REL:01/11/2013

SUPREME COURT OF ALABAMA

OCTOBER TERM, 2012-2013

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)

BOLIN, Justice.

The United States District Court for the Middle District

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[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."

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.
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> "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. The Weekses' complaint alleges that three brand-name manufacturers, Wyeth, Pfizer, Inc., and Schwarz Pharma, Inc. (hereinafter collectively referred to as "the Wyeth defendants"), 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.[2] The Weekses contend that the Wyeth defendants had a duty to warn Danny's physician about the risks associated with the long-term use of metoclopramide and that the Weekses, as third parties, have a right to enforce 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

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

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, "product-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.

We note that Alabama's Pharmacy Act 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, ___ U.S. ____, ____, 131 S.Ct. 2567, 2583 (2011)(Sotomayor, J., dissenting). That a pharmacy acted under § 34-23-8 and gave Danny a generic drug does not preclude his ability to assert a fraudulent-misrepresentation claim against the brand-name manufacturer. Additionally, many insurance plans are structured to promote the use of generic drugs. PLIVA, ___ 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 ("FDA"). "Congress had 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.[3]

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[3]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 §

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 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 of 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

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312.95

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 a NDA,[4] which allows the 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.

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[4]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 rather 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 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).

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. § 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], 550-571 (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, ___ 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, 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:

> "[b]rochures, 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, ___ 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, ___ 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-drug 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, ___ 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." ___ 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 maker's labeling to be the same as the brand-name drug maker's labeling because the brand-name drug is the basis for approval of the generic drug by the FDA. ___ 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 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. ___ 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-drug 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)."

___ U.S. at ___, 131 S.Ct. at 2574. The Supreme Court held that because the FDA prevented the generic-drug 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." ___ 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]
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> "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.
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> "[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."

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

As noted in the facts set out in the request for a 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, 719 F. Supp. 2d 1340 (S.D. Ala. 2010), the plaintiffs did not ingest Reglan but took a generic equivalent manufactured by another company. 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 their 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 the Wyeth defendants owed them a duty. Instead, they are arguing that the Wyeth defendants owed a duty to Danny Weeks's physician and that, under the learned-intermediary doctrine, they are entitled to rely on the representations made to their 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-drug 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 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 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 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 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-drug manufacturer responsible for damage caused by a generic brand of their 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, 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 warn users of the generic version of the prescription drug of the dangers associated with the drug.[5] 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

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[5]See, e.g., Baymiller v. Ranbaxy Pharm., Inc., [No. 3:11-cv-858-RCJ-VPC, September 6, 2012] ____ F. Supp. 2d ____ (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); 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 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, 32 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 negligence of or intentional misrepresentation by the brand-named 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 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. 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 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 or 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 the 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 the Wyeth defendants 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 obtained payment from the patient's insurer for services that were never rendered. The patient went 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.

The Wyeth defendants argue 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.

The Wyeth defendants also argue 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 life 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, 751 P.2d 740, 749 (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 the same as the label placed 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 the Wyeth defendants 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 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. 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.

Conclusion

We answer the 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. Unlike other consumer products, prescription drugs 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 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 provide that a generic-drug

manufacturer's labeling for a prescription drug must be exactly the same as the brand-name-drug manufacturer's labeling. The Supreme Court in PLIVA held that it would have been impossible for the generic-drug 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-drug 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 by the generic manufacturer.

QUESTION ANSWERED.

Malone, C.J., and Woodall, Stuart, Parker, Shaw, Main, and Wise, JJ., concur.

Murdock, J., dissents (writing to follow).