, 131 S.Ct. at 2578.

The Supreme Court recognized in PLIVA the seeming contradiction in preempting claims against a generic manufacturer in PLIVA but allowing state-law tort claims in Wyeth:

> "We recognize that from the perspective of [the plaintiffs], finding pre-emption here but not in Wyeth makes little sense. Had [the plaintiffs] taken Reglan, the brand-name drug prescribed by their doctors, Wyeth would control and their lawsuits would not be pre-empted. But because pharmacists, acting in full accord with state law, substituted generic metoclopramide instead, federal law pre-empts these lawsuits. See, e.g., Minn. Stat. § 151.21 (2010) (describing when pharmacists may substitute generic drugs); La. Rev. Stat. Ann. § 37:1241(A)(17) (West 2007) (same). We acknowledge the unfortunate hand that federal drug regulation has dealt [the plaintiffs] and others similarly situated.[9]

> "But 'it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre.' Cuomo v. Clearing House Assn., L.L.C., 557 U.S. 519, 556 (2009) (Thomas, J., concurring in part and dissenting in part) (internal quotation marks and brackets omitted). It is beyond dispute that the federal statutes and regulations that apply to brand name manufacturers are meaningfully different than those that apply to generic drug manufacturers. Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public. But different federal statutes and regulations may, as here, lead to different pre-emption results. We will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme. As always, Congress and the FDA retain the authority to change the law and regulations if they so desire.
>
> ---
>
> "[9]That said, the dissent overstates what it characterizes as the 'many absurd consequences' of our holding. Post, [131 S.Ct.] at 2592. First, the FDA informs us that '[a]s a practical matter, genuinely new information about drugs in long use (as generic drugs typically are) appears infrequently.' U.S. Brief 34–35. That is because patent protections ordinarily prevent generic drugs from arriving on the market for a number of years after the brand-name drug appears. Indeed, situations like the one alleged here are apparently so rare that the FDA has no 'formal regulation' establishing generic drug manufacturers' duty to initiate a label change, nor does it have any regulation setting out that label-change process. Id., at 20–21. Second, the dissent admits that, even under its approach, generic drug manufacturers could establish pre-emption in a number of scenarios. Post, [131 S.Ct.] at 2588–2589."

564 U.S. at ___, 131 S.Ct. at 2581-82.

As noted in the facts set out in the certified question, other federal courts applying Alabama law have held that Alabama law does not allow a person who consumed a generic version of a brand-name drug to sue the brand-name manufacturer based on fraudulent misrepresentation. In Mosley v. Wyeth, Inc., 719 F. Supp. 2d 1340 (S.D. Ala. 2010), the plaintiffs did not ingest Reglan but took a generic equivalent manufactured by a generic manufacturer. They sued the brand-name manufacturers of Reglan alleging, among other things, negligent and fraudulent misrepresentation regarding the warnings contained in the labels the plaintiffs argued the brand-name manufacturers knew would be relied upon by generic manufacturers in generating the warning labels for the generic version of the drug. The federal court held that the plaintiffs could not rely on any allegedly negligent misrepresentations made by the brand-name manufacturers to support their claim of negligent misrepresentation because the brand-name manufacturers did not owe a duty to the plaintiffs, who had ingested a generic version. The court also stated that the plaintiffs' claim of negligent misrepresentation

should fail because the brand-name manufacturers did not engage in any business transaction with the plaintiffs. With regard to fraudulent misrepresentation, the court held that the plaintiffs failed to present any binding authority for the assertion that a brand-name manufacturer owed a duty to the consumer of a generic version of its product and failed to cite any binding authority for the contention that an injury resulting from consuming a generic drug could be considered to be proximately caused by a brand-name manufacturer's alleged misrepresentation regarding the brand-name version of the generic drug. The court also noted that the fact that federal law allowed a generic manufacturer to streamline the approval process by relying on the initial warning labels provided by the brand-name manufacturers did not create a duty between the brand-name manufacturers and the consumer of the generic version because, after the ANDA process, generic manufacturers become responsible for their own warning labels and any necessary revisions to those labels.

Mosley is distinguishable from the present case. The Weekses are not arguing that Wyeth owed them a duty. Instead, they are arguing that Wyeth owed Danny Weeks's physician a

duty and that, under the learned-intermediary doctrine, the Weekses are entitled to rely on the representations made to Danny's physician. Also, we note that Mosley was issued before the United States Supreme Court in PLIVA, supra, expressly found that because it was impossible for the generic manufacturers to comply with both their state-law duty to change the drug label to a safer label adequately warning of the dangers inherent in long-term use and their federal-law duty to keep the label the same as the brand-name manufacturer's label, any state-law claims against a generic manufacturer were preempted. Reliance upon the reasoning in Mosley that a generic manufacturer is responsible for its own warning labels and revisions of those labels is unsound.

In Overton v. Wyeth, Inc. (No. CA 10-0491-KD-C, March 15, 2011) (S.D. Ala. 2011)(not reported in F. Supp. 2d), the brand-name manufacturers filed a motion to dismiss the plaintiffs' state-law claims of breach of warranty, fraudulent misrepresentation, and negligent misrepresentation where the plaintiffs had ingested the generic versions of the brand-name drug. The plaintiffs argued that the brand-name manufacturers placed false and misleading information in their labels, when

they knew the labels would be relied upon by the generic manufacturers in generating their own labels, and that their doing so was a direct and proximate cause of the plaintiffs' injuries. The federal court stated that the dispositive issue on the plaintiffs' misrepresentation claims was whether the brand-name manufacturers owed any duty to plaintiffs who ingested the generic version of their brand-name drug. The federal court held that the plaintiffs presented no evidence indicating that the brand-name manufacturers owed a duty to consumers of the generic version of the drug so that the plaintiffs' injuries could be considered to have been a proximate consequence of a brand-name manufacturers' alleged misrepresentation regarding the brand-name drug. The court noted that FDA regulations could not provide the requisite duty element because federal law allows a generic manufacturer to streamline the approval process by relying on the initial warning labels provided by the brand-name manufacturer, but that the generic manufacturer still had the burden of showing that its warning label adequately described the risk associated with the drug. "In other words, after the initial approval (ANDA approval), the generic manufacturers become

responsible for their own warning labels and any necessary revisions." Note 9. Overton was issued before the Supreme Court decided PLIVA. Accordingly, the federal court's conclusion in Overton that a generic manufacturer becomes responsible for its own warning label after the ANDA process is incorrect.

In Simpson v. Wyeth, Inc. (No. 7:10-cv-01771-HGD, December 9, 2010)(N.D. Ala. 2010)(not reported in F. Supp. 2d), the federal court held that the plaintiffs, who had ingested only the generic version of Reglan, could not recover for the alleged fraudulent misrepresentations made to the plaintiffs' doctor by the manufacturers of Reglan. The brand-name manufacturers argued that, because they did not manufacture the product the plaintiffs had ingested and that allegedly had caused their injuries, the brand-name manufacturers could not be held liable. The plaintiffs alleged that their claim against the brand-name manufacturers was based on the damage caused by the product as a result of the brand-name manufacturers' misinformation to the prescribing doctors, and the plaintiffs argued that they could recover from the brand-name manufacturers even though they

were third parties to the alleged deceit or concealment because, they argued, the deceit and concealment perpetrated against the plaintiffs' prescribing doctors proximately caused their damage. In support of their argument, the Simpson plaintiffs relied on Delta Health Group, Inc. v. Stafford, 887 So. 2d 887 (Ala. 2004), which held that in certain circumstances a plaintiff may properly state a fraud claim even though the defendant's false representation is made to a third party, rather than to the plaintiff. In discussing Delta Health, the federal court noted that Delta Health went on to hold that a plaintiff must establish that he or she relied on the misrepresentation.

The federal court in Simpson stated that the problem with the plaintiffs' reliance argument was that Alabama courts have repeatedly rejected a theory of liability when the plaintiffs have attempted to hold a brand-name manufacturer responsible for damage caused by a generic brand of its drug, citing Mosley, supra. The federal court also relied on the fact that the FDA regulation did not require a brand-name manufacturer to ensure that the label of the generic version is accurate, citing Swicegood v. PLIVA, Inc., 543 F. Supp. 2d 1351 (N.D.

Ga. 2008). "Thus, it is the duty of the generic drug manufacturer to correctly advise a physician using its product of any associated risks, not the brand name manufacturer." Simpson.

The federal court in Simpson went on to address the learned-intermediary doctrine:

> "Likewise, '[u]nder the learned intermediary doctrine, a manufacturer's duty to warn is limited to an obligation to advise a prescribing physician of any potential dangers that may result from the use of its product.' Walls v. [Alpharma] USPD, [Inc.], 887 So. 2d [881,] 883 [(Ala. 2004)]. Thus, the duty to warn of risks related to the use of a drug is owed to the prescribing physician by the drug manufacturer, not some other manufacturer of the same or a similar product. As a matter of law, the manufacturers of Reglan have no duty to communicate any information regarding the risks of taking this product to anyone other than their own customers."

Like Mosley and Overton, Simpson was issued before PLIVA was decided, and the federal court's conclusion in Simpson -- that generic manufacturers have their own duty to correctly advise a physician of risks associated with the generic drug regardless of the fact that a generic label is required to be the same as the brand-name label -- is questionable. Also, the plaintiffs in Simpson argued that they should be allowed to recover from the brand-name manufacturers even though they

were third parties to the alleged fraud perpetrated by those manufacturers upon the plaintiffs' prescribing physicians. The Simpson court stated that, even if the plaintiffs, under the learned-intermediary doctrine, could prove that their physicians had relied upon the brand-name manufacturer's warning, the plaintiffs still had to demonstrate that the brand-name manufacturer owed the plaintiffs a duty before the brand-name manufacturer could be liable.

We recognize that other jurisdictions,[6] primarily relying on Foster v. American Home Products Corp., 29 F.3d 165 (4th Cir. 1994), have concluded that a brand-name manufacturer does not owe a duty to users of the generic version of the

[6]It appears that this is the first time the highest court of a state has addressed the issue whether a manufacturer of a brand-name prescription drug may be held liable for the warning label on the drug when the plaintiff ingested a generic version of the brand-name drug. The numerous federal courts sitting in diversity have addressed this issue, predicting how the highest courts of those states would rule on the issue. Erie R.R. v. Tompkins, 304 U.S. 64 (1938). But see Huck v. Wyeth, Inc., [Ms. 12-0596, July 11, 2014] ___ N.W.2d ___ (Iowa 2014) (disagreeing with this Court's holding on original submission in the present case, but expressly acknowledging that Iowa law differs from Alabama law in that Iowa law requires a plaintiff seeking recovery for the side effects of a prescription drug who sues a pharmaceutical company under any theory, including misrepresentation, to prove that he or she was injured by using the prescription drug manufactured or supplied by that pharmaceutical company).

prescription drug to warn those users of the dangers associated with the drug.[7] In Foster, the plaintiffs' daughter died as a result of taking the generic form of Phenergan, a brand-name drug. They sued the brand-name manufacturer of Phenergan, alleging negligent misrepresentation and strict liability. The federal district court dismissed the strict-liability claim because the brand-name manufacturer had not manufactured the generic version taken by the daughter. However, the court allowed the negligent-misrepresentation claim to proceed. The brand-name

[7]See, e.g., Baymiller v. Ranbaxy Pharm., Inc., 894 F. Supp. 2d 1302 (D. Nev. 2012); Phelps v. Wyeth, Inc., 857 F. Supp. 2d 1114 (D. Or. 2012); Fisher v. Pelstring (No. 4:09-cv-00252-TLW, July 28, 2010)(D. S.C. 2010)(not reported in F. Supp. 2d)(collecting cases); Swicegood v. PLIVA, Inc., 543 F. Supp. 2d 1351, 1358 (N.D. Ga. 2008); Goldych v. Eli Lilly & Co. (No. 5:04-CV-1477, July 19, 2006)(N.D. N.Y. 2006)(not reported in F. Supp. 2d); Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 538-43 (E.D. Pa. 2006), aff'd in part and rev'd in part on other grounds, 521 F.3d 253 (3d Cir. 2008), vacated, 129 S.Ct. 1578 (2009); Tarver v. Wyeth, Inc. (No. Civ. A.3-04-2036, January 26, 2006)(W.D. La. 2006)(not reported in F. Supp. 2d); Sharp v. Leichus (2004-CA-0643, February 17, 2006)(Fla. Cir. Ct. 2006); Kelly v. Wyeth (CIV. A. MICV 2003-03324B, May 6, 2005)(Super. Ct. Mass. 2005); Sheeks v. American Home Prods. Corp. (No. 02CV337, October 15, 2004)(Colo. Dist. Ct. 2004); Doe v. Ortho-Clinical Diagnostics, Inc., 335 F. Supp. 2d 614, 626-30 (M.D. N.C. 2004); Block v. Wyeth, Inc. (No. Civ.A.3:02-CV-1077, January 28, 2003)(N.D. Tex. 2003)(not reported in F. Supp. 2d); and Beutella v. A.H. Robins Co. (No. 980502372, December 10, 2001) (Utah Dist. Ct. 2001).

manufacturer appealed. The federal appeals court noted that, under Maryland law, a plaintiff had to prove that the product in question was defective, attribute that defect to the seller of the product, and prove that there was a causal relationship between the defect and the plaintiff's injury. The federal appeals court stated that the plaintiffs were attempting to hold the brand-name manufacturer liable for injuries caused by another manufacturer's product and that Maryland courts would reject an effort to circumvent the necessity that a defendant be shown to have manufactured the product that caused the injury before the defendant could be held liable for such injury. The court held that the brand-name manufacturer did not owe a duty of care to the plaintiffs, even though the plaintiffs alleged that it was foreseeable to the brand-name manufacturer of Phenergan that statements contained in its label for the drug could result in injury to a user of a generic version of the drug. The court stated:

> "We do not accept the assertion that a generic manufacturer is not responsible for negligent misrepresentations on its product labels if it did not initially formulate the warnings and representations itself. When a generic manufacturer adopts a name brand manufacturer's warnings and representations without independent investigation, it does so at the risk that such warnings and

representations may be flawed. In cases involving products alleged to be defective due to inadequate warnings, 'the manufacturer is held to the knowledge and skill of an expert.... The manufacturer's status as expert means that at a minimum he must keep abreast of scientific knowledge, discoveries, and advances and is presumed to know what is imparted thereby.' Owens-Illinois v. Zenobia, 325 Md. 420, 601 A.2d 633, 639 (Md. 1992)(quoting Borel v. Fibreboard Paper Prods. Corp., 493 F.2d 1076, 1098 (5th Cir. 1973), cert. denied, 419 U.S. 869, 95 S.Ct. 127, 42 L.Ed.2d 107 (1974)). The same principle applies in the instant case; as an expert, a manufacturer of generic products is responsible for the accuracy of labels placed on its products. Although generic manufacturers must include the same labeling information as the equivalent name brand drug, they are also permitted to add or strengthen warnings and delete misleading statements on labels, even without prior FDA approval. 21 C.F.R. § 314.70 (1993). 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. Manufacturers of generic drugs, like all other manufacturers, are responsible for the representations they make regarding their products.

"We also reject the contention that a name brand manufacturer's statements regarding its drug can serve as the basis for liability for injuries caused by another manufacturer's drug. Name brand manufacturers undertake the expense of developing pioneer drugs, performing the studies necessary to obtain premarketing approval, and formulating labeling information. Generic manufacturers avoid these expenses by duplicating successful pioneer drugs and their labels. Name brand advertising benefits generic competitors because generics are generally sold as substitutes for name brand drugs,

> so the more a name brand drug is prescribed, the more potential sales exist for its generic equivalents. There is no legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products, over whose production the name brand manufacturer had no control. This would be especially unfair when, as here, the generic manufacturer reaps the benefits of the name brand manufacturer's statements by copying its labels and riding on the coattails of its advertising. The premarketing approval scheme Congress established for generic equivalents of previously approved drugs cannot be construed to create liability of a name brand manufacturer when another manufacturer's drug has been consumed."

Foster, 29 F.3d at 169-70.

The plaintiffs in Foster argued that the brand-name manufacturers owed a duty because it was foreseeable that misrepresentations regarding Phenergan could result in personal injury to the users of the generic equivalents of Phenergan. The Foster court concluded that to impose duty in that case would be to stretch the concept of foreseeability too far. "The duty required for the tort of negligent misrepresentation arises when there is 'such a relation that one party has the right to rely for information upon the other, and the other giving information owes a duty to give it with care,'" and the court concluded that no such relationship existed between the plaintiff who was injured by a product

that was not manufactured by the brand-name manufacturer. 29 F.3d at 171 (quoting Weisman v. Connors, 312 Md. 428, 443-44, 540 A.2d 783, 790 (1988)).

A few courts have held otherwise. In Conte v. Wyeth, Inc., 168 Cal. App. 4th 89, 85 Cal. Rptr. 3d 299 (2008), the California Court of Appeals, applying state negligence law, held as a matter of first impression that a manufacturer of a brand-name drug may be held liable for injuries suffered by a consumer who purchased a generic form of the drug if the consumer's injuries were foreseeably caused by the negligence of or an intentional misrepresentation by the brand-name manufacturer that developed the drug. Conte, the plaintiff in that case, sued the brand-name manufacturer and three generic manufacturers of Reglan and its generic version, metoclopramide, alleging that her use of metoclopramide over a four-year period caused her to develop tardive dyskinesia. Conte had ingested only the generic drug. "The crux of Conte's claims against all of the drug company defendants [was] that she was injuriously overexposed to metoclopramide due to their dissemination of false, misleading and/or incomplete warnings about the drug's side effect." 168 Cal.

App. 4th at 95, 85 Cal. Rptr. 3d at 305. The trial court entered a summary judgment for all the defendant drug manufacturers, and Conte appealed. The California appellate court reversed the summary judgment in favor of the brand-name manufacturer after concluding that Conte had presented a material factual dispute as to whether her doctor had in fact relied on information disseminated by the brand-name manufacturer of Reglan. Specifically, the appellate court held that the brand-name manufacturer knew or should have known "that a significant number of patients whose doctors rely on its product information for Reglan are likely to have generic metoclopramide prescribed or dispensed to them" and that the brand-name manufacturer's "duty of care in disseminating product information extends to those patients who are injured by generic metoclopramide as a result of prescriptions written in reliance on [the brand-name manufacturer's] product information for Reglan." 168 Cal. App. 4th at 107, 85 Cal. Rptr. 3d at 315. The appellate court affirmed the summary judgment in favor of each of the three generic manufacturers on the ground that Conte had conceded on appeal that there was no evidence indicating that the generic

manufacturers had disseminated any information concerning their generic product.

In Kellogg v. Wyeth, 762 F. Supp. 2d 694 (D. Vt. 2010), the Vermont federal district court held that a brand-name manufacturer of a drug has a duty to use reasonable care to avoid causing injury to consumers who have been prescribed the generic bioequivalent of its drug. Kellogg, the plaintiff in that case, sued the brand-name manufacturer and generic manufacturers of metoclopramide, alleging that her long-term ingestion of metoclopramide caused her to develop tardive dyskinesia; Kellogg had ingested only the generic drug. The crux of Kellogg's argument was that all the defendant manufacturers were liable because, she argued, they failed to adequately warn her doctors about the risks associated with the long-term use of metoclopramide. Both the brand-name manufacturer and each of the generic manufacturers filed a motion for a summary judgment on Kellogg's failure-to-warn claim; the federal district court denied the motions. The court held that, because all the parties agreed that the defendant drug manufacturers owed a duty to provide adequate warning to Kellogg's prescribing physicians, a jury question

existed as to whether the defendant drug manufacturers had provided accurate and adequate warnings. The federal district court further held that the defendant drug manufacturers were not entitled to summary judgments for lack of a triable issue on proximate cause. Specifically, the court stated that "[a] reasonable jury could conclude that inadequate, misleading and inaccurate information provided by the [defendant drug manufacturers] was a proximate cause of [Kellogg's] injury." 762 F. Supp. 2d at 702. The federal district court finally denied the summary-judgment motion filed by the brand-name manufacturer on Kellogg's negligent-misrepresentation, fraud, and fraud-by-concealment claims in which Kellogg alleged that the brand-name manufacturer of Reglan was liable for failing to use due care in disseminating information about the drug to physicians, thereby causing the physicians to over-prescribe metoclopramide to her. The brand-name manufacturer agreed that it had a duty to provide adequate warnings about Reglan to physicians. However, it contended that it owed no duty to a doctor who prescribes Reglan if the pharmacy fills the doctor's prescription with a generic brand of the drug. Applying Vermont's negligence law,

the federal district court noted that "a brand-name manufacturer owes a duty to use reasonable care to avoid causing injury to consumers of the generic bioequivalents of its drugs," 762 F. Supp. 2d at 706, because "it is reasonably foreseeable that a physician will rely upon a brand name manufacturer's representations -- or the absence of representations -- about the risk of side effects of its drug, when deciding to prescribe the drug for a patient, regardless of whether the pharmacist fills the prescription with a generic form of the drug." 762 F. Supp. 2d at 709. The federal district court therefore held that Kellogg had presented triable issues of fact regarding whether "her doctors relied on inaccurate and misleading information -- or the absence of accurate information -- from [the brand-name manufacturer] concerning the risks and effects of long-term use of [metoclopramide]." 762 F. Supp. 2d at 710.

In looking at the reasoning in Foster and Conte, we note that the Foster court relied on the finding that a generic manufacturer of a prescription drug is responsible for the accuracy of labels placed on its product. Foster was issued before the Supreme Court decided PLIVA, in which it held that

a generic manufacturer's label must be identical to the brand-name label and that a generic manufacturer cannot unilaterally change its label to update a warning. The Foster court's finding that manufacturers of generic drugs are responsible for the representations they make in their labeling regarding their products is flawed based on the "sameness" requirement subsequently discussed in PLIVA.

Moreover, the analysis in Foster confuses strict liability and tort law. The Foster court stated that there is "[n]o legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products, over whose production the name brand manufacturer had no control." 29 F.3d at 170. If a plaintiff brought a strict-liability claim and the issue was one of a defect in production of the product, then the Foster court's reasoning would be sound. Certainly, a manufacturer will not be held liable for another manufacturer's production, design, or manufacturing defect. However, the Foster court's reasoning that a brand-name manufacturer does not owe a duty to persons taking the generic version of their drug because the brand-name manufacturer did

not manufacture that drug is flawed when the cause of action relates to the warnings contained in the labeling relating to the drug and sound in tort. In Foster, the plaintiffs alleged that it was the inadequate warning that caused their daughter's death, not how the drug itself was produced. Because a warning label is not a part of the manufacturing process, we do not agree that the fact that a brand-name manufacturer did not produce the version of the drug ingested by the plaintiff bars the plaintiff's tort action when the plaintiff is arguing that he or she was injured by a failure to warn.

We recognize that the holding in PLIVA did not address foreseeability as the Foster court did. However, the Supreme Court concluded in PLIVA that the labeling for a generic drug is required by federal regulations to be the same as the labeling for the brand-name drug. Therefore, an omission or defect in the labeling for the brand-name drug would necessarily be repeated in the generic labeling, foreseeably causing harm to a patient who ingested the generic product. A brand-name manufacturer is well aware of the expiration of its patent and well aware that a generic version of the drug

will be made when that patent expires. It is recognized that generic substitutions are allowed in all 50 states. A brand-name manufacturer could reasonably foresee that a physician prescribing a brand-name drug (or a generic drug) to a patient would rely on the warning drafted by the brand-name manufacturer even if the patient ultimately consumed the generic version of the drug.

We now turn to the issue whether Wyeth owed a duty to the Weekses as third parties to the alleged fraud in failing to adequately warn of the risks of Reglan in its labeling. The Weekses rely on Delta Health Group, Inc. v. Stafford, supra, which involved an alleged misrepresentation made to a third party. Tim Stafford and Lana Stafford alleged that Delta Health Group and its insurer, Lumbermens Mutual Casualty Company, had falsely accused Tim Stafford of pilfering from a nursing home owned by Delta Health building material for use on the Staffords' personal residence. After Delta Health filed a claim with Lumbermens for its alleged loss and assigned its rights to Lumbermens, Lumbermens sued Tim Stafford, alleging conversion. The Staffords then sued Delta Health and Lumbermens, alleging, among other things,

fraudulent misrepresentation. This Court held that under limited circumstances a plaintiff may properly state a fraud claim based on a false representation to a third party rather than to the plaintiff. This Court stated:

> "We agree with Stafford that in certain limited circumstances not relevant here a plaintiff may properly state a fraud claim even though the defendant makes a false representation to a third party rather than to the plaintiff. However, we do not read Thomas [v. Halstead, 605 So. 2d 1181 (Ala. 1992),] as excusing a plaintiff from the requirement of establishing his reliance upon that misrepresentation. Thomas appears to contemplate that the plaintiff, in fact, has relied on the defendant's misrepresentation, even though the misrepresentation was made to another party. Neither have we located any other authority that purports to excuse a plaintiff in a fraud action from establishing the element of reliance.
>
> "In this case, the record is devoid of any evidence tending to establish that Stafford relied to his detriment on any of the alleged misrepresentations made by Delta Health to Lumbermens. For this reason, we conclude that Stafford failed to produce sufficient evidence to create a jury question on each of the elements necessary for his fraud claim. Therefore, the trial court erred in denying Delta Health's motion for a judgment as a matter of law regarding Stafford's fraud claim; that claim should not have been submitted to the jury."

887 So. 2d at 899.

Delta Health is not the first time this Court has addressed a fraud claim based on misrepresentations made not

to a plaintiff but to a third party. In Thomas v. Halstead, 605 So. 2d 1181 (Ala. 1992), a patient sued his dentist alleging fraud, specifically alleging that the dentist had obtained payment from the patient's insurer for services that were never rendered. The patient had gone to see the dentist, who took several X-rays of his mouth and told him he needed additional dental work. The patient claimed that the dentist was to submit a form to the patient's insurer to determine the insurance coverage. Instead, the dentist submitted a claim for the additional work on the patient's teeth, which had never been done. The patient argued that, even if the misrepresentation was not made directly to him, "a misrepresentation, made to his insurance carrier, which is legally obligated to pay valid claims submitted to it for dental expenses incurred by him, is sufficient to satisfy the misrepresentation element of fraud." 605 So. 2d at 1184. "While generally '[a] stranger to a transaction ... has no right of action [for fraud],' there is an exception to this general rule: 'If a third person is injured by the deceit, he may recover against the one who made possible the damages to him by practicing the deceit in the first place.' 37 C.J.S.

Fraud § 60, p. 344 (1943), see Sims v. Tigrett, 229 Ala. 486, 158 So. 326 (1934)." 605 So. 2d at 1184.

Sims v. Tigrett, 229 Ala. 486, 158 So. 326 (1934), involved deceit in the selling of bonds. This Court stated:

> "But we may observe that if defendant caused the representations to be made, and the public were intended to be thereby induced to act upon them, and plaintiff was within the class of those so contemplated, the action for deceit against defendant may be maintained by plaintiff, though defendant did not sell the bonds to plaintiff, but sold them to another, and he to plaintiff, both in reliance on the truth of the representations. King v. Livingston Mfg. Co., 180 Ala. 118, 126, 60 So. 143 [(1912)]; 26 C.J. 1121, §§ 47, 48."

229 Ala. at 491, 158 So. at 330.

Wyeth argues that Delta Health is distinguishable because this Court has never extended third-party fraud beyond the economic realm to claims alleging physical harm. We recognize that Delta Health, Thomas, and Sims did not involve a claim of physical injury. However, physical harm suffered by a consumer of prescription medication would have been reasonably contemplated by a manufacturer who made fraudulent statements on the warning label related to that medication.

Wyeth also argues that this Court has never extended third-party-fraud liability to a defendant who did not

manufacture the product about which the plaintiff is complaining. We again note that prescription medication is unlike other consumer products. Unlike "construction machinery," "lawnmowers," or "perfume," which are "used to make work easier or to provide pleasure," a prescription drug "may be necessary to alleviate pain and suffering or to sustain life." Brown v. Superior Court of San Francisco, 44 Cal. 3d 1049, 1063, 245 Cal. Rptr. 412, 420, 751 P.2d 470, 479 (1988). Prescription medication is heavily regulated by the FDA. It can be obtained only through a health-care provider who can make a determination as to the benefits and risks of a drug for a particular patient. Also, the Weekses' claims are not based on the manufacturing of the product but instead allege that the label -- drafted by the brand-name manufacturer and required by federal law to be replicated verbatim on the generic version of the medication -- failed to warn. Moreover, the brand-name manufacturer is under a continuing duty to supply the FDA with postmarketing reports of serious injury and can strengthen its warnings on its own accord. Wyeth v. Levine, supra; 21 C.F.R. § 201.57(c)(6)(I); 21 C.F.R. § 201.56(a)(2)-(b)(1). In contrast, a generic

manufacturer's label must be the same as the brand-name manufacturer's label, and the generic manufacturer cannot unilaterally change its warning label.

We recognize that the plaintiff in Delta Health did not succeed in his fraud claim because he failed to present evidence indicating that he relied to his detriment on any of the alleged misrepresentations made by his employer to the employer's insurer. In a fraud case, detrimental reliance is an essential aspect of showing that the injury suffered was caused by the fraud. "[A] fraud claim fully accrues once any legally cognizable damage has proximately resulted, i.e., once the plaintiff has 'detrimentally' relied on the fraud." Ex parte Haynes Downard Andra & Jones, LLP, 924 So. 2d 687, 694 (Ala. 2005). In the present case, the Weekses have alleged that Danny's physician reasonably relied on the representations made by Wyeth regarding the long-term use of Reglan in prescribing Reglan to Danny. In other words, the Weekses are arguing that if a defendant's misrepresentation to a third party causes the third party to take actions resulting in the plaintiff's injuries, then the factual causation link is satisfied and that, here, a misrepresentation to Danny's

physician would directly impact the medical care received by Danny.

In Stone v. Smith, Kline & French Laboratories, 447 So. 2d 1301 (Ala. 1984), this Court adopted the learned-intermediary doctrine in a case addressing whether a manufacturer's duty to warn extends beyond the prescribing physician to the physician's patient who would ultimately use the drugs. The principle behind the learned-intermediary doctrine is that prescribing physicians act as learned intermediaries between a manufacturer of a drug and the consumer/patient and that, therefore, the physician stands in the best position to evaluate a patient's needs and to assess the risks and benefits of a particular course of treatment for the patient. A consumer can obtain a prescription drug only through a physician or other qualified health-care provider. 21 U.S.C. § 353(b)(1). Physicians are trained to understand the highly technical warnings required by the FDA in drug labeling. 21 C.F.R. § 201.56. The learned-intermediary doctrine was established in Marcus v. Specific Pharmaceuticals, 191 Misc. 285, 77 N.Y.S.2d 508 (N.Y. Sup. Ct. 1948), as an absolute defense for "failure to warn" cases.

Mitesh Bansilal Shah, Commentary, As a Matter of Fact or a Matter of Law: The Learned Intermediary Doctrine in Alabama, 53 Ala. L. Rev. 1299, 1301 (2002).

> "Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is a task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative."

Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir. 1974).

The learned-intermediary doctrine recognizes the role of the physician as a learned intermediary between a drug manufacturer and a patient. As the United States Court of Appeals for the Eleventh Circuit has explained:

> "In cases involving complex products, such as those in which pharmaceutical companies are selling prescription drugs, the learned intermediary doctrine applies. Under the learned intermediary doctrine, a manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the use of its product. This standard is 'an understandable exception to the Restatement's general rule that one who markets goods must warn foreseeable ultimate users of dangers inherent in his products.' As such, we rely on the expertise of the physician intermediary to bridge the gap in special cases where the product and related warning are sufficiently complex so as not to be fully

> appreciated by the consumer. ... '[U]nder the "learned intermediary doctrine" the adequacy of [the defendant's] warning is measured by its effect on the physician, ... to whom it owed a duty to warn, and not by its effect on [the consumer].'"

Toole v. Baxter Healthcare Corp., 235 F.3d 1307, 1313-14 (11th Cir. 2000)(citations omitted).

A prescription-drug manufacturer fulfills its duty to warn the ultimate users of the risks of its product by providing adequate warnings to the learned intermediaries who prescribe the drug. Once that duty is fulfilled, the manufacturer has no further duty to warn the patient directly. However, if the warning to the learned intermediary is inadequate or misrepresents the risk, the manufacturer remains liable for the injuries sustained by the patient. The patient must show that the manufacturer failed to warn the physician of a risk not otherwise known to the physician and that the failure to warn was the actual and proximate cause of the patient's injury. In short, the patient must show that, but for the false representation made in the warning, the prescribing physician would not have prescribed the medication to his patient.

Wyeth argues that there is no relationship between Wyeth

and the Weekses so as to create a duty on Wyeth's part to adequately warn the Weekses and that the simple fact that it may be foreseeable that a physician would rely on Wyeth's representations in its warning label in determining whether a prescription drug originally manufactured by Wyeth was appropriate for a particular patient did not create a relationship between Wyeth and the patient. Wyeth argues:

> "Here, the brand-name defendants had absolutely no relationship with the Weekses. The Weekses never met with any representative of the brand-name defendants, transacted any business with the brand-name defendants, or did anything else that could have established the necessary relationship. Most significantly, the Weekses concede that Mr. Weeks didn't use the brand-name defendants' products. That concession is fatal. Without some product-use link, the Weekses can't establish a relationship; and without a relationship, they can't prove a duty."

Wyeth's brief, p. 42.

Wyeth's argument completely ignores the nature of prescription medication. The Weekses cannot obtain Reglan or any other prescription medication directly from a prescription-drug manufacturer.[8] The only way for a consumer to obtain a prescription medication is for a physician or other medical professional authorized to write prescriptions

[8]It is undisputed that Danny received metoclopramide through a prescription written by his physician.

(i.e., a learned intermediary) to prescribe the medication to his or her patient. This Court has adopted the learned-intermediary doctrine, which provides that a prescription-drug manufacturer fulfills its duty to warn users of the risk associated with its product by providing adequate warnings to the learned intermediaries who prescribe the drug and that, once that duty is fulfilled, the manufacturer owes no further duty to the ultimate consumer. When the warning to the prescribing health-care professional is inadequate, however, the manufacturer is directly liable to the patient for damage resulting from that failure. The substitution of a generic drug for its brand-name equivalent is not fatal to the Weekses' claim because the Weekses are not claiming that the drug Danny ingested was defective; instead, the Weekses' claim is that Wyeth fraudulently misrepresented or suppressed information concerning the way the drug was to be taken and, as discussed, the FDA mandates that the warning on a generic-drug label be the same as the warning on the brand-name-drug label and only the brand-name manufacturer may make unilateral changes to the label.[9]

[9]To allow labels on generic versions of a brand-name drug to differ from the labels on the brand-name versions could not

In support of its argument regarding lack of a relationship, Wyeth cites Keck v. Dryvit Systems, Inc., 830 So. 2d 1 (Ala. 2002); State Farm v. Owen, 729 So. 2d 834 (Ala. 1998); DiBiasi v. Joe Wheeler Electric Membership Corp., 988 So. 2d 454 (Ala. 2008); and Thompson-Hayward Chemical Co. v. Childress, 169 So. 2d 305 (Ala. 1964). Keck addressed the question whether faux stucco was a fixture attached to a house or part of the house in order to determine whether the AEMLD applied when the faux stucco failed. Because the faux stucco was not a "product" under the AEMLD, this Court turned to the Uniform Commercial Code to determine if it was a "good" and held that it was not. In short, this Court treated the faux

---

only insinuate that the generic versions were not the bioequivalent of the brand-name versions, but could also confuse physicians reviewing the different versions. The "FDA 'places a very high priority [on] assuring consistency in labeling,' so as 'to minimize any cause for confusion among health care professionals and consumers as well as to preclude a basis for lack of confidence in the equivalency of generic versus brand name products.'" Brief for the United States As Amicus Curiae Supporting Respondents, at 4, in PLIVA, Inc. v. Mensing, 564 U.S. ____, 131 S.Ct. 2567 (Nos. 09-993, 09-1039 and 09-1501) (alterations in original) (quoting Div. of Generic Drugs, FDA, Policy and Procedure Guide 37 (1989) (citing 57 Fed. Reg. 17,961 (1992))). Additionally, although both the brand-name manufacturer and the generic manufacturer have a continuing duty to report adverse reactions to the FDA, it may be that only the brand-name manufacturer has all the relevant data in light of trade-secrets concerns.

stucco as part of the house, and because the plaintiffs, who were not the first purchasers of the house, purchased the house "as is," they had no claim against the manufacturer of the faux stucco because there was no duty to disclose.

Owen held that an insurer had no duty to disclose that, although premiums on homeowners' insurance were based on the appraisal value of the insured property, the insurer would pay no more than replacement value in the event of a loss. DiBiasi involved an electrocution victim who was injured when he grabbed electrical transmission lines hanging over the roof of a house. The utility company that owned the pole to which the lines were attached argued that it owed no duty (the city supplied the electrical power) to the victim, who was inspecting the roof of the house when, among other things, there was no relationship shown between the owner of the utility pole and the victim. The wire that electrocuted the victim was owned by the city. In Thompson-Hayward, a case that predates the judicial adoption of the AEMLD, this Court held that the plaintiff's complaint failed to allege that the defendant had manufactured an injurious herbicide or to allege that the defendant sold the herbicide to the plaintiffs.

These cases are easily distinguishable from this case. Here, Wyeth authored the label with its warnings, and the generic manufacturers, as required by FDA regulations, copied that label verbatim. Wyeth continues to treat the Weekses' fraud claim as a products-liability claim where privity is needed.

In Carter v. Chrysler Corp., 743 So. 2d 456 (Ala. Civ. App. 1998), the Court of Civil Appeals, quoting Hines v. Riverside Chevrolet-Olds, Inc., 655 So. 2d 909 (Ala. 1994),[10] noted:

> "'Our case law, however, makes it very clear that in an action alleging suppression of a material fact, a duty to disclose may be owed to a person with whom one has not had a contractual relationship or other dealings. ...
>
> "'The extent of a legal duty not to make a false representation or to suppress a material fact informs our analysis of whether two parties have a sufficient relationship on which to base a duty to disclose. In Colonial Bank v. Ridley & Schweigert, 551 So. 2d 390, 396 (Ala. 1989), this Court stated:
>
> "'"There can be no

[10]Hines was overruled on other grounds in Owen. The Court of Civil Appeals noted that "the discussion in Hines concerning the determination of whether a legal duty to disclose exists remains precedential." 743 So. 2d at 461.

> actionable fraud without a breach of a legal duty owed by the defendant to the plaintiff.
>
> "'"There is a duty not to make a false representation to those to whom a defendant intends, for his own purposes, to reach and influence by the representation; to those to whom he has a public duty created by statute or pursuant to a statute; and to those members of a group or class that the defendant has special reason to expect to be influenced by the representation. W. Prosser, Misrepresentation and Third Persons, 19 Vand. L.Rev. 231, 254 (1966)."'

"655 So. 2d at 919-20 (emphasis added, footnote omitted).

"The Court in Hines then applied these principles to the particular question of the manufacturer's duty to disclose the repairs to the plaintiffs in the case before it:

> "'It is evident from these principles and our case law that the fact that two parties have had no contractual relationship or other dealings does not preclude the finding of a legal duty not to make a material misrepresentation or to suppress a material fact. The absence of a contractual relationship or other dealings, therefore, likewise does not preclude the finding of a relationship on which to base a duty to disclose. Whether a duty to disclose exists must be determined by examining the particular facts of each case.

"'....'

"655 So. 2d at 920."

Carter, 743 So. 2d at 461-62 (some emphasis added). Stated again, there is a duty not to make a false representation (1) to those to whom a defendant intends, for his own purposes, to reach and influence by the representation; (2) to those to whom the defendant has a public duty created by statute or pursuant to a statute; and (3) to those members of a group or class that the defendant has special reason to expect will be influenced by the representation.

Clearly, prescription drugs differ from lawnmowers, automobiles, and other products because of the FDA's unprecedented control and regulation of prescription drugs; the FDA has the responsibility of weighing (in terms of extremes) the potential benefit of lifesaving medication against potential severe side effects. Those side effects might not become apparent until after a drug has been on the market, and even then the benefits of the drug may outweigh the risks. Wyeth cannot argue that it owes no duty to the Weekses because it lacks a relationship with them.

Conclusion

We answer the certified question as follows: Under Alabama law, a brand-name-drug company may be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture of a brand-name prescription drug, by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company. Prescription drugs, unlike other consumer products, are highly regulated by the FDA. Before a prescription drug may be sold to a consumer, a physician or other qualified health-care provider must write a prescription. The United States Supreme Court in Wyeth v. Levine recognized that Congress did not preempt common-law tort suits, and it appears that the FDA traditionally regarded state law as a complementary form of drug regulation: The FDA has limited resources to monitor the approximately 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge; state-law tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly and serve a distinct compensatory function that may motivate injured

persons to come forward with information. Wyeth v. Levine, 555 U.S. at 578-79.

FDA regulations require that a generic manufacturer's labeling for a prescription drug be exactly the same as the brand-name manufacturer's labeling. The Supreme Court in PLIVA held that it would have been impossible for the generic manufacturers to change their warning labels without violating the federal requirement that the warning on a generic drug must match the warning on the brand-name version, preempting failure-to-warn claims against generic manufacturers.

In the context of inadequate warnings by the brand-name manufacturer placed on a prescription drug manufactured by a generic manufacturer, it is not fundamentally unfair to hold the brand-name manufacturer liable for warnings on a product it did not produce because the manufacturing process is irrelevant to misrepresentation theories based, not on manufacturing defects in the product itself, but on information and warning deficiencies, when those alleged misrepresentations were drafted by the brand-name manufacturer and merely repeated, as allowed by the FDA, by the generic manufacturer.

In answering the question of law presented to us by the federal court, we emphasize the following: We are not turning products-liability law (or tort law for that matter) on its head, nor are we creating a new tort of "innovator liability" as has been suggested. Instead, we are answering a question of law involving a product that, unlike any other product on the market, has unprecedented federal regulation. Nothing in this opinion suggests that a plaintiff can sue Black & Decker for injuries caused by a power tool manufactured by Skil based on labeling or otherwise. The unique relationship between brand-name and generic drugs as a result of federal law and FDA regulations, combined with the learned-intermediary doctrine and the fact that representations regarding prescription drugs are made not to the plaintiff but to a third party, create the sui generis context in which we find prescription medication. Again, the fraud or misrepresentation claim that may be brought under Alabama law against a drug manufacturer based on statements it made in connection with the manufacture of a brand-name prescription drug by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company is premised

upon liability not as a result of a defect in the product itself but as a result of statements made by the brand-name manufacturer that Congress, through the FDA, has mandated be the same on the generic version of the brand-name drug.[11]

APPLICATION OVERRULED; OPINION OF JANUARY 11, 2013, WITHDRAWN; OPINION SUBSTITUTED; QUESTION ANSWERED.

Stuart, Main, Wise, and Bryan, JJ., concur.

Shaw, J., concurs specially.

Moore, C.J., and Parker and Murdock, JJ., dissent.

[11]It should also be noted that we are not deciding the merits of the underlying case. It may be that a jury finds that the warnings on the label were adequate or that it finds that Danny's physician did not rely on the warnings on the label authored by Wyeth when prescribing the generic version of Reglan to Danny.

SHAW, Justice (concurring specially).

I concur fully in the Court's answer to the certified question. I write specially to note the following.

First, some preliminary observations:

1. The certified question is not posed within the context of a defective-product case. See note 13, infra. Our answer to the certified question in no way holds that a manufacturer of a product may be held liable, under general products-liability jurisprudence, for a product manufactured by another.

2. The certified question calls for an explanation of, and our answer applies, current Alabama law. We are not creating new law or doing something novel; we are applying established law to a factual and legal scenario that has never been addressed by this Court. Concomitant with that, we discuss Alabama law as it exists, not how some perceive it should exist.

3. Given the nature of the federal government's pervasive regulation of the prescription-drug industry, our answer is extremely narrow in scope and cannot conceivably apply outside that context.

4. No decision of any other jurisdiction addresses the precise question of Alabama law discussed in our answer.[12]

---

[12]Certain federal district court decisions cited in this Court's answer address the issue under the law that existed before the Supreme Court's decision in PLIVA, Inc. v. Mensing, 564 U.S. ___, 131 S. Ct. 2567 (2011), and are thus distinguishable. The numerous decisions from other jurisdictions that rely on principles rejected by PLIVA are similarly distinguishable.

The certified question asks this Court to apply current Alabama law as it relates to fraud.[13] For purposes of examining the purely legal issue presented in this certified question, I believe that we must accept the factual allegations of the plaintiffs, Danny Weeks and Vicki Weeks, as true. Those allegations are summarized as follows: Wyeth produced the brand-name drug Reglan, which is metoclopramide, and, through its "labeling" of the drug, misrepresented or failed to provide important facts to Danny Weeks's doctor about how metoclopramide is to be taken properly.[14]

---

[13]Given that the federal district court has decided that the action is not an Alabama Extended Manufacturer's Liability Doctrine ("AEMLD")/defective-product action, I decline to accept the invitation of Wyeth to recharacterize the action under the anti-circumvention rule stated in Pfizer, Inc. v. Farsian, 682 So. 2d 405 (Ala. 1996), as one that is, in substance, alleging a defective-product claim and not a fraud claim. The application for rehearing takes this Court to task for failing to address this issue. However, as this Court's answer explains, citing Tillman v. R.J. Reynolds Tobacco Co., 871 So. 2d 28, 34-35 (Ala. 2003), AEMLD claims and fraud claims are different. As cast by the district court in the question presented to us, this case presents a fraud action. I express no opinion as to whether it should be recharacterized. Thompson-Hayward Chemical Co. v. Childress, 169 So. 2d 305 (Ala. 1964), cited by Wyeth on rehearing, involves a negligence action, not a fraud action, and thus is inapplicable.

[14]Danny's doctor wrote him a prescription for "Reglan" and directed its use; Danny's pharmacy filled the prescription with metoclopramide that was manufactured by someone other

When Wyeth's ability to produce and sell metoclopramide exclusively lapsed, generic-drug companies became able to manufacture and sell metoclopramide. Those generic-drug companies may have wished to give Danny's doctor different facts or instructions about the use of metoclopramide, but, for all intents and purposes relevant in this case, the federal government will not allow them to do so. Essentially, federal law requires that those generic-drug companies repeat Wyeth's alleged misrepresentations or omissions. Wyeth knew that the generic-drug companies are required to do this; Wyeth knew that its instructions on the use of metoclopramide would be repeated by the generic-drug companies. The federal government has declared that generic-drug companies cannot be sued if a doctor prescribes and a patient takes metoclopramide manufactured by a generic-drug company in the manner in which Wyeth represented that it should be taken. In other words, the generic-drug companies must repeat Wyeth's purportedly fraudulent conduct and cannot be sued for doing so if Wyeth's misconduct ultimately harms the patient.

---

than Wyeth. It is the doctor's prescribed use of metoclopramide, which we must assume was based on what Wyeth told or failed to tell the doctor, that caused Danny's injury.

In this context, we look to see whether, "[u]nder Alabama law, [Wyeth may] be held liable for fraud or misrepresentation (by mistatement or omission), based on statements it made" about metoclopramide. As discussed below, Alabama law allows a plaintiff to sue a defendant based on the defendant's fraudulent conduct directed to a third person. A prior relationship between the two parties is not necessary. Two factors have been the focus of this case: foreseeability and duty. Although a controlling issue in other jurisdictions, I see no dispute as to foreseeability. As even Justice Murdock's dissenting opinion agrees, it is "eminently" foreseeable "that a generic version of a brand-name drug will be consumed in reliance upon labeling disseminated by the brand-name manufacturer for its brand-name drug."[15] ____ So. 3d at ____.

In cases where fraudulent conduct is directed to third parties, this State's caselaw generally holds that a duty to disclose may be owed to a person with whom the defendant has

[15]Thus, the numerous decisions of other jurisdictions that would hold that the injury that allegedly occurred in this case was not foreseeable are distinguishable. I would be hesitant to cite decisions rejecting foreseeability, as well as decisions that predate PLIVA, as calling into question the rationale of this Court's answer to the certified question.

had no prior dealings, specifically, where there is a "duty" not to make a false representation:

> 1. To those to whom a defendant intends, for his or her own purposes, to reach and influence by the representation;
>
> 2. to those to whom the defendant has a public duty created by statute or pursuant to a statute; and
>
> 3. to those members of a group or class that the defendant has special reason to expect to be influenced by the representation.

Hines v. Riverside Chevrolet-Olds, Inc., 655 So. 2d 909, 919-20 (Ala. 1994),[16] and Carter v. Chrysler Corp., 743 So. 2d 456, 461 (Ala. Civ. App. 1998); see also generally Potter v. First Real Estate Co., 844 So. 2d 540, 553 (Ala. 2002), and Colonial Bank of Alabama v. Ridley & Schweigert, 551 So. 2d 390, 396 (Ala. 1989).

In Hines, this Court held that an automobile manufacturer had a duty to disclose to subsequent purchasers of an automobile it had manufactured that the automobile had been repainted, even though the manufacturer had no relationship with the later purchasers, "[b]ecause the [subsequent purchasers] were members of a group or class of persons who

[16]Hines was overruled on other grounds by State Farm Fire & Casualty Co. v. Owen, 729 So. 2d 834 (Ala. 1998). See note 10, supra.

[the manufacturer] expected or had special reason to expect would be influenced by its decision not to disclose information ...." 655 So. 2d at 920. Thus, they "had a sufficient relationship on which to base a duty to disclose." Id. In Carter, an automobile manufacturer repurchased under the Lemon Law an automobile that was allegedly defective. This fact was disclosed to the party to whom the automobile was next sold. The Court of Civil Appeals held, however, that the Lemon Law created a duty to ensure that the fact that the automobile had been repurchased was disclosed to those who would later purchase the automobile from the second buyer, even though the manufacturer had no relationship with those later purchasers.

In both Carter and Hines there was a duty to not misrepresent or omit facts to those with whom the automobile manufacturers never had contact. Although those cases involved products that were actually manufactured by the defendants, the logic behind the creation of the duty has nothing to do with that fact. Here, federal law has created a scheme in which persons who purchased metoclopramide manufactured by generic-drug companies would have to rely on

Wyeth's representations about metoclopramide. Thus, Wyeth had a "special reason to expect" that purchasers of the generic metoclopramide "would be influenced" by its labeling information because that information--owing to federal law--would be the only information purchasers of both brand-name and generic metoclopramide would receive. That the metoclopramide was made by another manufacturer creates no distinction: for purposes of this case, metoclopramide is the same no matter who produced it. As required by federal law, Wyeth's alleged misrepresentations or omissions concerning metoclopramide also applied to metoclopramide manufactured by a generic-drug company. What Wyeth allegedly said (or failed to say) in its "labeling" about metoclopramide was intended to "reach and influence" users (through doctors or other health professionals) of metoclopramide, which, at that time, was manufactured only by Wyeth. This labeling, as required by federal law, also reached and influenced purchasers of generic metoclopramide. This federal law gave Wyeth "special reason to expect" that all users of metoclopramide would be influenced by its labeling.

Our answer to this certified question on original

submission has generated many responses, some of which expressed valid concerns, while others either shamefully misrepresented our holding or bordered on the hysterical. Our answer, however, is extraordinarily narrow in scope. The posture in which the certified question is asked (assuming a fraud cause of action), the facts of this case, and the impact of strict federal regulation on the prescription-drug industry drastically confine our holding and wholly remove the facts of this case from situations where parties are allegedly being held liable under general products-liability theories for products they did not make. I cannot see our answer to the certified question as in any way speaking to the applicability of Alabama law outside the narrow context created by federal law in this case.

I must disagree with the implication that our answer is based on a motivation other than stating current Alabama law. Nothing in our answer suggests that this Court is trying to "correct" a "wrong" "with a second 'wrong'" or to "correct" "unfairness" created by the federal government. ___ So. 3d at ___ (Murdock, J., dissenting). Although the members of this Court might respectfully disagree as to what Alabama tort law

does or should require, our answer does nothing more than apply established Alabama decisions (which have not been challenged) to a difficult and unique factual and legal scenario.

I also respectfully reject the implication that our answer, applying as it does established Alabama tort law providing a remedy for fraudulent conduct, might "create a climate in which trade and business innovation" cannot flourish or that it prevents "Americans [from] work[ing] hard to produce innovative goods and services that have benefited not only themselves, but also their children, their communities, and America as a whole." ___ So. 3d at ___ (Murdock, J., dissenting). Allowing fraudulent or tortious conduct in the marketplace to go unchecked--if that is what has occurred in this case--would not seem to promote this policy. The legal analysis set forth in this Court's answer, in my view, creates no new law, enforces existing law, and epitomizes the kind of judicial restraint that should be expected of an appellate court.

MOORE, Chief Justice (dissenting).

I respectfully dissent because I do not think that this Court should accept a certified question when critical facts are not before the Court.

I was not a member of this Court when the certified question from the United States District Court for the Middle District of Alabama was answered on original submission. However, I note that Danny Weeks and Vicki Weeks, the plaintiffs in the federal case, urged this Court at that time to decline to answer. Weekses' brief on original submission (hereinafter "Weekses' original brief"), at 8-13. One of the grounds urged was that "the answer would not be determinative of the cause, which is the purpose of certification." Id. at 13. I believe this suggestion points to the proper resolution of this application for rehearing.

The Alabama rule that provides for answering certified questions from the federal courts reads as follows:

> "When it shall appear to a court of the United States that there are involved in any proceeding before it questions or propositions of law of this State which are determinative of said cause and that there are no clear controlling precedents in the decisions of the Supreme Court of this State, such federal court may certify such questions or propositions of law of this State to the Supreme

> Court of Alabama for instructions concerning such questions or propositions of state law, which certified question the Supreme Court of this State, by written opinion, may answer."

Rule 18(a), Ala. R. App. P. (emphasis added). This Court consented to answer the certified question on October 17, 2011. However, that decision is subject to reconsideration. See Palmore v. First Unum, 841 So. 2d 233 (Ala. 2002) (declining to answer a certified question from a federal court that had erroneously been accepted).

Rule 18(a) allows a federal court to certify to this Court "questions or propositions of law of this State which are determinative of said cause," namely the proceeding pending before the federal court. In support of this requirement, the certifying court stated that "'[t]he question framed ... is "determinative" of this case in the sense that a negative answer would require dismissal of the Weekses' claims against the brand-named defendants ....'" ___ So. 3d at ___. The certifying court's statement omits any mention of whether a positive answer would also be determinative of the outcome of the case. If this Court's answer to the certified question is "no," the Weekses' claims must be dismissed for failure to state a claim. However, an answer of "yes," as

proposed by the majority, will not be "determinative of said cause." In that event, the Weekses may proceed with their cause of action for misrepresentation, but the ultimate success of their claims will depend upon facts not before us. For example, if Danny Weeks's prescribing physician did not rely on the Reglan labeling when prescribing the drug, then the Weekses will have failed to prove causation and their claims will fail. According to the Weekses, neither Danny's prescribing physician nor his other medical providers have yet been deposed. Weekses' original brief, at 3-4.

Additionally, as the Weekses stated in urging this Court to decline to answer the certified question, both Wyeth, Inc., and Schwarz Pharma, Inc., two of the three brand-name defendants,[17] apparently no longer had an interest in the Reglan brand at the time Danny Weeks's physician diagnosed him with tardive dyskinesia in 2009.[18] Wyeth sold its interest in Reglan to Schwarz Pharma on December 27,2001, and ceased manufacturing or selling Reglan after that date. Schwarz

[17]Pfizer, Inc., the third brand-name defendant, is the parent company of Wyeth. Brand-name defendants' brief on original submission, at 3 n.2.

[18]The Weekses allege that Danny first began ingesting metoclopramide, the generic name for Reglan, in 2007.

Pharma in turn sold its interest in Reglan to another company in February 2008. Weekses' original brief, at 10-12. According to the Weekses, Wyeth and Schwarz Pharma are both raising a federal-preemption defense, arguing that, after selling their interest in Reglan, they lost all ability to change Reglan's labeling. See PLIVA, Inc. v. Mensing, 564 U.S. ___, 131 S. Ct. 2567 (2011) (holding that state-law claims of misrepresentation in labeling were preempted by federal law when the defendant had no control over labeling of the product alleged to have injured the plaintiff).

Whether the federal-preemption defense will succeed is unknown, but its presence in the case renders an answer of "yes" to the certified question indeterminative of the cause. As the Weekses have argued, the certified question "should not be decided because it raises a federal question better addressed by the federal court." Weekses' original brief, at 13. See Palmore, 841 So. 2d at 235 (declining to answer a nondispositive certified question "lest our answer resemble an opinion on an abstract point of law irrelevant to the underlying case"). See also Stewart Title Guar. Co. v. Shelby Realty Holdings, LLC, 83 So. 3d 469, 472 (Ala. 2011) (holding

that the "determinative of said cause" requirement of Rule 18(a) prohibits the Court from answering a certified question that "would necessitate our fashioning a broad rule with the possibility that it would have no application to the particular facts presented"); Harrison v. Jones, 880 F.2d 1279, 1283 n.4 (11th Cir. 1989) (refusing to certify a question of law to the Alabama Supreme Court because the question "would not be dispositive" and noting that under Rule 18(a) "questions certified must be determinative").

The problem of factual uncertainty is most likely to occur, as in this case, in the context of a question certified from a federal trial court. Because the question of law before us was certified after the denial of the defendants' motion to dismiss, factual development is still incomplete in the federal case.

> "[W]e think it will be incumbent upon us to respond to questions only when it is apparent from the certification itself that all material facts have been either agreed upon or found by the court and that the case is in such posture in all respects that our decision as to the applicable [state] law will in truth and in fact be 'determinative of the cause' as the statute conferring jurisdiction upon us requires."

In re Richards, 223 A.2d 827, 833 (Me. 1966) (construing Me.

Rev. Stat. Ann., tit. 4, § 57). In this case, however, the facts have yet to be determined. See Hanchey v. Steighner, 549 P.2d 1310, 1310-11 (Wyo. 1976) (finding that a certified question from a federal trial court was "premature" when the case was "merely in the pleading stage" and "[i]t does not clearly appear that even if the question were answered, how the answer would be determinative of the cause pending in the federal court").

The United States Court of Appeals for the Fourth Circuit, considering certifying a question of state law to the Maryland Court of Appeals, addressed a situation somewhat like the one currently before this Court. If the state court answered "no" to the question, the case would be over, but if it answered "yes," "further proceedings would still be necessary in a federal tribunal and those proceedings might result in an adjudication which would render the certification and the opinion of the [state] court a futile, academic exercise with respect to final disposition of this case." Boyter v. Commissioner, 668 F.2d 1382, 1385 (4th Cir. 1981). In those circumstances the Fourth Circuit declined to certify the question of law for determination by the Maryland Court of

Appeals "unless and until it appears that the answer is dispositive of the federal litigation or is a necessary and inescapable ruling in the course of the litigation." Id. Similarly, in this case, we should decline to answer a question that may likely not be determinative of the federal case and thus fails to conform to the mandate of Rule 18 that creates our jurisdiction to answer such questions.[19]

I also believe that imposing an industry-wide duty on brand-name manufacturers through the procedural mechanism of a certified question is unwise. I would far prefer to address this issue, if necessary, on a complete record following a final judgment in a state trial court that resolved all factual questions.

For the reasons stated above, I believe that this Court's acceptance of the certified question was in error and that we

---

[19]Other states, following the language in the Uniform Certification of Questions of Law Act (1967), permit certification of questions of law that "may be determinative of the cause then pending in the certifying court" or, following the 1995 version of that Act, that "may be determinative of an issue in pending litigation in the certifying court." (Emphasis added.) These broader formulations do not reflect the Alabama rule, which requires the presence of "questions or propositions of law of this State which are determinative of said cause." (Emphasis added.)

should decline to answer the certified question. Palmore.

PARKER, Justice (dissenting).

Congressional legislation and regulations of the Food and Drug Administration have created a maze this Court has to navigate to determine the effect of federal preemption on the bedrock legal principles of this State's jurisprudence. As Justice Murdock so comprehensively demonstrated in his dissenting opinion in this case, our legal principles of duty based on privity, see e.g., State Farm Fire and Casualty Co. v. Owen, 729 So. 2d 834 (Ala. 1998),[20] have not been expressly subsumed by the federal legislation and regulations in this area in regard to a consumer of a generic drug vis-à-vis the originator/manufacturer of the brand-name drug.

This Court's modification of its bedrock legal principles in view of federal legislation and regulations in one area could have grave and unforseen effects in other areas. To guard against this, it is incumbent upon this Court to scrutinize any claim of federal preemption to determine the express wording of the limitations of such preemption.

[20]"[T]he concept of duty does not exist in a vacuum. It requires a relationship between two or more parties, a relationship that can be shown only through a history of contacts, conversations, and circumstances. Determining whether there is a duty necessarily requires analyzing the factual background of the case." 729 So. 2d at 839.

Nothing in federal legislation or regulations at issue here requires this Court to ignore, modify, or override our bedrock legal principles of duty and privity with regard to the originator of a pharmaceutical drug and a consumer who has not consumed a drug manufactured by the originator of the drug. PLIVA, Inc. v. Mensing, 564 U.S. ___, 131 S. Ct. 2567 (2011), and Mutual Pharmaceutical Co. v. Bartlett, ___ U.S. ___, 133 S. Ct. 2466 (2013), have made clear that such a consumer is left without a remedy absent a legislative change by Congress. The United States Supreme Court addressed this implausible result when it stated:

> "But 'it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre.' Cuomo v. Clearing House Assn., L.L.C., 557 U.S. 519, ___ (2009) (THOMAS, J., concurring in part and dissenting in part) (internal quotation marks and brackets omitted). It is beyond dispute that the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers. Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public. But different federal statutes and regulations may, as here, lead to different pre-emption results. We will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme. As always, Congress and the [Food and Drug Administration] retain the authority to change the

law and regulations if they so desire."

PLIVA, 564 U.S. at ___, 131 S. Ct. at 2582.

Based on the foregoing, I respectfully dissent.

MURDOCK, Justice (dissenting).

There is no good outcome in this case. In fairness to the main opinion, this Court has been put in a position from which it cannot give an answer that yields a just result for both plaintiffs and defendants in cases such as this. My understanding of certain bedrock principles of tort law and of the economic realities underlying those principles, however, compels me to dissent and to explain fully my concerns.

I.

A.

From the beginning, what Alexander Hamilton referred to as "[t]he spirit of enterprise, which characterizes the commercial part of America,"[21] has animated Americans to work hard to produce innovative goods and services that have benefited not only themselves, but also their children, their communities, and America as a whole. An enterprising spirit alone, however, is not enough. The law must protect the fruits of enterprise and create a climate in which trade and business innovation can flourish. Concomitantly, the law must justly allocate risks that are a function of that free trade

[21]The Federalist No. 7, at 63 (Alexander Hamilton) (Clinton Rossiter ed., 1961).

and innovation.

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

The path the Court takes today is in conflict with these notions. Impetus to take this path comes from a newfound and admittedly legitimate concern left in the wake of the United States Supreme Court's holding in PLIVA, Inc. v. Mensing, 564 U.S. ___, 131 S. Ct. 2567 (2011), that state-law tort claims against manufacturers of generic drugs are preempted by federal law. The resulting concern is that, if manufacturers of brand-name drugs are not responsible under state law for injuries caused by defects in generic drugs and their related labeling, then no one will be.

To see our way clear to placing such responsibility upon brand-name manufacturers, however, we must distance ourselves from the foregoing notions. We must overlook a foundational

element of tort law that these notions inform and in which they find voice: the necessity of a "duty" arising from a sufficient "relationship," or nexus, between the injured party and the defendant. We must focus on the role of "foreseeability" in the creation of a duty to the exclusion of "relationship." In doing so, this Court creates a precedent that poses danger for the prescription-medicine industry and, by extension, for all industry.

B.

As discussed in Part II of this writing, almost every one of the 47 reported cases decided before the United States Supreme Court's decision in PLIVA, including cases decided by two United States Circuit Courts of Appeals, held that a manufacturer of a brand-name drug has no duty to the consumer of a generic drug manufactured and sold by another company. Since the Supreme Court's 2011 decision in PLIVA, every one of the two dozen cases that have addressed the issue, including decisions by six United States Circuit Courts of Appeals, has reached this same conclusion.

As these numbers indicate, the Supreme Court's holding in PLIVA -- that state-law claims against generic-drug

manufacturers are preempted by the federal regulatory scheme -- did nothing to undermine the essential rationale in the plethora of pre- and post-PLIVA decisions holding that brand-name manufacturers are not liable for injuries caused by deficient labeling of generic drugs they neither manufactured nor sold. In fact, as discussed below, the opinion in PLIVA expressly says as much, and opinions in post-PLIVA cases are even more explicit in saying so.

It does indeed appear unfair -- an "unfortunate hand" in the words of the United States Supreme Court -- that a consumer harmed by a generic drug cannot seek compensation from the entity that manufactured and sold that drug. If this is unfair, however, it is an unfairness created by Congress and the Food and Drug Administration ("the FDA") in return for the perceived societal benefit of less expensive generic drugs, or perhaps instead by the manner in which the United States Supreme Court subsequently has applied the preemption doctrine to the legislative and regulatory scheme structured by those entities. It is not an unfairness created by the brand-name manufacturer. The just answer then, if there is to be one, must come from a change of federal policy or

preemption jurisprudence. It is not to come from ignoring age-old, elemental precepts of tort law in order to impose liability on an entity with whom the plaintiff has no relationship, in regard to a product that that entity did not manufacture or sell.

Having itself laid the blame for the present unfairness at the feet of Congress and the FDA, the United States Supreme Court concludes in PLIVA that this is not a problem for that Court to correct. If this is so, then, a fortiori, it is not a problem for this or any other state court to correct. And it certainly is not a "wrong" that this or any court should attempt to correct with a second "wrong."

II.

"The concept of duty does not exist in a vacuum." State Farm Fire & Cas. Co. v. Owen, 729 So. 2d 834, 839 (Ala. 1998). It requires a sufficient "relationship," or nexus, between two or more parties. Id. The duty this Court recognizes today is one based solely on "foreseeability." Given the existing federal regulatory scheme, I agree that it is "foreseeable" -- indeed, eminently so -- that a generic version of a brand-name drug will be consumed in reliance upon labeling disseminated

by the brand-name manufacturer for its brand-name drug. But this foreseeability alone is not enough to create a duty. There also must be a "relationship" or nexus between the parties.

For example, it might be foreseeable that one manufacturer would copy the design of an unpatented machine of some nature, which, unbeknownst to that manufacturer, was originally designed in a defective manner, and that a user of the copied device might be injured as a result of a replicated design defect. Nonetheless, the designer of the original machine did not manufacture or sell the copied machine. The law therefore recognizes the lack of any nexus between that designer and the injured party in relation to the machine that caused the injury and thus recognizes no duty on the part of that designer to the injured party.

The same principle applies to claims of misrepresentation and suppression. A viable claim depends upon the existence of a duty on the part of the defendant to the plaintiff. See, e.g., Nesbitt v. Frederick, 941 So. 2d 950, 955 (Ala. 2006) ("An essential element of fraudulent-misrepresentation and fraudulent-suppression claims is a duty to disclose.").

In Thompson-Hayward Chemical Co. v. Childress, 277 Ala. 285, 291-92, 169 So. 2d 305, 312 (1964), the Alabama Supreme Court addressed a common-law claim alleging failure to warn of the dangerous nature of a herbicide:

> "The breach of duty charged against defendants is the failure to give notice to or warn plaintiffs of the dangerous nature of the vine killer. Do the facts alleged in the complaint show that the defendant, Bertolla, owed a duty to warn plaintiffs? As plaintiffs candidly admit in brief, it is not alleged that plaintiffs purchased the vine killer from Bertolla. It is not alleged that Bertolla ever had possession of or any connection whatsoever with the particular substance which plaintiffs sprayed and which allegedly caused the death of plaintiffs' cattle. The rule, upon which plaintiffs' right to recover is based, imposes the duty on one who, with knowledge of its dangerous quality, manufactures or sells an imminently dangerous article and fails to warn. It is not alleged that Bertolla manufactured the dangerous article. It is not alleged that Bertolla sold it. How, then, did Bertolla owe a duty to warn?"

(Emphasis added.)

In a case in which it was foreseeable to the owner of a power pole that a defective power line hanging from its pole could injure someone in the plaintiff's position, this Court held that the lack of any relationship between the owner of the power pole and the injured party meant that no duty to warn of the danger existed:

"In addition to foreseeability, Alabama courts look to a number of factors to determine whether a duty exists, including '"(1) the nature of the defendant's activity; (2) the relationship between the parties; and (3) the type of injury or harm threatened."' Taylor [v. Smith], 892 So. 2d [887,] 892 [(Ala. 2004)] (quoting Morgan v. South Cent. Bell Tel. Co., 466 So. 2d 107, 114 (Ala. 1985)).

"[The plaintiff] argues that 'once [Joe Wheeler Electric Membership Corp.] had actual or constructive knowledge of the deadly hazard, it had a duty to require the removal of the hazard,' and she asserts that 'notice or knowledge of a dangerous condition can give rise to a duty of care.' [Plaintiff's] brief at 29 (citing [Alabama Power Co. v.] Cantrell, 507 So. 2d [1295,] 1297 [(Ala. 1986)] ('"'The duty of an electric company, in conveying a current of high potential, to exercise commensurate care under the circumstances, requires it to insulate its wires, and to use reasonable care to keep the same insulated wherever it may reasonably be anticipated that persons, pursuing business or pleasure, may come in contact therewith.'"' (quoting [Alabama Power Co. v.] Brooks, 479 So. 2d [1169,] 1172 [(Ala. 1985)], quoting in turn Bush [v. Alabama Power Co.], 457 So. 2d [350,] 353 [(Ala. 1984)])).

"The holding of Cantrell is not as broad as [the plaintiff] posits. Cantrell imposes a specific duty on utilities to insulate their own lines, in specific circumstances, whenever it is reasonably anticipated that people may come into contact with those lines. 507 So. 2d at 1297. Although the duty imposed on the utility companies in Cantrell is triggered when the utility company is aware that individuals may come in contact with its lines, Cantrell does not stand for the proposition that notice of a dangerous condition alone is sufficient to give rise to a duty of care. Further, none of the other cases cited by DiBiasi support her position. See ... Dominici v. Wal-Mart Stores,

> Inc., 606 So. 2d 555, 559 (La. Ct. App. 1992) ([stating that] ... '[a]ctual or constructive knowledge of a risk or injury gives rise to a duty to take reasonable steps to protect against injurious consequences resulting from the risk,' but noting that 'whether a legal duty is owed by one party to another depends upon the facts and circumstances of the case and the relationship of the parties....') ...; cf. Alabama Dep't of Corr. v. Thompson, 855 So. 2d 1016, 1021-22, 1025 (Ala. 2003) (noting that '"'[i]t is the general rule in Alabama that absent special relationships or circumstances, a person has no duty to protect another from criminal acts of a third party'"' (quoting Hail v. Regency Terrace Owners Ass'n, 782 So. 2d 1271, 1274 (Ala. 1999), quoting in turn Moye v. A.G. Gaston Motels, Inc., 499 So. 2d 1368, 1372 (Ala. 1986)), and holding that 'state correctional officers owe a general duty to the public, not a duty to a specific person, to maintain custody of inmates').
>
> "Although it may be true that foreseeability is a key factor in determining whether a duty exists in a particular circumstance, and knowledge of a dangerous condition may establish foreseeability, Alabama caselaw does not hold that knowledge, by itself, is sufficient to impose a duty."

DiBiasi v. Joe Wheeler Elec. Membership Corp., 988 So. 2d 454, 461-62 (Ala. 2008) (emphasis added; footnote omitted). See also, e.g., David G. Owen et al., Madden & Owen on Products Liability § 2:9 (3d ed. 2000) ("As is true in tort law generally, foreseeability, although necessary, is not in itself a sufficient criterion for negligence in products

liability cases.").[22]

Prescription-Drug Cases Decided Before PLIVA

In the leading case involving the question of liability on the part of the manufacturer of a brand-name drug for harm caused by deficient labeling of the generic version of the drug, the United States Court of Appeals for the Fourth Circuit recognized not only the necessity of a duty owed by

[22]There has been criticism of the notion that foreseeability should be understood as significant in determining duty. Some courts and commentators have attempted to explain that foreseeability that a given act will lead to a given harm goes only to the issue whether that act is unreasonable and thus falls short of the standard of care or to the issue whether the harm can be considered to have been proximately caused by the act. They view the existence vel non of a duty as a threshold issue determined solely by the relationship or nexus of the parties. See, e.g., Gipson v. Kasey, 214 Ariz. 141, 144, 150 P.3d 228, 231 (2007) ("[F]oreseeability often determines whether a defendant acted reasonably under the circumstances or proximately caused injury to a particular plaintiff. ... Foreseeability, as this Court noted in Martinez [v. Woodmar IV Condos. Homeowners Ass'n, Inc., 189 Ariz. 206, 211, 941 P.2d 218, 223 (1997)], is more properly applied to the factual determinations of breach and causation than to the legal determination of duty."); W. Jonathan Cardi, Purging Foreseeability, 58 Vand. L. Rev. 739 (April 2005).

It is not necessary here to grapple with this fundamental question. It is enough for present purposes to recognize that foreseeability alone is not enough to create a duty and that a relationship between the parties is essential.

the defendant to the plaintiff, but also that the source of that duty must be a relationship created by the plaintiff's consumption of the defendant's product. In Foster v. American Home Products Corp., 29 F.3d 165, 167 (4th Cir. 1994), the Court expressly held that "a name brand manufacturer cannot be held liable on a negligent misrepresentation theory for injuries resulting from use of another manufacturer's product."

The plaintiffs attempt to discount Foster and other cases that reach the same conclusion. According to the plaintiffs, the opinions in those cases were based on the assumption that generic manufacturers were available to bear the liability for any deficiencies in the labeling that accompanies their products. Such an assumption, they note, is no longer viable in light of the Supreme Court's decision in PLIVA.

The issue of the generic manufacturer's liability, however, was not the issue in Foster and the dozens of similar cases decided before PLIVA. Although the courts in some of those cases might have taken some comfort in the availability of a generic manufacturer as a responsible party, the conclusion reached by the Foster court and other courts as to

the lack of liability on the part of brand-name manufacturers for injuries caused by deficient labeling of generic drugs was not dependent upon that availability. Thus, after expressing in dicta its views as to the potential liability of generic manufacturers, the Foster court proceeded to explain separately as follows:

> "We also reject the contention that a name brand manufacturer's statements regarding its drug can serve as the basis for liability for injuries caused by another manufacturer's drug. Name brand manufacturers undertake the expense of developing pioneer drugs, performing the studies necessary to obtain premarketing approval, and formulating labeling information. Generic manufacturers avoid these expenses by duplicating successful pioneer drugs and their labels. Name brand advertising benefits generic competitors because generics are generally sold as substitutes for name brand drugs, so the more a name brand drug is prescribed, the more potential sales exist for its generic equivalents. There is no legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products, over whose production the name brand manufacturer had no control. This would be especially unfair when, as here, the generic manufacturer reaps the benefits of the name brand manufacturer's statements by copying its labels and riding on the coattails of its advertising. The premarketing approval scheme Congress established for generic equivalents of previously approved drugs cannot be construed to create liability of a name brand manufacturer when another manufacturer's drug has been consumed."

29 F.3d at 170 (emphasis added).

Furthermore, in a separate portion of its opinion, the court explains unequivocally, and without any reference to the prospects for liability on the part of the generic manufacturer, that a brand-name manufacturer simply has no "duty" to the consumer of a generic drug the brand-name manufacturer did not produce or distribute and that, therefore, the brand-name manufacturer cannot be liable under a negligent-misrepresentation theory:

> "The Fosters' negligent misrepresentation action against Wyeth also fails because Wyeth is under no duty of care to the Fosters. ... An action for negligent misrepresentation will not lie unless the defendant owes the plaintiff a duty of care. Weisman v. Connors, 312 Md. 428, [442-47,] 540 A.2d 783, 790-92 (1988)."

29 F.3d at 171. The court then expressly rejects the same foreseeability argument urged upon us by the plaintiffs in this case, explaining that foreseeability alone is not enough to create a duty and that a relationship between the parties is necessary:

> "The Fosters contend that a duty exists in this case because it was foreseeable to Wyeth that misrepresentations regarding Phenergan could result in personal injury to users of Phenergan's generic equivalents. They point to Jacques v. First National Bank, a negligence action, which noted:
>
> "'Where the failure to exercise due care

> creates a risk of economic loss only, courts have generally required an intimate nexus between the parties as a condition to the imposition of tort liability. This intimate nexus is satisfied by contractual privity or its equivalent. By contrast, where the risk created is one of personal injury, no such direct relationship need be shown, and the principal determinant of duty becomes foreseeability.'
>
> "307 Md. 527, [534-35,] 515 A.2d 756, 759-60 (1986). 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 for the tort of negligent misrepresentation 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.' Weisman v. Connors, 312 Md. 428, 540 A.2d [783] at 790 [(1988)] (quoting Holt v. Kolker, 189 Md. 636, [640,] 57 A.2d 287, 288 (1948)). There is no such relationship between the parties to this case, as Brandy Foster was injured by a product that Wyeth did not manufacture. As Wyeth has no duty to the users of other manufacturers' products, a negligent misrepresentation action cannot be maintained against it on the facts of this case."

29 F.3d at 171 (emphasis added).

By my count,[23] from the time Foster was decided until the issuance of the Supreme Court's decision in PLIVA, 43 reported cases applying the law of 18 states were decided in accordance

[23]My count might be low. An appendix to the appellants' application for rehearing lists more cases.

with the Foster decision.[24] Aside from the

[24]The following pre-PLIVA cases involve the same drug at issue in this case; many of them involve one or both of the same corporate defendants. In all of them, the court holds that the defendant brand-name manufacturer has no duty or liability with respect to generic metoclopramide not manufactured or sold by it: Mensing v. Wyeth, Inc., 588 F.3d 603, 612-14 (8th Cir. 2009), rev'd in part on other grounds sub nom. PLIVA, Inc. v. Mensing, 564 U.S. ___ ,131 S. Ct. 2567 (2011); Bell v. Pfizer Inc., No. 5:10CV00101 BSM (E.D. Ark. Mar. 16, 2011) (not reported in F. Supp. 2d); Overton v. Wyeth, Inc., No. CA 10-0491-KD-C (S.D. Ala. Mar. 15, 2011) (not reported in F. Supp. 2d), findings and recommendation adopted (S.D. Ala. Apr. 7, 2011) (not reported in F. Supp. 2d); Simpson v. Wyeth, Inc., No. 7:10-cv-01771-HGD (N.D. Ala. Dec. 9, 2010) (not reported in F. Supp. 2d), report and recommendation adopted (N.D. Ala. Jan. 4, 2011) (not reported in F. Supp. 2d); Gross v. Pfizer, Inc., No. 10-CV-00110-AW (D. Md. Nov. 9, 2010) (not reported in F. Supp. 2d); Cooper v. Wyeth, Inc., No. 09-CV-929 (M.D. La. Oct. 26, 2010) (not reported in F. Supp. 2d); Fullington v. Pfizer, Inc., No. 4:10CV00236 JLH (E.D. Ark. Sept. 17, 2010) (not reported in F. Supp. 2d); Johnson v. Teva Pharm. USA, Inc., No. 2:10 CV 404 (W.D. La. Aug. 16, 2010) (not reported in F. Supp. 2d); Fisher v. Pelstring, No. 4:09-cv-00252-TLW (D.S.C. July 28, 2010) (not reported in F. Supp. 2d); Neal v. Teva Pharm. USA, Inc., No. 09-CV-1027 (W.D. Ark. July 1, 2010) (not reported in F. Supp. 2d); Mosley v. Wyeth, Inc., 719 F. Supp. 2d 1340 (S.D. Ala. 2010); Phelps v. Wyeth, Inc., No. 09-6168-TC (D. Or. May 28, 2010) (not reported in F. Supp. 2d), findings and recommendation adopted (D. Or. June 21, 2010) (not reported in F. Supp. 2d); Craig v. Pfizer, Inc., No. 3:10-00227 (W.D. La. May 26, 2010) (not reported in F. Supp. 2d); Finnicum v. Wyeth, Inc., 708 F. Supp. 2d 616, 619-21 (E.D. Tex. 2010); Howe v. Wyeth Inc., No. 8:09-CV-610-T-17 AEP (M.D. Fla. Apr. 26, 2010) (not reported in F. Supp. 2d); Hardy v. Wyeth, Inc., No. 9:09CV152 (E.D. Tex. Mar. 8, 2010) (not reported in F. Supp. 2d), report and recommendation adopted (E.D. Tex. Mar. 29, 2010) (not reported in F. Supp. 2d); Couick v. Wyeth, Inc., 691 F. Supp. 2d 643, 645-46 (W.D. N.C. 2010); Levine v. Wyeth Inc., 684 F. Supp. 2d 1338, 1344-48 (M.D. Fla. 2010);

Washington v. Wyeth, Inc., No. 3:09-CV-01343 (W.D. La. Feb. 8, 2010) (not reported in F. Supp. 2d); Morris v. Wyeth, Inc., No. 09-0854 (W.D. La. Nov. 23, 2009) (not reported in F. Supp. 2d); Meade v. Parsley, No. 2:09-cv-00388 (S.D. W. Va. Nov. 13, 2009) (not reported in F. Supp. 2d); Burke v. Wyeth, Inc., No. G-09-82 (S.D. Tex. Oct. 29, 2009) (not reported in F. Supp. 2d); Stoddard v. Wyeth, Inc., 630 F. Supp. 2d 631, 633-34 (E.D.N.C. 2009); Fields v. Wyeth, Inc., 613 F. Supp. 2d 1056, 1060-61 (W.D. Ark. 2009); Moretti v. Wyeth, Inc., No. 2:08-cv-00396-JCM-(GWF) (D. Nev. Mar. 20, 2009) (not reported in F. Supp. 2d); Schrock v. Wyeth, Inc., 601 F. Supp. 2d 1262, 1266-67 (W.D. Okla. 2009); Cousins v. Wyeth Pharm., Inc., No. 3:08-CV-0310-N (N.D. Tex. Mar. 10, 2009) (not reported in F. Supp. 2d); Smith v. Wyeth, Inc., No. 5:07-CV-18-R (W.D. Ky. June 30, 2008) (not reported in F. Supp. 2d), aff'd, 657 F.3d 420 (6th Cir. 2011); Wilson v. Wyeth, Inc., No. 3:07-CV-378-R (W.D. Ky. June 30, 2008) (not reported in F. Supp. 2d), aff'd, 657 F.3d 420 (6th Cir. 2011); Morris v. Wyeth, Inc., No. 1:07-CV-176-R (W.D. Ky. June 30, 2008) (not reported in F. Supp. 2d), aff'd, 657 F.3d 420 (6th Cir. 2011); Pustejovsky v. Wyeth, Inc., No. 4:07-CV-103-Y (N.D. Tex. Apr. 3, 2008) (not reported in F. Supp. 2d); Swicegood v. PLIVA, Inc., 543 F. Supp. 2d 1351, 1358 (N.D. Ga. 2008); Tarver v. Wyeth, Inc., No. Civ.A.3-04-2036 (W.D. La. Jan. 26, 2006) (not reported in F. Supp. 2d); Tarver v. Wyeth, Inc., No. Civ.A.3-04-2036 (W.D. La. June 7, 2005) (not reported in F. Supp. 2d); Block v. Wyeth, Inc., No. Civ.A. 3:02-CV-1077 (N.D. Tex. Jan. 28, 2003) (not reported in F. Supp. 2d); and Sharp v. Leichus, 952 So. 2d 555 (Fla. Dist. Ct. App. 2007).

In addition to Foster, the other pre-PLIVA cases holding that a manufacturer of a brand-name drug has no duty or liability to the consumer of a generic drug manufactured and sold by another company include Barnhill v. Teva Pharmaceuticals USA, Inc., No. 06-0282-CB-M (S.D. Ala. Apr. 24, 2007) (not reported in F. Supp. 2d); Leblanc v. Wyeth, Inc., No. CIV A 04-0611 (W.D. La. Oct. 5, 2006) (not reported in F. Supp. 2d); Goldych v. Eli Lilly & Co., No. 5:04-CV-1477 (GLS/GJD) (N.D. N.Y. July 19, 2006) (not reported in F. Supp. 2d); Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 540-41 (E.D. Pa. 2006), rev'd on other grounds, 521 F.3d 253 (3d Cir.

decision of the court certifying the question in this case, only two courts held to the contrary -- an intermediate state appeals court in California and a district court in Vermont.[25]

The United States Court of Appeals for the Eighth Circuit is the court from which the PLIVA case came and to which it was returned on remand by the United States Supreme Court. See Mensing v. Wyeth, Inc., 588 F.3d 603, 612-14 (8th Cir. 2009), rev'd in part on other grounds sub nom., PLIVA, Inc. v. Mensing, 564 U.S. ___, 131 S. Ct. 2567 (2011). Before the Supreme Court weighed in, the Eighth Circuit Court of Appeals held that state-law claims against generic-drug manufacturers

---

2008), vacated and remanded, 129 S. Ct. 1578 (2009); Possa v. Eli Lilly & Co., No. 05-1307-JJB-SCR (M.D. La. May 10, 2006) (not reported in F. Supp. 2d); Stanley v. Wyeth, Inc., 991 So. 2d 31, 34-35 (La. Ct. App. 2008); and Flynn v. American Home Products Corp., 627 N.W.2d 342, 350 (Minn. Ct. App. 2001).

In addition, according to briefs filed in this case, two Alabama circuit courts also have addressed the issue of liability for injuries allegedly caused by generic metoclopramide, both concluding that the brand-name manufacturer was not liable for injury caused by the generic drug manufactured and sold by another company. See Buchanan v. Wyeth Pharm., Inc., No. CV-2007-900065, Oct. 20 2008; Green v. Wyeth, Inc., No. CV-2006-3917, May 14, 2007.

[25]See Weeks v. Wyeth, No. 1:10-cv-602-MEF (M.D. Ala. Mar. 31, 2011) (not reported in F. Supp. 2d); Conte v. Wyeth, Inc., 168 Cal. App. 4th 89, 85 Cal. Rptr. 3d 299, 315-18 (2008); and Kellogg v. Wyeth, 762 F. Supp. 2d 694 (D. Vt. 2010).

were not preempted by federal law. 588 F.3d at 611. In the same opinion, however, that court was called upon to decide whether a brand-name manufacturer could be held liable for injuries caused by generic metoclopramide manufactured and sold by another party. In a soundly reasoned opinion, that court answered in the negative:

> "[R]egardless 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. 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 [v. American Home Prods. Corp.], 627 N.W.2d [342,] 350 [(Minn. Ct. App. 2001)]. Since Mensing 'did not purchase or use [the name brand defendants'] product, ... there was no direct relationship between 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."

588 F.3d at 613-14 (some emphasis added; footnote omitted).

In a footnote, the Eighth Circuit also provided this

instructive insight:

> "Mensing'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."

588 F.3d at 613 n. 9 (emphasis added).

Among the other pre-PLIVA decisions are four decisions from federal district courts in Alabama applying Alabama law: Mosley v. Wyeth, Inc., 719 F. Supp. 2d 1340 (S.D. Ala. 2010); Simpson v. Wyeth, Inc., No. 7:10-CV-01771-HGD (N.D. Ala. Dec. 9, 2010) (not reported in F. Supp. 2d); Overton v. Wyeth, Inc., No. CA 10-0491-KD-C (S.D. Ala. Mar. 15, 2011) (not reported in F. Supp. 2d); and Barnhill v. Teva Pharm. USA, Inc., No. 06-0282-CB-M (S.D. Ala. 2007) (not reported in F. Supp. 2d). In all four of these cases, the court held that claims could not be maintained under Alabama law against the manufacturer of a brand-name drug for injuries resulting from a consumer's use of a generic version of that drug

manufactured and sold by another company. The first of these, Mosley, is representative of the other Alabama federal district court decisions, as well as the other district court decisions identified above. As the federal district court in Mosley explained regarding precisely the same drug, the same defendants, and the same legal issue as are presented in the case at hand:

> "The argument is not that Defendants' product caused Plaintiff harm, but rather that their dissemination of false and misleading information, which they knew would be relied upon by the generic manufacturers in generating their own labels, was the direct and proximate cause of Plaintiff's injuries."

719 F. Supp. 2d at 1344-45. The court rejected this argument because, under Alabama law, no "relationship" existed between the manufacturer of the brand-name drug and the consumer of the generic drug, and thus no "duty" was owed. 719 F. Supp. 2d at 1346-47.

Contrary to the main opinion, but consistent with all the foregoing authority, Wyeth's argument does not "ignore[] the nature of prescription medication." ___ So. 3d at ___. Obviously, a duty must be understood to run from a drug manufacturer to a consumer if that consumer is to be able to state a claim against the manufacturer. (If the duty ran only

to an intermediary or other third party, such as a physician or pharmacist, then only the intermediary or third party would have a cause of action and be a proper plaintiff.) The controlled nature of prescription drugs, see 21 U.S.C § 353(b)(1), simply means that the drug manufacturer fulfills its duty of disclosure to the consumer by making disclosures to the consumer's physician and/or pharmacist, who receives the disclosures and acts upon them on behalf of the consumer. In essence, the consumer's physician serves as the agent of the consumer for purposes of receipt of and reliance upon the disclosures, or omissions, of the manufacturer. See, e.g., Stone v. Smith, Kline & French Labs., 447 So. 2d 1301, 1305 (Ala. 1984)(quoting Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir. 1974)):

> "'As a medical expert, the prescribing physician can take into account the propensities of the drug as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.'"

(Emphasis added.)[26]

Wyeth's position fully accommodates the notion that a prescription drug is consumed only if it is prescribed by a physician and dispensed by a pharmacist, and that the physician and pharmacist act as agents of the consumer of a generic drug for purposes of receiving and acting upon whatever warnings and representations the drug's manufacturer intends for that consumer. The fact that there is such a "learned intermediary" acting in this manner on behalf of the

---

[26]See also, e.g., Tetuan v. A.H. Robins Co., 241 Kan. 441, 464, 738 P.2d 1210, 1228 (1987) ("[W]here a patient relies on a physician for treatment or advice ..., justifiable reliance by the physician on misrepresentations or concealment by the manufacturer of [a] device constitutes justifiable reliance by the patient."); Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir. 1974) ("Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a 'learned intermediary' between manufacturer and consumer."); and Lovejoy v. AT&T Corp., 92 Cal. App. 4th 85, 95, 111 Cal. Rptr. 2d 711, 718 (2001) ("Under the principle of indirect reliance, a fraudulent misrepresentation is actionable if it was communicated to an agent of the plaintiff and was acted upon by the agent to the plaintiff's damage. A classic example of indirect reliance would be a drug manufacturer's misrepresentation to physicians about the safety of its drug. A patient injured by the drug is permitted to sue the manufacturer for fraud without proof that his doctor repeated the falsehood to him, under the theory that the doctor was acting as plaintiff's agent.").

ultimate consumer does not in itself create a relationship between the brand-name manufacturer and the consumer. Regardless of the fact of, or content of, a given prescription, if a person consumes a generic drug, the nexus created is with the manufacturer of the generic drug. The physician's involvement does nothing to create some sort of relationship between the consumer and some different entity. The consumer has no more relationship with the brand-name manufacturer in such a scenario than he or she would have if the learned intermediaries were not involved and the consumer purchased the generic drug directly from the generic manufacturer.

As the Eighth Circuit Court of Appeals indicated in Mensing, perhaps there is confusion resulting from the fact that, in prescribing or dispensing a generic drug, physicians or pharmacists might in fact rely upon labeling that previously was published by a brand-name manufacturer in conjunction with the marketing by it of its own brand-name drug. As that court also pointed out, however, the labeling of the brand-name manufacturer is not intended for that purpose; it is published by the brand-name manufacturer solely

for the purpose of fulfilling the brand-name manufacturer's own duty to provide adequate labeling to the consumers of its product. To say that a physician's or pharmacist's reliance upon a brand-name manufacturer's labeling in prescribing or dispensing a generic drug makes the brand-name manufacturer liable for injuries suffered by the generic-drug consumer is to "bootstrap" into existence a duty on the part of the brand-name manufacturer to that consumer; the first inquiry must be whether the brand-name manufacturer had a duty to one who did not consume its product to publish adequate labeling. Apart from such bootstrapping, there is no basis to declare the existence of such a duty. See, e.g., Mensing, 588 F.3d at 613 ("Regardless of whether her doctor relied upon the Reglan label, Mensing must show that the name brand manufacturers owed her a duty of care.").[27]

[27]Of course, the corollary of this fact is that the generic manufacturer does have a duty to the consumer of its generic drug to publish a label upon which that consumer, through his or her physician or pharmacist, can rely. It does not change the lack of a duty by the brand-name manufacturer as to the manufacturer of the generic drug to say that the generic manufacturer must replicate for use with its own drug the wording of the dosing instructions and warnings approved by the FDA for use by the brand-name manufacturer. That fact, and whatever effect it may or may not have upon the generic manufacturer's liability to its consumer, is a matter between the generic manufacturer and the consumer, with "input" from

The present case is not distinguishable from the above-discussed cases on the ground that the present case involves common-law claims of fraud in relation to deficient labeling. Foster, the Eighth Circuit Court of Appeals' Mensing case, Alabama federal district court decisions such as Mosley, and dozens of other well considered decisions cited above involve alleged defects in labeling. Indeed, many, if not most, of them involve common-law claims of misrepresentation of some sort. They consider, and often explain, the necessity of a duty arising from a relationship as no less applicable to claims of defects in the warnings that accompany a product than to defects in the pharmacology of the product.[28]

Congress, the FDA, and the United States Supreme Court. The brand-name manufacturer plays no role in the generic manufacturer's decision to enter the market, and it is not responsible for crafting the regulatory and legal framework within which the generic manufacturer chooses to do so.

[28]These cases take this approach because pharmacological defects and defective warnings are indistinguishable for purposes of considering liability associated with the consumption of a drug. As the United States Supreme Court recently explained in a non-drug case:

> "According to petitioners, these claims do not fall within the [Locomotive Inspection Act's] pre-empted field because '[t]he basis of liability for failure to warn ... is not the "design" or "manufacture" of a product,' but is instead 'the failure to provide

adequate warnings regarding the product's risks.' ...

"We disagree. A failure-to-warn claim alleges that the product itself is unlawfully dangerous unless accompanied by sufficient warnings or instructions. Restatement (Third) of Torts: Products Liability § 2(c) (1997) (A failure-to-warn claim alleges that a product is defective 'when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, ... and the omission of the instructions or warnings renders the product not reasonably safe'); see also id., Comment l, at 33 ('Reasonable designs and instructions or warnings both play important roles in the production and distribution of reasonably safe products')."

Kurns v. Railroad Friction Prods. Corp., ___ U.S. ___, ___, 132 S. Ct. 1261, 1268 (2012) (emphasis added).

The indistinguishability of labeling and product is even clearer -- and more tangible -- in the case of prescription drugs. Prescription drugs are approved for sale by the FDA as safe and effective only for use as recommended in the approved labeling. As an amicus brief in another case recently explained:

"Attempts to selectively untether the design of a prescription drug from its labeling by allowing a claim that 'the drug's risks outweighed its benefits' making it unreasonably dangerous ignore one very salient fact: The FDA-approved 'benefit' is derived only by reference to the approved indications in the product labeling, and the source of the 'risks' to which the benefits are compared also is the FDA-approved labeling. In other words, a pharmaceutical product cannot be divorced from its label as it is not possible to conduct a risk/benefit (i.e., design defect) evaluation

PLIVA

On June 23, 2011, the United States Supreme Court decided PLIVA. The Court held that state tort-law claims against manufacturers of generic drugs were preempted by the statutory and regulatory scheme that had been adopted by Congress and the FDA. 564 U.S. at ___, 131 S. Ct. at 2581-82. It is clear from the text of the PLIVA opinion itself that PLIVA did not

---

without the product labeling."

Brief of the Generic Pharmaceutical Association as amicus curiae in support of the petitioner in Mutual Pharm. Co. v. Bartlett, No. 12-142, Jan. 22, 2013, p. 16 (appellate brief to United States Supreme Court 2013) (emphasis added). See also note 31, infra. Indeed, the United States Supreme Court in PLIVA itself treated the label and warnings that accompanied the drug as an integral part of the drug itself. Adequate warnings, or lack thereof, are an inseparable part of the product purchased and consumed by the plaintiff. (No one, for example, would contend that Tylenol brand acetaminophen sold to consumers as a pain remedy, but without any labels prescribing dosages or warning of the harmful side effects of taking more than the prescribed dosage would amount to the same product as Tylenol sold with a label prescribing a dosage of only two tablets every six hours and warning of harmful side effects if that dosage is exceeded.)

Even this Court has had occasion to express its understanding that the dosing instructions and the warnings of contraindications and side effects set out in a drug's label make the drug what it is. In Stone v. Smith, Kline & French Lab., 447 So. 2d 1301, 1304 (Ala. 1984), this Court analyzed a "failure to warn" as an aspect of products-liability law, and explained that "the adequacy of the accompanying warning determines whether the drug, as marketed, is defective, or reasonably dangerous."

undermine the rationale of the dozens of pre-PLIVA decisions discussed and cited above.

Foremost in this regard is the simple fact that the issue discussed in PLIVA was the effect of the federal law of preemption on the liability of generic manufacturers for their own drugs. Nothing in the Court's reasoning as to this issue has any bearing on the unrelated question under state law of relationship and duty of brand-name manufacturers with respect to drugs they do not manufacture.

Second, the PLIVA Court includes statements in the opinion that contemplate that its ruling as to generic manufacturers does not mean that consumers injured by generic drugs will now be able to turn to manufacturers of brand-name drugs for compensation. The Supreme Court expressly recognizes the "unfortunate hand" that has been dealt to consumers of generic drugs given its decision:

> "We acknowledge the unfortunate hand that federal drug regulation has dealt Mensing, Demahy, and others similarly situated.
>
> "But 'it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre.' Cuomo v. Clearing House Assn., L.L.C., 557 U.S. 519, 556 (2009) (THOMAS, J., concurring in part and dissenting in part) (internal quotation marks and brackets omitted)."

564 U.S. at ___, 131 S. Ct. at 2581-82. As Justice Sotomayor subsequently explained, under the majority decision, a consumer of a generic drug "now has no right to sue." 564 U.S. at ___, 131 S. Ct. at 2592 (Sotomayor, J., dissenting).

Moreover, the Supreme Court expressed its understanding that the consumption of the brand-name manufacturer's drug remained a prerequisite to holding that manufacturer liable for a labeling deficiency: "Had Mensing and Demahy taken Reglan, the brand-name drug ..., Wyeth [v. Levine, 555 U.S. 555 (2009),[29]] would control and their lawsuits would not be pre-empted." 564 U.S. at ___, 131 S. Ct. at 2581.

Cases Decided in the Wake of PLIVA

In the year and a half after PLIVA was decided, but before this Court issued its opinion on original submission in this case, 11 decisions applying the law of 10 states were reported. Every one of those decisions held that manufacturers of brand-name drugs had no duty or liability to the consumer of a generic drug manufactured and sold by

[29]In Wyeth v. Levine, 555 U.S. 555 (2009), the Supreme Court held that lawsuits against brand-name manufacturers of prescription drugs were not preempted by federal law.

another company.[30] Accordingly, there was (and, as will be seen, still is) unanimity among the courts that addressed the question in the wake of PLIVA that the holding of PLIVA as to the preemption of state-law claims against generic manufacturers does not undermine the rationale of the pre-PLIVA decisions discussed above or justify making brand-name manufacturers liable for a product they have not manufactured or sold. This includes each of the three United States Courts of Appeals to address the issue in the first year and a half following PLIVA -- the Courts of Appeals for the Fifth, Sixth, and Eighth Circuits.

---

[30]See Demahy v. Schwarz Pharma, Inc., 702 F.3d 177 (5th Cir. 2012); Smith v. Wyeth, Inc., 657 F.3d 420 (6th Cir. 2011); Mensing v. Wyeth, Inc., 658 F.3d 867 (8th Cir. 2011); Baymiller v. Ranbaxy Pharm., Inc., 894 F. Supp. 2d 1302 (D. Nev. 2012); Strayhorn v. Wyeth Pharm., Inc., 882 F. Supp. 2d 1020 (W.D. Tenn. 2012); Phelps v. Wyeth, Inc., 857 F. Supp. 2d 1114 (D. Or. 2012); Metz v. Wyeth LLC, 830 F. Supp. 2d 1291 (M.D. Fla. 2011); Lashley v. Pfizer, Inc., 877 F. Supp. 2d 466 (S.D. Miss. 2012); Guarino v. Wyeth LLC, No. 8:10-cv-2885-T-30GTW (M.D. Fla. Apr. 3, 2012) (not reported in F. Supp. 2d); Gross v. Pfizer, Inc., No. 10-CV-00110-AW (D. Md. Sep. 7, 2011) (not reported in F. Supp. 2d); and Fullington v. PLIVA, Inc., No. 4:10CV00236JLH (E.D. Ark. Dec. 12, 2011) (not reported in F. Supp. 2d). Some of these are cases in which a court that addressed the issue before PLIVA had an opportunity after PLIVA to revisit its previous ruling, only to reaffirm that previous ruling and implicitly or explicitly conclude that the Supreme Court's holding in PLIVA did not alter the court's pre-PLIVA analysis.

Perhaps the most noteworthy of the aforesaid three Court of Appeals' decisions was the short order issued on remand by the Eighth Circuit Court of Appeals in the PLIVA case itself. The same court whose judgment had just been reversed by the United States Supreme Court on the issue of preemption as to the liability of generic manufacturers evidently felt no compunction in deciding expressly to "reinstate Section III of [its original] opinion," the same section quoted at length above in which it had held that brand-name manufacturers were not liable for defects or deficiencies in the labeling of products manufactured and sold by others. Mensing v. Wyeth, Inc., 658 F.3d 867 (8th Cir. 2011).

In Smith v. Wyeth, Inc., 657 F.3d 420 (6th Cir. 2011), the United States Court of Appeals for the Sixth Circuit also acknowledged, but was unaffected by, the holding in PLIVA. The court began by noting the applicability of the Kentucky Products Liability Act, which, it explained, was merely a codification of preexisting common-law principles, including common-law principles regarding the misrepresentation and "failure-to-warn" claims asserted against the manufacturers of

brand-name drugs in that case. 657 F.3d at 423.[31] The court then proceeded, undeterred in any way by the PLIVA holding as to manufacturers of generic drugs, to explain its rejection of the misrepresentation claims against the brand-name manufacturer, Wyeth, as to the same drug that is at issue here:

"A threshold requirement of any products-

---

[31]The court explained that the term "products liability action" was simply a reference to "'any action brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formulation ... warning, instructing, marketing, advertising, packaging or labeling of any product.'" 657 F.3d at 423 (quoting Ky. Rev. Stat. § 411.300(1) (2010)).

Cases from jurisdictions decided under a legislatively, or in some cases judicially, crafted "products liability doctrine" that has supplanted or supplemented traditional common-law theories of recovery are entirely apposite to the question at hand. Such doctrines, as in Kentucky, invariably reflect common-law theories of recovery, including misrepresentation and suppression relating to labeling and warnings, and, like the common-law claims alleged here, also require the existence of a duty arising out of a sufficient nexus between the manufacturer and consumer in relation to the product consumed.

For the same reason, it is not necessary to address the issue whether the claims made by the plaintiffs in this case should be considered Alabama Extended Manufacturer's Liability Doctrine claims or may be considered conventional products-liability claims based on common-law theories of fraud and suppression. A duty arising from a relationship or nexus between the parties would be necessary in either case; none exists here.

> liability claim is that the plaintiff assert that the defendant's product caused the plaintiff's injury. See Holbrook v. Rose, 458 S.W.2d 155, 157 (Ky. 1970). The plaintiffs in this case concede that they had consumed only generic versions of metoclopramide and not Reglan. As the district court observed, adopting their theory of liability would require the court to attribute any deficiency in a name-brand manufacturer's labeling and marketing of its products to products manufactured by its generic competitors. Such a theory, however, fails to satisfy the threshold requirement of a products-liability action -- that the defendant's product have injured the plaintiff. As the district court stated, 'Just because a company is in the same business as a tortfeasor, the company is not automatically liable for the harm caused by the tortfeasor's product.'
>
> "The plaintiffs' argument -- that the name-brand defendants' liability stems from the fact that the regulatory structure governing name-brand and generic drugs makes it foreseeable that patients and their physicians will rely on the name-brand labels to use and prescribe generic drugs -- has been rejected by all but one of the courts that have considered it. The leading case is Foster v. American Home Products Corp., 29 F.3d 165 (4th Cir. 1994), in which the court held that the manufacturer of a name-brand drug has no duty to patients who ingested only a generic version of the drug manufactured by the name-brand drug company's competitors. ... As have the majority of courts to address this question, we reject the argument that a name-brand drug manufacturer owes a duty of care to individuals who have never taken the drug actually manufactured by that company."

657 F.3d at 423-24 (some emphasis added).

In the last of the aforesaid decisions by federal courts

of appeals, the United States Court of Appeals for the Fifth Circuit explicitly held in Demahy v. Schwarz Pharma, Inc., 702 F.3d 177, 184 (5th Cir. 2012), that PLIVA changed nothing as to brand-name manufacturers:

> "We do not view [PLIVA] as overruling Foster [v. American Home Products Corp., 29 F.3d 165 (4th Cir. 1994),] because the court in Foster did not reach its holding by relying on the ability of a plaintiff to sue generic manufacturers. Instead, the court's holding was based on its interpretation of Maryland law and the conclusion that a name-brand manufacturer has no duty of care to consumers that are not using the manufacturer's product. Foster, 29 F.3d at 171–72; see also Smith v. Wyeth, 657 F.3d 420, 423–24 (6th Cir. 2011) (following Foster's conclusion that name-brand manufacturers have no duty to generic-brand consumers). The Foster court's opinion in dicta on the viability of suits against generic manufacturers was proved wrong, but this fact does not impose on name-brand manufacturers a duty of care to customers using generic products."

In Phelps v. Wyeth, Inc., 857 F. Supp. 2d 1114 (D. Or. 2012), the federal district court for Oregon also explicitly rejected the notion that PLIVA changed anything as to brand-name manufacturers. In an opinion reflective of the other post-PLIVA decisions by federal district courts, it explained:

> "[W]hile [PLIVA] overrules Foster [v. American Home Products Corp., 29 F.3d 165 (4th Cir. 1994),] with respect to a generic manufacturer's ability to alter labels, it does not overrule Foster's holding regarding the liability of name-brand manufacturers.

> Indeed, the Foster court's reluctance to hold name-brand defendants liable for generic drugs did not depend on a generic manufacturer's ability to alter the label, but rather on concepts of foreseeability and duty. Consequently, [PLIVA] does not overturn the central holding in Foster."

857 F. Supp. 2d at 1119 (emphasis added).

The Oregon court provided an instructive analysis as to the necessity of a relationship in order for there to exist a duty for purposes of a common-law claim based on deficient labeling of drugs:

> "It is undisputed that Mrs. Phelps never ingested metoclopramide manufactured by any of the name-brand defendants. ... Under Oregon's product liability law, the name-brand defendants cannot be found liable for plaintiffs' injuries because plaintiffs cannot show that their injuries resulted from the use of the name-brand manufacturers' product. See McEwen v. Ortho Pharma. Corp., 270 Or. 375, 407, 528 P.2d 522 (1974). Nonetheless, plaintiffs request that the court apply common law principles of negligence, fraud, and misrepresentation to extend liability to the name-brand defendants. They argue that regardless of whether Mrs. Phelps ingested the name-brand defendants' product, the name-brand defendants owed her a duty of care.
>
> "....
>
> "Plaintiffs cite neither Oregon nor federal law to support this proposition. Instead, plaintiffs argue that manufacturers owe a general duty to use care in connection with their conduct to all who may [be] injured by it, if such conduct is carried out in a negligent manner and results in foreseeable injuries. ... (citing Palsgraf v. Long Island R.R.

> Co., 248 N.Y. 339, 162 N.E. 99 (1928)). Plaintiffs assert that, based on federal regulations, name-brand defendants should have known that all generic manufacturers were required to duplicate the information on name-brand labels for generic drugs, and that generic manufacturers were prevented from including additional warnings or independently warning doctors of metoclopramide's risks. Additionally, plaintiffs argue that name-brand defendants knew or should have known that their label did not adequately warn of the risks associated with metoclopramide. Consequently, plaintiffs assert that the generics defendants' reliance on name-brand defendants' labels was a foreseeable cause of their injuries.
>
> "... [In Foster v. American Home Products Corp., 29 F.3d 165 (4th Cir. 1994),] [t]he plaintiffs brought suit against the name-brand manufacturer for negligent misrepresentation, but the Fourth Circuit ruled that Maryland law did not allow a manufacturer to be liable for an injury caused by a competitor's product. Id. at 171. While Foster recognized that reliance on the label was foreseeable, the court explained that foreseeability alone does not create a duty of care, and the court specifically rejected the plaintiffs' negligence claim. Id. ... The Foster court found that there is '(n)o legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability [for] injuries caused by other manufacturers' products, over whose production the name brand manufacturer had no control.' Id. at 170. Name-brand defendants cite a plethora of courts which have followed Foster and concluded that name-brand defendants cannot be held liable for injuries caused by products produced by a generic manufacturer. See e.g. Smith v. Wyeth, Inc., 657 F.3d 420, 424 (6th Cir. 2011); Metz v. Wyeth LLC, 830 F. Supp. 2d 1291 (M.D. Fla. 2011)."

857 F. Supp. 2d at 1120-21 (emphasis added).

Finally, the Oregon court expressed the same understanding of the text of the PLIVA decision that is offered above:

> "In fact, the Supreme Court [in PLIVA] acknowledged that the dual holdings of Foster and [PLIVA] left the plaintiff there with no remedy, as she could not successfully bring a claim against name-brand manufacturers under Foster and was barred on other grounds from suing the generic manufacturers. [PLIVA], [564 U.S. at ___,] 131 S. Ct. at 2581 (acknowledging 'the unfortunate hand that federal drug regulation has dealt' plaintiff). The majority further stated that Congress or the FDA could change the law ...."

857 F. Supp. 2d at 1119-20 (emphasis added).

In an opinion issued not long after PLIVA, a federal district court applied the law of our neighboring state of Florida:

> "The vast majority of courts, in Florida and elsewhere, that have addressed the issue now before the Court have consistently held that consumers may not bring claims for negligence, fraud, strict liability, misrepresentation, or breach of warranty against a brand name pharmaceutical manufacturer when the consumers only ingested generic versions of the drug manufactured by third parties. [Numerous citations omitted.]
>
> "Plaintiffs attempt to overcome the nearly unanimous adverse precedent by arguing that the Supreme Court's decision in PLIVA, Inc. v. Mensing, 564 U.S. ___, 131 S. Ct. 2567, 180 L.Ed.2d 580 (2011), warrants a change in how Florida law is applied to producers of brand name pharmaceuticals.

> The thrust of Plaintiffs' argument is that the Fourth Circuit's holding in the seminal case of Foster v. American Home Products Corp., 29 F.3d 165 (4th Cir. 1994), was based on the proposition (discussed in dicta) that consumers could recover from generic manufacturers for misrepresentations relating to their products. Id. at 170. While it is true that this proposition was rejected by the Supreme Court in [PLIVA], this proposition was by no means central to the ultimate holding in Foster. The Fourth Circuit's holding in Foster was based on its interpretation of Maryland law and the general rule that one manufacturer cannot be held liable on a negligent misrepresentation theory for injuries caused by another manufacturer. Id. In fact, the Foster court held that, irrespective of whether consumers could recover from generic drug manufacturers, a brand name manufacturer simply had no duty of care to individual consumers that did not use the named brand manufacturer's product. Id. at 171."

Metz v. Wyeth LLC, 830 F. Supp. 2d 1291, 1293-94 (M.D. Fla. 2011) (emphasis added).[32]

---

[32]The Florida federal district court went on to explain that "many of the pre-[PLIVA] decisions in Florida and elsewhere apparently assumed that consumers would have a remedy against generic drug manufacturers" but that this assumption was not the basis for those decisions. 830 F. Supp. 2d at 1294.

As did the Oregon federal court in Phelps v. Wyeth, supra, the federal district court in Metz explained how the opinion in PLIVA itself reveals the Supreme Court's understanding that its decision in PLIVA changed nothing as to the lack of a duty on the part of brand-name manufacturers with respect to those injured as a result of deficient labeling of other manufacturers' products:

"Tellingly, the Supreme Court in [PLIVA] appeared to

This Court's Opinion

In addition to dozens upon dozens of cases from other jurisdictions directly addressing the issue before us, Wyeth cites four Alabama cases for the proposition that a duty arising from a relationship or nexus between the parties is necessary: Keck v. Dryvit Systems, Inc., 830 So. 2d 1 (Ala. 2002); State Farm v. Owen, 729 So. 2d 834 (Ala. 1998); DiBiasi v. Joe Wheeler Electric Membership Corp., 988 So. 2d 454 (Ala. 2008); and Thompson-Hayward Chemical Co. v. Childress, 169 So. 2d 305 (Ala. 1964). The main opinion responds to these four cases by stating: "These cases are easily distinguishable from this case. Here, Wyeth authored the label with its warnings, and the generic manufacturers, as required by FDA regulations, copied that label verbatim." ___ So. 3d at ___. The fact that the generic manufacturer's label must contain the same information as the label published by Wyeth, the

---

> contemplate that consumers of generic drugs may be without a remedy when it noted 'the unfortunate hand that federal drug regulation has dealt [consumers of generic drugs].' [564 U.S. at ___, 131 S.Ct.] at 2581; see [564 U.S. at ___, 131 S.Ct.] at 2592 (Sotomayor, J., dissenting)(noting that under the majority's decision, a consumer of a generic drug 'now has no right to sue')."

830 F. Supp. 2d at 1294.

name-brand manufacturer, is true, but that fact does not make the present case distinguishable from the four cases cited.

In each of those four cases, it was foreseeable that the plaintiff would be injured by the tortious conduct of the defendant. Despite this foreseeability, each of those cases was decided based on the fact that the alleged tortfeasor had no relationship or nexus with the plaintiff giving rise to a duty to the plaintiff.

Likewise, and admittedly without question given the federal regulatory scheme for generic drugs, it was foreseeable that a generic drug might one day be produced and that, if it was, it would replicate any deficiency in Wyeth's brand-name drug, including its labeling, that might have been approved by the FDA. As was true in each of those other cases, however, such foreseeability, no matter how clear, simply is not all that is required. There was no liability in those four cases because the defendant did not have the requisite relationship or nexus with the injured party. Because the same is true here, those cases are not distinguishable, but instead support Wyeth's position.[33]

[33]The problem in this case is that the relationship or nexus to which one would normally look as the basis for a duty

The main opinion concludes its analysis by quoting a passage from a 1998 opinion of the Court of Civil Appeals in Carter v. Chrysler Corp., 743 So. 2d 456 (Ala. Civ. App. 1998), which, in turn, quotes a 1994 decision of the Alabama Supreme Court, Hines v. Riverside Chevrolet-Olds, Inc., 655 So. 2d 909, 919-20 (Ala. 1994). As a threshold matter, I find the premise of the analysis quoted from Hines circular and confusing: "'"The extent of a legal duty not to make a false representation or to suppress a material fact informs our analysis of whether two parties have a sufficient relationship

---

exists between the consumer and the generic manufacturer. As discussed, see note 27, supra, one therefore would expect that it would be the generic manufacturer that would bear responsibility for the plaintiffs' injuries. Nor would such an outcome be unfair. The generic manufacturer is not required to take on the manufacture or distribution of the generic drug. It does so freely, weighing the risks and rewards of manufacturing and selling a generic drug under whatever conditions are imposed by federal law. No one requires it to enter the market -- not the federal government, and certainly not the brand-name manufacturer that developed the drug and that stands to lose market share and attendant profits if the the generic manufacturer does enter the market. The generic manufacturer makes these decisions freely, knowing that when it seeks to profit from marketing a generic drug, certain risks come with that decision. It is not the fault of the brand-name manufacturer that the federal government has decided that the consumer of a competitor's product is to be blocked from imposing on that competitor the costs that would normally accompany the rewards attendant to the sale of that product.

on which to base a duty to disclose."'" ___ So. 3d at ___ (emphasis added). This passage essentially says that "the extent of a legal duty" will determine whether there is enough of a relationship on which "to base a duty."

Leaving aside the circularity of its premise, Hines does state that "the fact that two parties have had no contractual relationship or other dealings does not preclude the finding of a legal duty not to make a material misrepresentation or to suppress a material fact." 655 So. 2d at 920. It adds, however, that "whether a duty to disclose exists must be determined by examining the particular facts of each case." Id.

Hines did not involve an attempt to hold a manufacturer liable for injuries where the plaintiff has not used a product manufactured or sold by the defendant. Instead, Hines is a classic "privity" case. The question presented and addressed in Hines is whether the lack of a contract or other direct dealing between the plaintiff and the defendant -- lack of privity -- prevents the plaintiff from suing the defendant to recover for personal, or bodily, injuries. It is critical to a proper prospective of the Hines decision to note that the

injury litigated in that case resulted from the plaintiff's use of the defendant's product.

Carter v. Chrysler and the cases cited in Hines address the same question as did Hines.[34] In accordance with the movement of American jurisprudence in the last century away from a privity-based model for recovery for personal injuries, Hines and those other cases found privity to be unnecessary for a claim based on personal injuries. The lack of privity in those cases does not mean, however, that there was not a "relationship," or nexus, between the plaintiff and the defendant arising out of the fact that the plaintiff was injured by the defendant's product; there was. There is not here.

Ultimately, the main opinion is inextricably grounded on a single notion: The foreseeability of a deficiency in a brand-name drug, including its labeling, being replicated in a generic drug, including its labeling, is so great that we

[34]"Johnny Spradlin Auto Parts, Inc. v. Cochran, 568 So. 2d 738, 742-43 (Ala. 1990); Lawyers Title Ins. Corp. v. Vella, 570 So. 2d 578, 585 (Ala. 1990); Hopkins v. Lawyers Title Ins. Corp., 514 So. 2d 786 (Ala. 1986); Mid-State Homes, Inc. v. Startley, 366 So. 2d 734 (Ala. Civ. App. 1979); Chandler v. Hunter, 340 So. 2d 818 (Ala. Civ. App. 1976). Cf. Sims v. Tigrett, 229 Ala. 486, 158 So. 326 (1934)." Carter v. Chrysler Corp., 743 So. 2d at 461.

must recognize a duty owing from the brand-name manufacturer to whomever might be hurt by the deficiency in the generic drug. But the clear foreseeability upon which this notion is based has either been explicitly acknowledged or clearly understood by each of the scores of other federal and state courts that have addressed the issue we now address. Yet, essentially all of them reach a different conclusion than do we. They do so on the same ground that Professor Prosser implores us to remember: Foreseeability alone is not enough. See discussion, infra, citing W. Prosser, Law of Torts, 708 (4th ed. 1971). In the words of the main opinion, therefore, I can reach no conclusion other than that the "ground" we plow today is "new." And we are the only court in the nation plowing it.[35]

---

[35]The special concurrence states that "[n]o decision of any other jurisdiction addresses the precise question of Alabama law discussed in our answer." ___ So. 3d at ___ (Shaw, J., concurring specially). Beginning with Foster, however, there has been an almost endless stream of published opinions discussed hereinafter that address the exact issue we address here: a claim of "fraud," "suppression," or "misrepresentation" in connection with a generic manufacturer's use of deficient labeling in the "pervasively" regulated prescription-drug industry. And the fundamental legal principles employed in the analysis of this issue in these other cases are as elemental and imbedded in the law of this State as they are in the law of the other states discussed in those decisions.

A "Mountain of Authority" and an "Overwhelming National Consensus"

Aside from the discussion of the four cases and Hines reviewed above, the discussion and rationale offered by the main opinion today on application for rehearing are essentially unchanged from those offered in the opinion on original submission. Therefore, it is noteworthy that, since that original decision, there have been another dozen or more decisions on this issue by federal and state courts around the country, including decisions by four federal courts of appeals, two of them weighing in for the first time. In addition, the United States Supreme Court has now denied certiorari review in Demahy v. Schwarz Pharma, Inc., 702 F.3d 177 (5th Cir. 2012), cert. denied, 134 S. Ct. 57 (2013).[36] None of these courts have been persuaded by the rationale offered by this Court's original opinion.

Among the courts that have not been persuaded by our original decision is the Court of Appeals for the Fifth Circuit, which has decided two additional cases reaffirming the sound rationale it first embraced in Demahy. See Lashley

[36]The Supreme Court previously had denied certiorari review in Smith v. Wyeth, Inc., 657 F.3d 420(6th Cir. 2011), cert. denied, 132 S. Ct. 2103 (2012).

v. Pfizer, Inc., 750 F.3d 470 (5th Cir. 2014); Del Valle v. Teva Pharm. USA, Inc., 750 F.3d 470 (5th Cir. 2014) (consolidated cases).

Likewise, the Court of Appeals for the Eighth Circuit has decided yet another case reaffirming its position. In Bell v. Pfizer, Inc., 716 F.3d 1087 (8th Cir. 2013), the Eighth Circuit held that, under Arkansas law, (i) the plaintiff's contention that "her injuries were foreseeable" was "insufficient" to impose a duty on the brand-name defendants; (ii) that the plaintiff had to "show that a product manufactured or distributed by the brand[-name] defendants caused her injuries"; and (iii) that because the plaintiff "never used Reglan the brand[-name] defendants manufactured, [she] could not hold them liable under Arkansas law." 716 F.3d at 1092-93. Further, the Eighth Circuit flatly rejected the plaintiff's suggestion that there was an "exception" to the "Arkansas product identification requirement" for "misrepresentation and fraud." Id.

Recent appellate court decisions in Iowa are in accord. In Huck v. Trimark Physicians Group, 834 N.W.2d 82 (Iowa Ct. App. 2013) (unpublished disposition), the Iowa Court of

Appeals reaffirmed the settled, common-law rule that "'a plaintiff in a products liability case must prove that the injury-causing product was a product manufactured or supplied by the defendant.'" (Quoting Mulcahy v. Eli Lilly & Co., 386 N.W.2d 67, 76 (Iowa 1986).) Furthermore, much like decisions of this Court in the past, see, e.g., Pfizer, Inc. v. Farsian, 682 So. 2d 405 (Ala. 1996), the Huck court explained that plaintiffs who allege physical injuries caused by a product have, "regardless of the theory of liability" asserted, a products-liability claim that requires "product identification," a requirement that cannot be circumvented by pleading claims of "strict liability, negligence, misrepresentation, breach of warranties," and the like. See also note 31, supra.

Shortly before the release of the opinion in this case on rehearing, the Iowa Supreme Court vacated the decision of the Iowa Court of Appeals. It did so, however, in an opinion specifically rejecting this Court's opinion on original submission in the present case and agreeing with the Iowa Court of Appeals' position on the issue before us: "We adhere to [certain] bedrock principles ..., and join the multitude of

courts that have concluded brand[-name] defendants owe no duty to consumers of generic drugs." Huck v. Wyeth, Inc., [Ms. 12-0596, July 11, 2014] ___ N.W.2d ___, ___ (Iowa 2014) (also declining, in its words, "to step onto the slippery slope" that could lead to brand-name-manufacturer liability for harm caused by copies of other types of products manufactured by competitors).

Three of the federal courts of appeals that have addressed the issue since our opinion on original submission specifically acknowledge our decision. All three of them, the United States Courts of Appeals for the Sixth, Tenth, and Eleventh Circuits, rejected our reasoning. See Strayhorn v. Wyeth Pharm., Inc., 737 F.3d 378 (6th Cir. 2013); Schrock v. Wyeth, Inc., 727 F.3d 1273 (10th Cir. 2013); and Guarino v. Wyeth, LLC, 719 F.3d 1245 (llth Cir. 2013).[37] See also Metz v. Wyeth, LLC, 525 F. App'x 893 (11th Cir. 2013) (not

[37]In each of these three cases, the federal Court of Appeals refers to this Court's decision on original submission as being one of only two or three that have held as it did. See, e.g., Guarino, 719 F.3d at 1253, citing in juxtaposition to the "mountain" of cases to the contrary, this court's decision and the decisions of the Vermont district court in Kellogg v. Wyeth, 762 F. Supp. 2d 694, 708–09 (D. Vt. 2010), and the California district court in Conte v. Wyeth, Inc., 168 Cal. App. 4th 89, 85 Cal. Rptr. 3d 299, 310 (2008).

published in F.3d). Two of those circuits, the Tenth Circuit and the Eleventh Circuit, have now weighed in for the first time.

Specifically, in Schrock v. Wyeth, the Court of Appeals for the Tenth Circuit joined all the other federal courts of appeals that have addressed the issue by declining to "impose a duty on drug manufacturers to warn of dangers in their competitors' products" because the brand-name defendants "d[id] not have any relationship with the [plaintiffs]." 727 F.3d at 1283. And in Guarino v. Wyeth, LLC, the Eleventh Circuit explained in no uncertain terms that there simply can be "no liability when we know with certitude that a given manufacturer did not produce the allegedly dangerous product." 719 F.3d at 1251.

This Court continues to stand alone as the only appellate court in the country to hold that a brand-name manufacturer may be responsible for injuries caused to a party who ingests a generic drug that the brand-name manufacturer did not manufacture or sell. According to Wyeth, over 90 cases (a figure that includes trial courts) have now been decided in 25 states, including every state that borders Alabama, the

federal circuit court that encompasses Alabama, and all six federal courts of appeals to have considered the issue. With the exception of two or three federal district court decisions already identified, all of them disagree with the position taken by this Court.

If the cases that decide the issue differently than we do were not logical and well reasoned, if they were not based on time-tested, bedrock legal principles, or if they did not resolve all the alleged distinctions between prescription-drug cases and other types of cases that have been raised in the main opinion and in the special concurrence, then perhaps their sheer number would not matter. But they are all these things.

The Eleventh Circuit Court of Appeals has put it this way:

> "Our conclusion is fortified by the fact that the overwhelming national consensus -- including the decisions of every court of appeal and the vast majority of district courts around the country to consider the question -- is that a brand-name manufacturer cannot be liable for injuries caused by the ingestion of the generic form of a product. See, e.g., Bell v. Pfizer, Inc., 716 F.3d 1087, No. 12-1674 ... (8th Cir. June 14, 2013) (rejecting negligence, misrepresentation, and fraud claims against the brand manufacturer of metoclopramide, and explaining that '[a]n overwhelming majority of

courts considering this issue ... have rejected [plaintiff's] theory of liability' (internal quotation marks omitted)); Demahy v. Schwarz Pharma, Inc., 702 F.3d 177, 182–83 (5th Cir. 2012) (per curiam), petition for cert. filed, 81 U.S.L.W. 3519 (U.S. Mar. 7, 2013) (No. 12–1093); Smith [v. Wyeth, Inc.], 657 F.3d [420] at 423–24 [(6th Cir. 2011)] ('The plaintiffs' argument -- that the name-brand defendants' liability stems from the fact that the regulatory structure governing name-brand and generic drugs makes it foreseeable that patients and their physicians will rely on the name-brand labels to use and prescribe generic drugs -- has been rejected by all but one of the courts that have considered it.'); Mensing [v. Wyeth, Inc.], 658 F.3d [862] at 867 [(8th Cir. 2011)] (expressly reinstating the portion of the opinion holding that brand-name manufacturers cannot be held liable under Minnesota law for damage caused by generic drugs); Foster v. Am. Home Prods. Corp., 29 F.3d 165, 170–71 (4th Cir. 1994); Gardley–Starks v. Pfizer, Inc., 917 F. Supp. 2d 597 ... (N.D. Miss. Jan. 10, 2013) ('The Court concludes that Mississippi law, consistent with the vast majority of courts to consider this issue, would not recognize a cause of action -- however styled -- against a brand manufacturer for injuries caused by use of its competitors' generic product.'); see also id. at ... n. 4 (noting the defendants' citation to 'sixty-six decisions applying the law of twenty-three different jurisdictions holding that brand-name manufacturers of a drug may not be held liable under any theory for injuries caused by the use of a generic manufacturer's product'). But see Kellogg v. Wyeth, 762 F. Supp. 2d 694, 708–09 (D. Vt. 2010); Wyeth, Inc. v. Weeks, ... No. 1101397 ... (Ala. Jan. 11, 2013), reh'g granted (June 13, 2013); Conte v. Wyeth, Inc., 168 Cal. App. 4th 89, 85 Cal. Rptr. 3d 299, 310 (2008). Although only the law of Florida controls the outcome here, the cases denying recovery to plaintiffs bringing claims identical to those we confront in this case are legion, and this

> mountain of authority steels us in our determination that Florida law does not recognize a claim against the brand manufacturer of a prescription drug when the plaintiff is known to have consumed only the generic form."

Guarino, 719 F.3d at 1252-53 (emphasis added).

The bedrock principles of tort law in this State are no different than the bedrock principles of tort law in every other state in this country, including the two dozen states whose laws have been considered in what the Eleventh Circuit call an "overwhelming national consensus." There is no reason for this State not to be part of that consensus.[38]

---

[38]The special concurrence characterizes the main opinion as simply applying "established Alabama decisions," "established Alabama tort law" and "existing law," concluding that the main opinion therefore "epitomizes ... judicial restraint." ___ So. 3d at ___ (Shaw, J., concurring specially). For the reasons explained in this writing, however, existing Alabama precedents do not support the holding of this Court today. To the contrary, the decision of this Court today essentially stands alone against Alabama cases recognizing and applying the fundamental principles of relationship and duty discussed at length herein and against an unprecedented number (approaching 100 cases) from other jurisdictions applying the same fundamental principles specifically to the prescription-drug industry. As the Eleventh Circuit puts it, these latter cases do indeed constitute a "mountain of authority" representing an "overwhelming national consensus" to the contrary of the conclusion reached by this Court today.

As for the persistent suggestion that this "mountain of authority" somehow addresses some issue or issues different

III.

One of the many amici curiae briefs supporting Wyeth asserts, with supporting authority:

> "Developing a prescription drug and taking it to market is a monumental undertaking. On average, it requires more than seven years and almost $2 billion to develop a single drug, obtain FDA approval for it, and bring it to market. 'Name brand manufacturers undertake the expense of developing pioneer drugs, performing the studies necessary to obtain premarketing approval, and formulating labeling information.' Foster [v. American Home Products Corp.], 29 F.3d [165] at 170 [(4th Cir.

---

than the issue this Court addresses today, I can do little more than once again point the reader to the discussion of and the quotations from so many of the cases that are part of that "mountain," as set out extensively on the several dozen pages that immediately precede this one. As already observed, beginning with Foster, most of this almost endless stream of precedents involves the exact issue addressed here, a claim of "fraud," "suppression," or "misrepresentation" in connection with a generic manufacturer's use of deficient labeling in the "pervasively" regulated prescription-drug industry. And, again, the fundamental legal principles employed in the analysis of this issue in these other cases are as elemental to the law of this State as they are to the law of the states discussed in those decisions.

Finally, although I think it clear enough from the discussion that both precedes and follows this footnote, let me be explicit in stating that any discussion of economic or other practical concerns found herein is not offered out of a perceived need to supplant or to supplement the case authority cited. It is but to further explain the reason and soundness of that authority and, to that end, the ramifications generally and in regard to the prescription-drug industry in particular of an abandonment of the fundamental legal principles that inform that authority.

1994)].

> "Brand-name manufacturers make research and development decisions against a particular legal backdrop. Under traditional tort principles, the brand-name manufacturer knows that it can be held responsible for injuries caused by its products under certain circumstances. See Wyeth v. Levine, 555 U.S. 555 (2009). The brand-name manufacturer also knows, however, that it will not be held liable for injuries caused by products that it neither made nor distributed. See, e.g., Foster, 29 F.3d at 168, 171.
>
> "....
>
> "... [T]he Plaintiffs' novel liability theory would retroactively frustrate legitimate investment-backed expectations. Decisions were made and capital invested decades ago to produce a drug for sale in a legal system that (as is traditional) allows recovery for injuries caused by the brand-name company's own product, but not for injuries caused by the products made by its competitors. The abrupt change that the Plaintiffs seek would wipe away that system and replace it with bet-the-company uncertainty.
>
> "[Looking forward], Plaintiffs' theory would destroy the predictability needed by brand-name manufacturers trying to decide whether to invest almost $2 billion and seven years of time to develop a new drug. ..."

Brief of amici curiae, The Chamber of Commerce of the United States of America and the Business Council of Alabama, at 20-24 (emphasis in original; some citations omitted).

Even proponents of the result urged by the plaintiffs

admit that such a result is unfair to the brand-name manufacturers. See, e.g., Allen Rostron, Prescription for Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers, 60 Duke L.J. 1123, 1181 (Feb. 2011) (admitting that "[u]nder the [approach of the California appeals court in] Conte[39] if a drug lacks adequate warnings, its brand-name manufacturer may wind up being liable for harm to those who took either the brand-name or the generic version of the drug, whereas the generic manufacturers likely will wind up not being liable to anyone. That asymmetry is particularly unfair given that the brand-name manufacturers make substantial investments in developing new drugs from which generic producers profit by copying."); Wesley E. Weeks, Picking Up the Tab for Your Competitors: Innovator Liability After PLIVA, Inc. v. Mensing, 19 Geo. Mason L. Rev. 1257, 1259 (Summer 2012) (conceding that holding brand-name manufacturers liable "is far from ideal. The brand-name manufacturer invests resources to produce helpful pharmaceuticals, and under innovator liability, it would be liable for harm caused by its

[39]Conte v. Wyeth, Inc., 168 Cal. App. 4th 89, 85 Cal. Rptr. 3d 299 (2008).

competitors' drugs. As this reduces the profitability of creating new drugs, it could provide drug developers with a negative incentive, reducing the number of beneficial drugs developed in this country. Meanwhile, generic drug manufacturers are insulated from failure-to-warn lawsuits by the preemption recognized in [PLIVA].").

Another concern is insurability:

> "[G]iven the near impossibility of formulating bulletproof labeling, insurability represents a concern: cost spreading would further burden the shrinking share of customers for the brand-name drug (or else later patients taking unrelated drugs produced by that defendant) for the benefit of customers of the competitor's drug (who are already free riding on the original research and development efforts of the brand-name manufacturer). This threatens to chill therapeutic product innovation ...."

Lars Noah, Adding Insult to Injury: Paying for Harms Caused by a Competitor's Copycat Product, 45 Tort Trial & Ins. Prac. L.J. 673, 695 n.69 (2010).

All of these concerns are elevated by the realization that there will be no correlation between the brand-name manufacturer's continued participation in the marketplace with its own drug and its responsibility for generic drugs manufactured and sold by others. Under the rationale urged by

the plaintiffs, and accepted by the majority of the Court today, a brand-name manufacturer's complete departure from the marketplace would offer no logical reason for terminating its responsibility for the deficiencies in the labeling associated with generic versions of its drugs that may be marketed indefinitely thereafter by its former competitors and perhaps even new entrants into the market.[40] At least one commentator has noted that this is a distinct possibility. See Noah, 45 Tort Trial & Ins. Prac. L.J. at 691-92 (noting as an example Hoffmann-La Roche's recent decision to withdraw its much litigated drug Accutane from the market and observing that, "[a]s a regulatory matter, so long as FDA does not withdraw the innovator's NDA [new drug approval] on safety or effectiveness grounds, existing (and the possibility for future) ANDAs [abbreviated new drug approvals] would remain unaffected").

Finally, and most troubling, I see no principled barrier to the extension of the "foreseeability" doctrine to deficient

[40]In fact, one of the defendants in the case before us today, Wyeth, Inc., ceased manufacturing Reglan or making any representations concerning it in about 2002; it sold its right to produce the drug to codefendant Schwarz Pharma, Inc.

representations or design defects made by developers of other types of popular products copied by competitors. See, e.g., Huck v. Wyeth, supra. The line drawn today between the prescription-drug industry and all other industry exists only because we say it does; it will continue to exist only for so long as we say it does. There may be differences in the degree of foreseeability, but if foreseeability without relationship is to be the test, the line between the prescription-drug industry and other industry is arbitrary, and there is no principle to which this or other courts may anchor themselves in an effort to hold that line.[41]

---

[41]Even the United States District Court for the Middle District of Alabama, in its order certifying to us the question at hand, agrees:

> "[T]he question's significance extends well beyond the Reglan litigation -- and for that matter, even beyond pharmaceutical litigation. It is likely to recur any time a brand-name manufacturer (of any product) is sued on fraud, misrepresentation, and/or suppression theories by a plaintiff who claims to have been injured while using a generic-equivalent product."

See also Alissa J. Strong, "But He Told Me It was Safe!": The Expanding Tort of Negligent Representation, 40 U. Mem. L. Rev. 105, 142 (Fall 2009) (explaining that it is "not unreasonable to assume" that the Conte decision could be applied outside the drug context).

Again, however, even if somehow this Court could guarantee that the "foreseeability" analysis embraced today never finds its way into cases involving other products or endeavors, either in this jurisdiction or in others, the potential deleterious effect on the prescription-drug industry and those that depend upon it provide more than enough concern. In a 1977 case in which a federal court in New York explained that the fact that it was foreseeable that a statement might be relayed to and relied upon by a party with whom the maker had no relationship was not sufficient to create a duty to that party. In so doing, the court heeded the concerns of none other than Professor Prosser:

> "[W]here misstatements are claimed to be the cause of loss, even a 'reasonable anticipation that the statement will be communicated to others whose identity is unknown to the defendant, or even knowledge that the recipient intends to make some commercial use of it in dealing with unspecified third parties, is not sufficient to create a duty of care towards them.' W. Prosser, Law of Torts, 708 (4th ed. 1971). The reason for such a rule is obvious. To quote Prosser again, it is required in order to avoid '[t]he spectre of unlimited liability, with claims devastating in number and amount crushing the defendant because of a momentary lapse from proper care. ...' Id."

Demuth Dev. Corp. v. Merck & Co., 432 F. Supp. 990, 993-94 (E.D.N.Y. 1977). We too should heed Professor Prosser's

concerns.

The investment and innovation that over the past 50 years have resulted in the fastest pace of medical advances in human history have depended upon the incentives made available by America's free-market system. As they have for all types of products, the free-market system and the legal framework in which it has operated have coupled the risks and rewards of developing and distributing new medicines and, in so doing, have allowed entrepreneurs and innovators to assume both in corresponding measure. We now disrupt this critical dynamic.