No. 1101397

SUPREME COURT OF ALABAMA

WYETH, INC., et al.,

Defendant-Appellants,

v.

DANNY WEEKS AND VICKI WEEKS,

Plaintiffs-Appellees.

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND THE BUSINESS COUNCIL OF ALABAMA AS AMICI CURIAE IN SUPPORT OF APPELLANTS WYETH LLC, PFIZER INC., AND SCHWARZ PHARMA, INC.

CERTIFIED QUESTION FROM THE UNITED STATES DISTRICT COURT OF THE MIDDLE DISTRICT OF ALABAMA, SOUTHERN DIVISION
CASE NO.1:10-CV-00602-MEF-TFM

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INTEREST OF *AMICI CURIAE*

The Chamber of Commerce of the United States of America (the Chamber) is the world's largest business federation. The Chamber represents 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files amicus curiae briefs in -- or itself initiates -- cases that raise issues of vital concern to the Nation's business community.

The Business Council of Alabama (the BCA) is a non-profit association comprising approximately 5,000 member companies that conduct business in Alabama. The BCA's business members are both large and small and include grocers, dry cleaners, plumbers, hardware stores, furniture stores, appliance stores, utilities, banks, and insurers. The BCA's members employ thousands of Alabama citizens in all 67 counties and are vitally interested in court decisions affecting the economic stability of business in

Alabama. The BCA frequently appears in litigation as amicus curiae where the issues raised are of widespread importance and concern to its respective members.

The Chamber and the BCA have a particular interest in this case because, if adopted, Plaintiffs' so-called "innovator-liability" theory would (1) represent a sweeping judicial expansion of existing tort doctrine, (2) put Alabama in stark conflict with scores of other States to address the same issue, and (3) undermine the predictability, consistency, and stability that are essential to sustain and support American economic enterprise.

INTRODUCTION

From the beginning, "[t]he spirit of enterprise, which characterizes the commercial part of America," has animated all Americans – and Alabamians – to work hard to produce innovative goods and services, not only to benefit themselves, but also to benefit their children, their communities, and the nation as a whole. The Federalist No. 7, at 63 (Alexander Hamilton) (Clinton Rossiter ed. 1961). An enterprising spirit alone, however, is not enough. The

law must protect the fruits of enterprise and create a climate in which free trade and business innovation can flourish.

When basic principles of law are contorted and twisted, business, and the economy more generally, suffers. Nowhere is that more true than in Alabama. There was a time, not long ago, that Alabama was lampooned nationwide as a "tort hell." See, e.g., Gregory Jaynes, Where the Torts Blossom: While Washington Debates Rules About Litigation, Down in Alabama, the Lawsuits Grow Thick and Wild, TIME, Mar. 20, 1995, at 38. And with good reason. See, e.g., BMW of North America, Inc. v. Gore, 646 So. 2d 619 (Ala. 1994) (affirming conditionally $2 million punitive award for defective paint on automobile), rev'd, 517 U.S. 559 (1996); Henderson v. Alabama Power Co., 627 So. 2d 878 (Ala. 1993) (striking down statutory cap on punitive damages as violating state constitution's right to trial by jury); Ex parte Voyager Guaranty Ins. Co., 669 So. 2d 198 (Ala. Civ. App. 1995) (allowing ex parte class certification); Hickox v. Stover, 551 So. 2d 259 (Ala. 1989) (adopting justifiable reliance standard under which plaintiffs could contradict written terms of contract with allegations of oral

misrepresentations); Donald v. City Nat'l Bank, 329 So. 2d 92, 96 (Ala. 1976) (applying "scintilla" rule to reverse, in part, summary judgment).

Facing what seemed to be, at best, a lukewarm commitment to certain basic principles of law, businesses fled Alabama and the State's economy faltered. See generally Kelly Greene, Tort Reform in Alabama May Finally Get a Hearing, Wall St. J., March 18, 1998, at S2; Linda Himelstein, Jackpots from Alabama Juries, BUS. WK., Nov. 28, 1994, at 83; Jerry Underwood, Big-Money Verdicts Scare State Farm[,] Bypasses State for New Site, Birmingham News, Dec. 6, 1995, at 6D.

In recent years, this Court and the Alabama Legislature have moved to renew respect for these basic principles of law. See, e.g., Wal-Mart Stores, Inc. v. Goodman, 789 So. 2d 166, 170 (Ala. 2000) (remitting punitive award to three times compensatory damages); Ex parte Apicella, 809 So. 2d 865, 874 (Ala. 2001) (overruling Henderson and upholding statutory caps on punitive damages); Ex parte Citicorp Acceptance, Inc., 715 So. 2d 199 (Ala. 1997) (eliminating ex parte class certifications); Foremost Ins. Co. v. Parham, 693 So. 2d 409 (Ala. 1997) (overruling Hickox and

adopting reasonable reliance standard for fraud cases); Ala. Code § 12-21-12 (2006) (replacing "scintilla" rule with substantial evidence requirement effective June 11, 1987).

Recognizing the progress of this Court and the Legislature in re-establishing core principles of law in this State, business has been coming back to Alabama. Automobile manufacturers Mercedes Benz, Honda, Hyundai, and Toyota have spent hundreds of millions of dollars to locate plants around the State[1]; steelmaker ThyssenKrup has spent billions on a mill outside Mobile[2]; and biotech companies

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[1] See Mercedes Expanding Alabama Plant, Al.com, http://www.al.com/newsflash/index.ssf/story/mercedes-expanding-alabama-plant/fe0be91913c349808c4b7608e4c67b75 (noting a total of $2.4 billion investment in Tuscaloosa plant); Donald W. Nauss, Honda to Build Light-Truck Plant in Alabama, Los Angeles Times, May 07, 1999, http://articles.latimes.com/1999/may/07/business/fi-34763 (discussing $400 million plant that is located in Lincoln, Alabama); Andy Ellis, The impact of the $1 Billion Hyundai Plant in Alabama is Already Being Felt in the Montgomery Area and Throughout the State, Partners Magazine (Spring 2004), http://www.edpa.org/docs/partners-magazine/sp04art1.pdf; Toyota Manufacturing of Alabama, http://www.toyota.com/about/our_business/engineering_and_manufacturing/tmmal/ (listing investment of over $400 million and employment of over 700 at Huntsville plant).

[2] ThyssenKrup Steel USA, ("In 2007, ThyssenKrupp invested nearly $5 billion to create a steel company in Calvert, Alabama . . . ."), http://www.thyssenkrupp steelusa.com/en/career.

Biocryst and Agenta have chosen Birmingham in which to develop drugs to treat influenza, cancer, and burns.[3] The societal benefits, of course, are clear: more jobs, increased community investment, and a broader and deeper tax base.

The upshot is that businesses, in order "to structure their primary conduct," absolutely depend on "predictability" and consistency in the law. World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 297 (1980) (internal quotation marks and citation omitted); see also, e.g., Penn Cent. Transp. Co. v. New York City, 438 U.S. 104, 124 (1978) (emphasizing consideration of investment-backed expectations in regulatory takings analysis). They need to know that they will be held responsible when they are truly at fault, but that they will not be subjected to liability based on post-hoc applications of newfangled tort theories.

In this case, Danny and Vicki Weeks (Plaintiffs) assert a novel "innovator-liability" theory that would hold a

[3] See Biocryst, A Pipeline of Next Generation Therpouetics, http://www.biocryst.com; Agenta Biotechnologies, Manipulating Proteoglycans for Therapeutic Use, http://www.agentabio.com/overview.html.

brand-name drug manufacturer liable for injuries caused by a generic drug that it did not make or sell. This theory has been rejected by nearly every court to consider it and is contradicted by settled Alabama law. The Plaintiffs' theory thus threatens the predictability, consistency, and stability of traditional tort law's principle of holding manufacturers responsible only for their own products (not their competitors' products) and would upset investment-backed expectations founded on that principle.

SUMMARY OF THE ARGUMENT

The Plaintiffs' theory that a manufacturer is liable for harm caused by its competitor's product should fail for two reasons. First, Alabama law does not allow a plaintiff to plead a products liability claim, which fails for want of proof that the defendant manufactured the product, as a negligence or fraud claim, nor does Alabama law impose a duty of care or disclosure on a defendant absent a relationship with the plaintiff. See Pfizer, Inc. v. Farsian, 682 So. 2d 405, 407-08 (Ala. 1996); DiBiasi v. Joe Wheeler Elec. Mbrshp. Corp., 988 So. 2d 454, 461 (Ala. 2008).

Second, adopting the Plaintiffs' innovator-liability theory, in the face of existing Alabama law, would frustrate legitimate investment-backed expectations, chill investment in new medicines, and make developing a brand-name drug a bet-the-company proposition.

ARGUMENT

This case arises in the prescription-drug context, which, of course, is intensively regulated by federal law. See, e.g., 21 U.S.C. § 301 et seq.; 21 CFR §§ 314.94(a)(8), 314.127(a)(7). Within that context, this case presents a question of state law: Whether a brand-name drug manufacturer can be held liable to a plaintiff who alleges injury caused by his ingestion of a drug product made and sold by a different company. The Plaintiffs' "innovator-liability" theory answers the question, "Yes." This theory and this result lie far outside the mainstream of Alabama (and American) tort law, and would severely undermine the predictability and stability of the commercial landscape.

Up to this point, courts around the country have very nearly unanimously rejected plaintiffs' attempts to hold one drug company liable for an injury caused by a product

manufactured by another company. The leading case is Foster v. American Home Products Corp., 29 F.3d 165 (4th Cir. 1994). The Fourth Circuit relied on two principal grounds in rejecting innovator liability. First, it held that when a plaintiff complains about a physical injury allegedly caused by a pharmaceutical product, he cannot plead his claim in fraud terms in "an effort to recover for injuries caused by a product without meeting the requirements the law imposes in products liability actions." Foster, 29 F.3d at 168. Second, the court held that because "[t]here is no . . . relationship between" a drug company and a plaintiff who "was injured by a product that [that company] did not manufacture," imposing a duty on the non-manufacturing company "would . . . stretch the concept of foreseeability too far." Id. at 171.

In the years since Foster was decided, some 60 cases in 22 States have followed its holding and rejected the innovator-liability theory. See Brand-Name Defendants' Br. pp. 19-23. Lower courts applying Alabama law have agreed. See, e.g., Overton v. Wyeth, Inc., No. CA 10–0491–KD–C, 2011 WL 1343392 (S.D. Ala. Mar. 15, 2011), report and recommendation adopted by 2011 WL 1343391 (S.D. Ala. Apr.

7, 2011); Simpson v. Wyeth, Inc., No. 7:10-CV-01771-HGD, 2010 WL 5485812 (N.D. Ala. Dec. 9, 2010), report and recommendation adopted by 2011 WL 10607 (N.D. Ala. Jan. 4, 2011); Mosely v. Wyeth, Inc., 719 F. Supp. 2d 1340 (S.D. Ala. 2010); Buchanan v. Wyeth Pharm., Inc., No. CV-2007-900065, Order (Ala. Cir. Ct. Oct. 20, 2008); Green v. Wyeth Pharm., Inc., No. CV-06-3917 ER, 2007 WL 6428717 (Ala. Cir. Ct. May 14, 2007).

Only two courts have reached the opposite conclusion -- first a California state court in Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299 (Cal. App. 1st Dist. 2008), and then a Vermont federal district court in Kellogg v. Wyeth, 762 F. Supp. 2d 694, 699 (D. Vt. 2010).

The Chamber and the BCA offer two arguments for this Court's consideration in whether to adopt the mainstream American view or the Conte-Kellogg view. First, established Alabama tort law contradicts the reasoning underlying the Conte and Kellogg decisions. Second, the abrupt changes necessary to accommodate the Plaintiffs' theory would destabilize settled law and upset existing investment-backed expectations.

I. The Reasoning Underlying the Conte and Kellogg Decisions Is Fundamentally Incompatible With Settled Alabama Law.

A. Conte and Kellogg Contradict Settled Alabama Law, Which Has Long Held That If A Plaintiff Seeks To Recover For Physical Injury Caused By A Product, He Has Alleged, And Must Prove, A Products Liability Claim.

In Conte, 85 Cal. Rptr. 3d at 309-10, the California Court of Appeals rejected scores of decisions around the country by holding that a plaintiff claiming physical injury caused by a drug product can avoid having to prove that the defendant manufactured the product -- a necessary element of a products liability claim -- simply by recasting his cause of action as a negligent or fraudulent failure-to-warn claim. In Kellogg, 762 F. Supp. 2d at 704, the district court in Vermont held the same. In short, these plaintiffs were allowed to label their way around their inability to prove that the name-brand defendants manufactured the drug that allegedly caused their injuries.

Alabama law does not permit that sort of circumvention. This Court has long held that when a plaintiff claims an injury caused by a manufactured product and that claim fails for want of proof of a necessary element, the plaintiff cannot, as a means of keeping the claim alive,

recast the alleged wrong as negligence or fraud. In Pfizer, Inc. v. Farsian, 682 So. 2d 405 (Ala. 1986), a plaintiff who couldn't prove that his artificial heart valve had actually failed tried suing the device manufacturer for fraud. This Court refused to allow the end-run: "Regardless of how Farsian pleads his claim, his claim is in substance a product liability/personal-injury claim -- Farsian seeks damages because of the risk that his heart valve may one day fail. . . . [P]laintiffs 'cannot avoid the physical harm requirement by recasting their product liability claims as fraud claims.'" Id. at 407-08 (Ala. 1996) (quoting Walus v. Pfizer, Inc., 812 F. Supp. 41, 45 (D.N.J. 1993)).

Here, the Plaintiffs cannot show that the brand-name manufacturers' product was "expected to and d[id] reach the user or consumer." Sears, Roebuck & Co. v. Haven Hills Farm, Inc., 395 So. 2d 991, 994 (Ala. 1981). To the contrary, Plaintiffs have expressly conceded that Mr. Weeks didn't use the brand-name manufacturers' drug. Under Farsian, the Plaintiffs cannot paper over that gap in their case simply by re-pleading their claims in fraud or negligence terms.

The Plaintiffs' invocation of the Conte court's reasoning -- i.e., so long as the plaintiff pleads only negligence or fraud, he need not bother with product-liability requirements -- contradicts Alabama law and common sense by elevating stylistic form over legal substance. As a judge posited at oral argument of a case in which the Sixth Circuit ultimately rejected the innovator-liability theory: "The normal product liability [cause of action] requires you to have bought the product. Why wouldn't whenever you have that problem you don't bring a product liability action [and] now it's a misrepresentation claim? It just end runs decades and decades of law." Tr. of Oral Argument at 15, Smith v. Wyeth, Inc., 657 F.3d 420 (6th Cir. 2011) (argued July 28, 2010) (holding brand-name company not liable for harm allegedly caused by drug it did not manufacture).

As this Court has recognized: "If it looks like a duck, walks like a duck, and quacks like a duck, it must be a duck." Raley v. Main, 987 So. 2d 569, 579 (Ala. 2007) (internal quotation marks and citations omitted). Although Plaintiffs label their claims "negligence" and "fraud," the

claims are in substance products liability claims -- claims for alleged injuries arising from a manufactured product.

B. Conte and Kellogg Contradict Settled Alabama Law, Which Does Not Recognize A "Duty" Running From The Manufacturer Of One Product To The User Of Another Product Made By A Different Company.

In Conte, 85 Cal Rptr. 3d at 310-13, the court also concluded that, despite the absence of any relationship between them, brand-name drug manufacturers have a legal duty to consumers of generic drug products. In so holding, the Conte court relied almost exclusively on its view that it is in some sense "foreseeable" to a brand-name manufacturer that, on the basis of its statements about its product, a consumer might ultimately ingest and be injured by a generic drug. See Conte, 85 Cal. Rptr. 3d at 311-13. The court in Kellogg, 762 F. Supp. 2d at 708-09, did the same.

Imposing a duty to warn on a manufacturer that did not make the product that allegedly injured the Plaintiffs would require a radical departure from settled Alabama law. That is so for two reasons.

First, Alabama looks to a number of factors -- not just foreseeability -- to determine whether a duty exists,

including the nature of the defendant's activity, the relationship between the parties, and the type of injury or harm threatened. See DiBiasi v. Joe Wheeler Elec. Mbrshp. Corp., 988 So. 2d 454, 461 (Ala. 2008 (citing Morgan v. South Cent. Bell Tel. Co., 466 So. 2d 107, 114 (Ala. 1985). In DiBiasi, 988 So. 2d at 461, the plaintiff argued that one utility, "Joe Wheeler," should have a duty to a customer of a second utility, "Hartselle," because Joe Wheeler owned the pole on which Hartselle's transmission line was hanging and knew or should have known that Hartselle's line was hanging too low. The plaintiff's decedent died when he touched that energized transmission line. See id. The electricity in Hartselle's transmission line was identical to the electricity sold by Joe Wheeler.

This Court reasoned that the nature of Joe Wheeler's activity was to allow Hartselle to hang on its pole a line delivering electricity. See id. at 463. This Court held that "[a]side from the fact that that transmission line was attached to a pole owned by Joe Wheeler, there is no apparent relationship between [the decedent] and Joe Wheeler." Id. at 464. While electricity in general can be dangerous, this Court concluded that Joe Wheeler's

providing a pole to hang a transmission line on was not an egregious harm. See id. This Court then held: "Even assuming that [the decedent's] injuries were foreseeable, we conclude that none of the other Morgan factors support the existence of a legal duty [owed by Joe Wheeler] sufficient to support an action for negligence. Therefore, based on our review and application of the Morgan factors, we hold that Joe Wheeler did not owe a duty of care to [the decedent]." Id. at 464 (internal quotation marks and citation omitted).

The nature of the activity in this case is that the brand-name manufacturers developed a formula and a label (like the utility pole) that other manufacturers later decided, on their own, to use. As in DiBiasi, there is no relationship between the brand-name manufacturers and the Mr. Weeks, who consumed a drug made by other companies. And as to the type of injury, the brand-name manufacturer did not provide the drug that caused the alleged harm to the Plaintiffs here. Accordingly, "[e]ven assuming that [the Plaintiffs'] injuries were foreseeable, [this Court should] conclude that none of the other Morgan factors support the existence of a legal duty [owed by the brand-

name manufacturers] sufficient to support an action for negligence." DiBiasi, 988 So. 2d at 464 (internal quotation marks and citation omitted). There is no duty.

Second, this Court has held that for a duty to extend to a third party, there must be a "relationship" between the defendant and the third-party plaintiff (i.e., the third-party plaintiff must have used the defendant's product). For example, in Thompson-Hayward Chem. Co. v. Childress, 169 So. 2d 305 (Ala. 1964), a farmer, whose cattle were killed by a herbicide, sued a manufacturer and a seller of a similar herbicide, but could not prove that the defendants manufactured or sold the specific herbicide that killed the cattle. This Court looked to the "relationship of the parties" -- the manufacturer and seller and the cattle farmer. Id. at 312. Because of the lack of proof that the manufacturer or the seller made or sold the specific herbicide that killed the farmer's herd, there was no relationship and no duty. Id. And in DiBiasi, 988 So. 2d at 464, the decedent did not use Joe Wheeler's utility pole, but the transmission line owned by Hartselle. There was no relationship and no duty.

Likewise, there is no relationship between the brand-name manufacturers and the Plaintiff who consumed a drug manufactured by different companies. The Plaintiffs would decouple the party that issued the warning from the party that provided the product. "[T]o impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far." Foster, 29 F.3d at 171.

Moreover, in concluding that a brand-name drug manufacturer owes a duty to warn even those plaintiffs who consume drugs made and distributed by other companies, Conte, 85 Cal. Rptr. 3d at 312-13, relied, in part, on a broad interpretation of sections 310 and 311 of the Restatement (Second) of Torts. Those provisions state that in certain circumstances, a party who makes a misrepresentation can be liable for physical harm that results from an act done in reliance on the misrepresentation if the party "should realize that it is likely to induce action by the other, or a third person" and that liability can extend "to such third persons as the actor should expect to be put in peril by the action taken." Restatement (Second) of Torts §§ 310, 311 (1965).

This Court has never adopted Sections 310 and 311, and they are inapplicable here, in any event. With respect to private property for which access is controlled, like a prescription drug, the comments to section 310 assume a product-use relationship, stating: "[O]ne who, by actively concealing a defect, misrepresents the condition of a chattel which he furnishes to another for use is liable . . . [to a third-party user]. His liability is the same irrespective of whether he sells it, leases it, supplies it for a use in which he has a business interest, or permits its use as a mere gratuity." Restatement § 310 cmt. c. (emphases added). By contrast, a brand-name manufacturer does not furnish, sell, lease, supply, or permit the use of a drug it did not make. There is no relationship and thus no duty.

That sections 310 and 311 do not countenance the innovator-liability theory is demonstrated by the fact that a number of States that have adopted sections 310 and/or 311 in other contexts have rejected the innovator-liability theory in the context of a lawsuit by the consumer of one drug against the manufacturer of another. Compare, e.g., Bloskas v. Murray, 646 P.2d 907, 914 (Colo. 1982) (adopting

section 311), with Sheeks v. Am. Home Prods. Corp., No. 02CV337, 2004 WL 4056060, at *2 (Colo. Dist. Ct. Oct. 15, 2004) (rejecting innovator liability and adopting Foster); and Gulf Prod. Co. v. Hoover Oilfield Supply, Inc., 672 F. Supp. 2d 752, 759 (E.D. La. 2009) (relying on section 310), with Stanley v. Wyeth, Inc., 991 So. 2d 31, 34-35 (La. App. 1 Cir. 2008) (rejecting innovator liability and adopting Foster); and Reynolds v. Lancaster Cnty. Prison, 739 A.2d 413, 422 (N.J. Super. Ct. App. Div. 1999) (adopting section 311), with Sloan v. Wyeth, No. MRS-L-1183-04, slip op. at 5 (N.J. Super. Ct. Oct. 13, 2004) (rejecting innovator liability and following Foster). No relationship; no duty.

In sum, Alabama law contradicts the Conte and Kellogg view and squares with the mainstream of American law. In Alabama, there must be a relationship between the manufacturer of a product and a consumer who sues for an injury allegedly caused by a product.

II. Adopting The Plaintiffs' Innovator-Liability Theory, Without Any Precedent In Alabama Law, Would Frustrate Product Manufacturers' Legitimate Investment-Backed Expectations.

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.[4] "Name brand manufacturers undertake the expense of developing pioneer drugs, performing the studies necessary to obtain premarketing approval, and formulating labeling information." Foster, 29 F.3d at 170.

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.

This traditional liability system, which rewards innovation but holds the innovator liable for injuries that its own products cause, has a crucial advantage -- it

[4] See Salomeh Keyhani, et al., Are Development Times For Pharmaceuticals Increasing Or Decreasing?, http://content.healthaffairs.org/content/25/2/461.full; Steven M. Paul, et al., How to Improve R&D Productivity: The Pharmaceutical Industry's Grand Challenge, http://www.nature.com/nrd/journal/v9/n3/full/nrd3078.html.

works. While protecting consumers, the system has enabled great advances in medical science. Just a few examples: New medicines have reduced by 50% the number of fatal heart attacks,[5] increased by 20% the five-year survival rate for women diagnosed with breast cancer,[6] and raised by 40% the five-year survival rate for children diagnosed with cancer.[7]

The Plaintiffs' proposed abrupt change in the settled law would make multi-year, multi-billion dollar investment decisions for developing new drugs next to impossible. Under the Plaintiffs' theory, a brand-name manufacturer could be liable for an untold number of pills sold by its competitors. This would produce a dramatic shift in the risk-return calculus facing investors who can choose

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[5] See, e.g.,Kaiser Family Foundation, How Changes in Medical Technology Affect Health Care Costs (March 2007) ("From 1980-2000, the overall mortality rate from heart attack fell by almost half, from 345.2 to 186.0 per 100,000 persons."),http://www.kff.org/insurance/snapshot/chcm030807oth.cfm.

[6] See Phrma, New Medicines are Transforming Patient Care ("Between 1975 and 2003 (the most recent data available) five year survival went up 19 percent for women with breast cancer (from 75.5 percent to 89.9 percent) . . . ."), http://www.phrma.org/new-medicines-transforming-patient-care.

[7] See id. ("For all childhood cancers combined, the number of children surviving five years after diagnosis has grown from 58 percent in 1975 to 81 percent today due in part to new and improved treatments.").

between investing in the development of a new cancer drug in America or in a toy factory overseas.[8]

The Plaintiffs' theory would also make management of a brand-name manufacturer impracticable by divorcing operational and legal responsibility. A brand-name drug manufacturer would be liable for injuries caused by a competitor's drug even though the brand-name company had no control over who the competing company hired, what management practices it adopted, or its decision to produce and market the drug at all. Imposing unlimited liability in these circumstances would be draconian.

In addition, the 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

[8] See generally S. Kevin, Security Analysis and Portfolio Management 13 (2006).

that system and replace it with bet-the-company uncertainty.

Finally, 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. For example, at the end of the patent period, will competitors be selling similar drugs? If so, might competitors' sales occur in States that have adopted previously unknown theories of tort liability that aim to put manufacturers on the hook for harms caused by other companies' products? And if so, will an insurance company cover losses caused by competitor's products?

If the door to innovator liability is opened, there will be no end to the contingencies and essentially no way for brand-name manufacturers to develop a reliable business plan. The only thing predictable would be the result of all the legal unpredictability: Less investment, less innovation, and fewer new drugs.

CONCLUSION

This Court should adhere to its precedents and the mainstream of American law by holding that a brand-name drug manufacturer owes no duty to a plaintiff allegedly injured by a drug made by a different and unrelated company.

Respectfully submitted this 12th day of December, 2011.

/s/ Ed R. Haden
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I hereby certify that on December 12, 2011 the foregoing was filed with the Clerk of the Court and served on the following by U.S. Mail, first-class postage, pre-paid or electrically upon the following parties and participants:

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Case No. 1101397
Wyeth v. Weeks, et al.

Appendix A

Buchanan v. Wyeth Order

IN THE CIRCUIT COURT OF DALE COUNTY, ALABAMA

RAECHEL BUCHANAN, individually, and TROY BUCHANAN, individually, Plaintiffs, v. WYETH PHARMACEUTICALS, INC.; WYETH INC.; BAXTER HEALTHCARE CORPORATION; SCHWARZ PHARMA, INC.; USMAN A. KHAN, M.D.; et al., Defendants.	Case No. CV-2007-900065

ORDER

This matter is before the Court on the Motion for Summary Judgment filed by Defendants Wyeth (incorrectly sued as "Wyeth Pharmaceuticals, Inc." and "Wyeth, Inc.") and Schwarz Pharma, Inc. ("Schwarz"). After considering the Motion and other relevant pleadings, the Court finds that the motion is due to be granted. The Court finds that there is no genuine issue as to any material fact and that Wyeth and Schwarz are entitled to judgment in their favor as a matter of law.

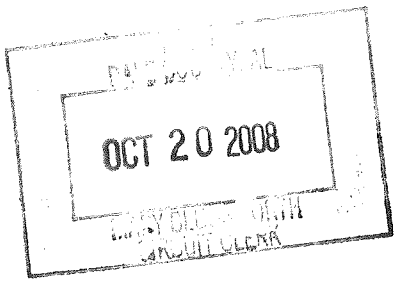
IT IS THEREFORE ORDERED, ADJUDGED AND DECREED as follows:

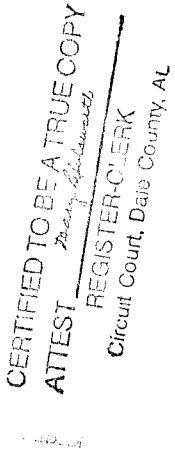
1. Wyeth and Schwarz's Motion for Summary Judgment is hereby GRANTED and judgment is hereby entered in favor of Wyeth and Schwarz pursuant to Rule 56(b) and (c)(3) of the Alabama Rules of Civil Procedure.

2. The Court expressly finds that there is no just reason for delay and accordingly certifies this judgment as final pursuant to Rule 54(b) of the Alabama Rules of Civil Procedure.

ORDERED on this the 20th day of October, 2008.

Circuit Court Judge





Case No. 1101397
Wyeth v. Weeks, et al.

Appendix B

Sloan v. Wyeth

SUPERIOR COURT OF NEW JERSEY

Chambers of
David B. Rand
Judge

Morris County Courthouse
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October 13, 2004

Advokat & Rosenberg
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Morristown, New Jersey 07962-1997

Re: Sloan v. Wyeth, et. als.
Docket No.: MRS-L-1183-04

Dear Counsel:

Preliminary Matters

Wyeth, Inc. ("Wyeth") is the successor in interest to A.H. Robbins Co., Inc., and American Home Products Corporation named in counts IV – VI and IX –XI of the complaint filed by the plaintiffs, Diane and Paul Sloan. Plaintiffs assert that Wyeth was guilty of common law fraud, made negligent representations, committed fraud by concealment and violated the Consumer Fraud Act (N.J.S.A. 56:8-1 et seq.). The defendant Wyeth moves for Summary Judgment.

The action is factually predicated upon the allegation that Wyeth manufactured and distributed the drug metoclopramide under the brand name "Reglan" until December 27, 2001. The plaintiff, purchased and consumed generic versions of Reglan between June 1999 and April 2002.

These "generic" versions of Reglan were manufactured and distributed by co-defendants Pliva, Sidmak and Harvard Drug Group. Plaintiff alleges that the generic versions of the drug caused her to develop tardive dyskinesia, a neurological syndrome.

The gravamen of plaintiff's complaint against Wyeth is predicated upon the assertion that Wyeth is responsible for the injuries caused by the co-defendants' generic drugs because the plaintiff's physicians, who prescribed the drug, relied on information derived from Wyeth which that defendant promulgated in connection with its brand name product Reglan.

It is not disputed, however, that the brand name drug was never actually used by plaintiff. As noted she actually used "generic" versions of the drug, manufactured and distributed by co-defendants. For reasons, which more particularly are set forth below, Summary Judgment will be granted in favor of Wyeth and those claims asserted against it in the complaint will be dismissed.

Discussion

This action presents a case of first impression in New Jersey, ie., whether a brand name drug manufacturer can be held liable for injuries caused by the generic drug manufactured by another company.

Wyeth cites three decisions as persuasive authority in support of its argument to dismiss plaintiffs' claims. Forster v. American Home Products, 29 F.3d 165 (4th Cir. 1994); Block v. Wyeth, Inc., et al, 2003 WL 203067 (N.D. Texas Jan. 28, 2003): and Beutella v. AH Robbins et al., #980502372

slip opinion at 6 (Utah 5th Judicial District, Washington County, Nov. 7, 2001).

In Forster, the United States Court of Appeals for the Fourth Circuit (applying Maryland law) dismissed an action which involved a similar situation to the instant litigation. In that case, the Court of Appeals considered the decision of the lower Court, which held that a manufacturer of a brand name prescription drug could be liable for an alleged negligent misrepresentation relating to a death caused by another company's generically equivalent drug. The Court of Appeals considered whether the trial court was correct dismissing the plaintiffs' claim for failure to show reasonable reliance by the plaintiffs on the representations made by the brand name drug company. Because the Court in Forster held that the brand name manufacturer could not be held liable for a negligent misrepresentation, it did not reach the second issue on appeal. Id. at 167.

In Forster, Wyeth, as successor to American Home Products, was sued arising from its manufacture of a brand name drug known as Phenergan. The drug was prescribed by a physician in syrup form to the plaintiff's infant twins Brandy and Bradley Forster, who were suffering from colic. The infant twins were given a generic version of the drug several times. One of the infants, Brandy, was found deceased in her crib shortly following the last administration of the drug. An autopsy report attributed the child's death to Sudden Infant Death Syndrome (SIDS), however, a pediatrician related to the University of Maryland attributed the

infant's death to the use of the drug Promethazine, the generic version of Phenergan.

The trial court in Forster granted summary judgment in favor of Wyeth on the product's liability counts based upon the assertion that the product actually sold in the Forster case was not manufactured by the defendant. The drug taken by the infants was a generic version of the brand name drug and was manufactured by others. The District Court stated that if plaintiffs were able to establish that the defendant actually made false presentations concerning the safety of the drug itself, ie. the chemical substance which comprises both the generic and brand name drug, then the drug company "...maybe liable for any harm caused..." to plaintiffs or their children as a result of the ingestion of such drugs. Forster, 29 F.3rd at 67.

The trial court in Forster drew a distinction between the negligent misrepresentation claim and the products liability claims. However, on the particular facts of that action, the trial court granted the defendant's motion for Summary Judgment on grounds that the plaintiffs had failed to establish that the physician relied upon the representations made by the brand name drug company in his decision to prescribe the generic drug to the children. Hence, all claims made by the plaintiffs were dismissed. The plaintiff and defendant appealed and cross-appealed.

Subsequently, the Fourth Circuit acknowledged that there presently existed no recognizable Maryland cause of action based upon negligent misrepresentation against one manufacturer for injuries sustained from

the use of another manufacturer's product. Id. at 168. The Court in Forster further stated:

> "We 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." Id. at170.

The Court also noted that Maryland law requires that a plaintiff seeking to recover for injuries by a product must demonstrate that the defendant manufactured the product at issue.See eg., Tidler v. Eli Lily and Co., 851F. 2nd 418 (D.C. Cir. 1988) (applying Maryland law).

Here, the plaintiff seeks to avoid the fatal results dictated by Forster, Block and Beutella, by asserting that there is a distinction to be drawn by the Court, that defendant Wyeth, was a "disseminator" of negligently false and misleading information, rather than a "manufacturer" of a defective product. Plaintiff relies on decisions such as Reynolds v. Lancaster County Prison, 325 N.J. Super. 298 (App. Div. 1999) to demonstrate the generic view that New Jersey has adopted towards the Restatement (Second) of Torts § 311, which permits third parties to assert claims for negligent misrepresentation involving risk of physical harm to third parties.

Reynolds involved a case action in which plaintiff brought an action against the defendant predicated upon the tort of negligent misrepresentation. There, defendant donated an attack dog to the plaintiff's business without disclosing its vicious nature. Subsequent to the donation, the dog caused serious injuries to the plaintiffs in an alleged

unprovoked and vicious attack. The jury awarded substantial damages to the plaintiffs and the defendants appealed. The Appellate Division upheld the jury verdict on various grounds including the applicability of the Restatement (Second) of Torts § 311.

Hence, it is quite clear that presently in New Jersey, in the appropriate circumstance, the tort predicated upon negligent misrepresentation may be viable. It should be noted, however, in Reynolds there was no issue regarding the connection between the cause of plaintiffs' injuries, ie. a vicious dog, and the source or identity of that injury, ie. the receipt of the animal from the defendants.

The ultimate analysis here requires the Court to determine the effect, if any, of the New Jersey Product Liability Act, N.J.S.A. 2A:50C-1 et seq., ("PLA") upon the ability of the plaintiff to recover in this context. Stated succinctly, does the PLA immunize Wyeth from plaintiffs' claims when it admittedly was not the manufacturer of the product that caused plaintiff's injuries?

More particularly, Wyeth relies upon N.J.S.A. 2A:52C-2 and asserts that under this part of the PLA any product liability action must, by necessity, involve "...a claim or action brought by a claimant for harm brought by a product, irrespective of the theory of the claim." The complaint alleges "harm caused by a product" as defined by the PLA. Under the PLA, the defendant asserts "harm includes"

> (a) Physical damage to property, other than the product itself; (b) personal physical injury or death; (c) pain and suffering,

> mental anguish or emotional harm; (d) any loss of consumption of services or other loss deviating from any type of harm described in paragraphs (a) thru (c) of this paragraph. N.J.S.A. 2A:58C-1(b)2.

Hence, Wyeth asserts that for it to be held liable, the cause of action or mechanism of the injury must flow from a product manufactured by Wyeth or a product under its immediate direction or control.

Plaintiffs counter this argument by asserting that the PLA hardly constitutes their exclusive remedy and maintain that causes of action may also arise by virtue of common law principles of fraud, misrepresentation, etc. Alloway v. General Marine Industries, LP, 149 N.J. 620, 639-40 (1997). Alloway, was not a personal injury action but addressed the appropriate theory of liability a plaintiff must pursue in circumstances of economic or non-personal injury. Nevertheless, the plaintiffs seek to apply generalized dictum that appearing in Alloway to the facts and circumstances.

The Court, however, notes that it has generally been held that the PLA is not merely plaintiffs' proper remedy in New Jersey, it is their exclusive remedy. "the PLA, by its terms," made clear 'three causes of action 'ie; manufacturing defects, failure to warn, [and] design defect' are intended to be inclusive, as the sole basis for recovery on a product claim against the manufacturer or seller to the other terms of the statute." See Dryer, Keefe and Katz, "NJ Products Liability and Torts Law" at 16 (Gann 2000 ed.).

As noted by the defendants in Tirrell v. Navistar, Inter., Inc., 248 N.J. Super. 390 (App. Div. 1991), cert. denied, 126 N.J. 390 (1991), the Appellate Division held a litigant's negligence and implied warranty claims are subsumed by the PLA because "...the act established a sole method to prosecute a product liability action." Id. at 398, 399. Other cases posit a similar rule. See Ropela v. Morebark Industries, 934 F.2nd 383 (3rd Cir. 1991); Brown X Well Brown v. Philip Morris Inc., 228 F.Supp. 205 (D.N.J. 2002); Reef v. Convergent Technologies, 957 F.Supp. 573 (D.N.J. 1997).

In this action, plaintiffs seek to bypass the PLA through application of a generic Restatement (Second) of Torts provision (§311). It seeks to expand the liability of brand name manufacturers to damages caused by generic versions of their product. Does a duty even exist upon Wyeth in this action?

Indeed, it is well established that whether a duty exists in a given context is in the first instance for the Court to determine. Carvalho v. Toll Brothers, 143 N.J. 565, 573 (1996) and Wang v. Allstate Insurance, 125 N.J. 2, 15 (1991).

The question of whether a duty exists to exercise reasonable care to avoid harm to another is determined by fairness and policy considerations and may implicates complex factors. See Carvalho, 143 N.J. at 573 and Dunphy v. Gregor, 136 N.J. 99 (1994). Certainly, foreseeability of harm is an important consideration in the determination of the existence of a duty to exercise reasonable care. Carter Lincoln-Mercury Inc. v. Emar Group, Inc., 135 N.J. 182 (1994). As held by the Supreme Court of New Jersey,

once foreseeability of injuries has been established, policy considerations and fairness govern whether the imposition of a duty is warranted. Carter, 135 N.J. at 194-195.

Here, policy considerations must weigh against imposing liability on defendant Wyeth under these circumstances. Certainly, it can hardly be persuasively argued that the PLA was intended to expand the liability of manufacturers, such as defendant, in contexts such as the one presented here. The sole basis for the policy advanced by the plaintiffs at oral argument was that "plaintiffs should have recourse and injured plaintiffs should have the right to recover."

The Court notes that nothing before it allows for any viable argument that either New Jersey or the Federal authorities intended to expand prescription drug manufacturer liability to injuries sustained by consumers of products manufactured by generic drug companies, which use formulations developed by the brand name company. Indeed, there is nothing in the PLA or elsewhere which would suggest such liability will advance the affordably of drugs, one of the main policy foundations for the Hatch-Waxman amendments to the Federal Food Drug and Cosmetic Act.

The Court agrees with Wyeth's assertion that as a practical matter, imposing additional liability upon brand name drug manufacturers would achieve the exact opposite effect sought by the Federal Legislation. Brand name manufacturers would be less likely to develop new products if liability were imposed upon these companies for injuries wrought by products of generic manufacturers.

On the other hand, plaintiffs are hardly without a remedy. Their recourse remains viable against the manufacturers of the generic drug that was in fact prescribed and utilized. Generic manufacturers can hardly claim immunity from liability merely because they relied upon warnings appearing on the defendant's brand name product. (See Forster, 29 F.3d at 169). These entities have the same duty under the PLA as the brand name defendant Wyeth.

For all the foregoing reasons, therefore, Summary Judgment is hereby granted to the defendant Wyeth dismissing all claims against it brought by the plaintiffs.

Very truly yours,

David B. Rand, J.S.C.