No. 1101397

IN THE SUPREME COURT OF ALABAMA

WYETH, INC., ET AL.,

Appellants,

v.

DANNY WEEKS, ET AL.,

Appellees.

Certified Question from the United States District Court for the Middle District of Alabama, Southern Division: Case No. 1:10-cv-602

APPELLANTS' BRIEF IN SUPPORT OF APPLICATION FOR REHEARING

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STATEMENT CONCERNING ORAL ARGUMENT

Appellants Wyeth LLC, Pfizer Inc., and Schwarz Pharma, Inc. (the "brand-name defendants") request oral argument. If ever a case demanded oral argument, this one does.

The majority opinion dramatically expands Alabama tort law by holding that a brand-name drug manufacturer may be liable — seemingly indefinitely — for injuries caused by products that it neither made nor sold. In adopting the novel "innovator liability" theory, the opinion —

- disregards key principles of Alabama law and a number of this Court's controlling precedents;
- implicitly overrules several longstanding lines of Alabama authority concerning pleading standards, product-liability limitations, and tort duties;
- embraces an extreme outlier view that contradicts the holdings of 78 courts in 25 States and has been adopted by only two lower courts in California and Vermont;
- rejects unanimous nationwide precedent holding that the U.S. Supreme Court's generic-preemption decision in PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011), does not support brand-name liability; and
- makes the State of Alabama a magnet for personal-injury lawsuits that other States' courts would refuse.

All agree that the certified question has far-reaching implications for businesses and consumers in Alabama. The majority opinion acknowledges that the question's "signifi-

cance extends well beyond the Reglan® litigation — and for that matter, even beyond pharmaceutical litigation." Slip op. 5. In the same way, Justice Murdock's dissenting opinion — which the full Court had not yet had the opportunity to review when the majority opinion was released — observes that the decision "poses danger for the prescription-medicine industry and, by extension, all industry." Dissent 3. Particularly given the "importance of the issues presented," the Court should at a minimum hear argument. Langan v. Altmayer, 539 So. 2d 173, 176 (Ala. 1988).

Separately, the Court should hear argument to explore an important post-decision development. The majority opinion relies heavily on the Supreme Court's decision in Mensing, which the majority read to foreclose all failure-to-warn claims against generic manufacturers. See, e.g., Slip op. 25, 52. As explained below, since this Court ruled, the Department of Justice has formally advised the Supreme Court that FDA "is considering a regulatory change that would allow generic manufacturers, like brand-name manufacturers, to change their labeling in appropriate circumstances," thereby overruling Mensing and "eliminat[ing] preemption of failure-to-warn claims against generic-drug

manufacturers." Br. for the U.S. 15 n.2, Mutual Pharm. Co. v. Bartlett, No. 12-142. FDA has "confirm[ed]" that it is "contemplating altering the regulations" applicable to generic manufacturers. Greg Ryan, FDA Mulls Dramatic Shift In Generic-Drug Labeling Regs, Law360 (Feb. 11, 2013) (**Appendix A**). Accordingly, the policy concern that so clearly animates the majority opinion may well soon completely evaporate.

Finally, in light of the dramatic changes wrought by its decision, the Court should hear argument to consider whether, if the decision stands, due process requires that it be applied prospectively only.

To be clear, the Court's decision to forgo oral argument at the merits stage does not preclude hearing argument now. In Michaud v. Morris, 603 So. 2d 886 (Ala. 1992), for instance, after initially affirming the judgment without oral argument, this Court granted rehearing, held oral argument, withdrew its earlier opinion, and reversed. See also, e.g., Cline v. Ashland, Inc., 970 So. 2d 755 (Ala. 2007) (conducting oral argument for the first time on rehearing); Wiley v. Gen. Motors & Acceptance Corp., 624 So. 2d 518 (Ala. 1993) (same).

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Appellants Wyeth LLC, Pfizer Inc., and Schwarz Pharma, Inc. (the "brand-name defendants") respectfully submit this brief in support of their Application for Rehearing.

SUMMARY OF THE ARGUMENT

Rehearing, of course, is reserved for extraordinary cases. The decision here is extraordinary by any measure.

Concerned that the Supreme Court's decision in PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011), might prevent consumers of generic drugs from suing generic manufacturers, the majority opinion strains mightily to reach what it believes to be a "just result." Dissent 1. But in so doing, the opinion badly distorts Alabama law. To the extent that federal law may deal generic-ingesting plaintiffs an "unfortunate hand," Mensing, 131 S. Ct. at 2581, that is an issue for federal regulators, not state courts. Particularly now — when FDA is actively reconsidering the generic-liability issue — there is no warrant for the majority's adoption of the aberrant "innovator liability" theory.

The majority opinion overlooks longstanding Alabama law in numerous important respects. Most notably, the opinion simply ignores a number of this Court's key precedents holding, for instance, that a "relationship" is a prerequi-

site to a tort duty and that a plaintiff cannot evade established tort limitations through artful pleading.

In addition, the opinion defies an overwhelming national consensus and instead embraces an extreme outlier position. Some **78** courts in **25** States — including all four U.S. Courts of Appeals to address the issue, as well as courts in every State that borders Alabama — have rejected innovator liability in cases materially identical to this one. See **Appendix B**. This Court joins only two lower courts in California and Vermont in embracing it.

Moreover, the Court is completely alone in concluding that Mensing supports innovator liability: **Every other court** to consider that suggestion — including three U.S. Courts of Appeals — has rejected it. See **Appendix C**. Indeed, Mensing itself refutes the majority's unprecedented position. From its opinion, it is clear that the Supreme Court recognized that state law prevents generic-ingesting consumers from suing brand-name manufacturers — hence the Court's recognition that its holding that federal law preempts claims against generic manufacturers dealt plaintiffs an "unfortunate hand." 131 S. Ct. at 2581. Exercising judicial restraint, however, the Court left it to the

political branches to address any resulting unfairness.

Significantly, it now appears that the political process may indeed resolve the dilemma that prompted the majority here to radically reformulate Alabama tort law. Since this Court's decision, FDA has announced that it "is considering a regulatory change that would allow generic manufacturers, like brand-name manufacturers, to change their labeling in appropriate circumstances," thereby overruling Mensing and "eliminat[ing] preemption of failure-to-warn claims against generic-drug manufacturers." Br. for the U.S. 15 n.2, Mutual Pharm. Co. v. Bartlett, No. 12-142; Greg Ryan, FDA Mulls Dramatic Shift In Generic-Drug Labeling Regs, Law360 (Feb. 11, 2013) (**Appendix A**).

In any event, unfairly saddling brand-name drug manufacturers — and all manufacturers doing business in Alabama — with open-ended liability for their competitors' products based on such a sharp (and unexplained) break from preexisting Alabama law contravenes due process principles.

ARGUMENT

This Court recently reaffirmed (on rehearing) its belief that that "'there is merit, if not honor, in admitting prior mistakes and correcting them.'" Ex parte Capstone

Bldg. Corp., 96 So. 3d 77, 88 (Ala. 2012) (quoting Foremost Ins. Co. v. Parham, 693 So. 2d 409, 421 (Ala. 1997) (Houston, J.)); see also, e.g., Williamson v. Indianapolis Life Ins. Co., 741 So. 2d 1057 (Ala. 1999) (granting rehearing on certified questions to withdraw negative answers and substitute affirmative answers). With respect, the opinion here rests on several mistakes that require correction.

I. The Majority Opinion Overlooks Several Bedrock Principles of Alabama Tort Law.

The majority opinion disregards multiple principles of Alabama law — and a number of leading Alabama precedents — that bear directly on the innovator-liability issue.

A. A Preexisting "Relationship" Is A Necessary Precondition To The Existence Of A Tort "Duty."

The majority opinion acknowledges that the Weekses' claims require proof that the brand-name defendants owed them a "duty." Slip op. 6–7. But the opinion disregards the corollary principle that duty requires proof of a "relationship" between plaintiff and defendant. See Dissent 5–14, 20–25. This Court's precedents (which the brand-name defendants repeatedly invoked) clearly establish that prerequisite, which is indisputably lacking here. See, e.g., DiBiasi v. Joe Wheeler Elec. Membership Corp., 988 So. 2d

454, 460–62 (Ala. 2008); Taylor v. Smith, 892 So. 2d 887, 891–92 (Ala. 2004); State Farm Fire & Cas. Co. v. Owen, 729 So. 2d 834, 839 (Ala. 1998); Thompson-Hayward Chem. Co. v. Childress, 169 So. 2d 305, 312 (Ala. 1964).

Without mentioning any of these decisions, the majority opinion proceeds as if ordinary "foreseeability" suffices to establish a tort duty. Slip op. 41–42. But this Court has repeatedly held (again, in cases the majority opinion fails to acknowledge) that foreseeability alone cannot establish a duty in "the absence of any relationship between the [plaintiffs] and the ... defendants." Keck v. Dryvit Sys., Inc., 830 So. 2d 1, 10–11 (Ala. 2002); accord DiBiasi, 988 So. 2d at 462–63 (same); Dissent 10 n.7.

By abandoning the "relationship" limitation in favor of an infinitely manipulable "foreseeability" criterion, the majority opinion threatens to impose an "endless duty" on all product manufacturers. Keck, 830 So. 2d at 11.

B. A Plaintiff May Not Circumvent Settled Tort Limitations Through Artful Pleading.

Alabama law also clearly holds that no matter how creatively a plaintiff "couch[es]" his claims, the "'substance of the allegation, and not its form, determines the character of a complaint.'" Bailey v. Faulkner, 940 So. 2d 247,

249, 253 (Ala. 2006). Indeed, in Pfizer, Inc. v. Farsian, 682 So. 2d 405 (Ala. 1996), the Court applied this anti-circumvention rule in a case just like this one, where the plaintiff alleged physical harm caused by a product: "Regardless of how [the plaintiff] pleads his claim, his claim is in substance a product liability/personal injury claim" subject to all attendant limitations. Id. at 407. Because the Weekses' claims indisputably "alleg[e] physical harm" caused by a product (Slip op. 45), they too are "product liability/personal injury claim[s]."

Without even mentioning Bailey or Farsian, the majority opinion allows plaintiffs to evade product-liability limitations simply by re-labeling their claims, thereby dramatically expanding product manufacturers' exposure.

C. Claims Based On A Failure To Warn Of Product Risks Require Proof Of Product Identification.

Longstanding Alabama law holds that a defendant cannot be held liable on a failure-to-warn theory absent proof that it "manufactured and placed on the market the very substance complained of." Thompson-Hayward, 169 So. 2d at 309. Indeed, Thompson-Hayward mirrors this case almost precisely. There, this Court held that a defendant who made only a replica of the product that actually injured

the plaintiff could not be held liable for "breach of [a] duty to warn." Id. at 306.

Without even acknowledging Thompson-Hayward or its "product identification" requirement, the majority opinion simply asserts that when a plaintiff's claim relates to "warning deficiencies," the entire "manufacturing process," including the product-identification requirement, is "irrelevant." Slip op. 52. But as Justice Murdock explains, courts have always treated allegations of "product defects and defective warnings as indistinguishable" — particularly in the pharmaceutical context, where FDA reviews and approves drug products in tandem with their constituent warning labels. Dissent 24 n.11.

By jettisoning the product-identification prerequisite for warning-based claims, the majority opinion exposes manufacturers to an entirely new universe of liability.

D. Neither The Learned-Intermediary Doctrine Nor The "Limited" Third-Party-Fraud Theory Supports Innovator Liability.

The majority opinion seems to assume that the learned-intermediary doctrine can somehow be understood to expand pharmaceutical manufacturers' duty to warn about their competitors' products — and, further, to create an independent

duty running from manufacturer to physician. See Slip op. 48–50. But this Court has held that the doctrine recognizes only a manufacturer's "limited" obligation to warn about "its product." Walls v. Alpharma USPD, Inc., 887 So. 2d 881, 883 (Ala. 2004). And even then, the doctrine does not impose a freestanding duty to physicians, but simply allows a manufacturer "to bridge the gap" by discharging any duty it might owe to a consumer by warning the consumer's doctor. Morguson v. 3M Co., 857 So. 2d 796, 802 n.1 (Ala. 2003); see also Dissent 19 n.10 ("In essence, the consumer's physician serves as the agent of the consumer ....").

The majority opinion never engages Walls, Morguson, or the "limit[ations]" they impose. Indeed, although the opinion (at one point) correctly recognizes that a manufacturer has only a limited "duty to warn the ultimate users of the risks of its product," Slip op. 50 (emphasis added), it totally fails to enforce those key restrictions.

Compounding its misunderstanding of the learned-intermediary doctrine, the majority opinion for the first time "extend[s]" the "third-party-fraud" theory "beyond the economic realm to claims alleging physical harm." Slip op. 45. But the majority's cited cases do not remotely support

that "exten[sion]." To the contrary, both Thomas v. Halstead, 605 So. 2d 1181 (Ala. 1992), and Delta Health Group v. Stafford, 887 So. 2d 887 (Ala. 2004), narrow the third-party-fraud theory's application to the "limited circumstance[]" — not present here — in which the plaintiff and defendant have a preexisting relationship, such as employer/employee or doctor/patient. Those decisions further require that the plaintiff be "within the class of those ... contemplated" by the defendant's statements. Thomas, 605 So. 2d at 1184. That element fails here, too, because "Reglan manufacturers intend[] to communicate with their customers, not the customers of their competitors." Mensing v. Wyeth, Inc., 588 F.3d 603, 613 n.9 (8th Cir. 2009), rev'd on other grounds sub nom. PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011), reinstated in relevant part, 658 F.3d 867 (8th Cir. 2011).

In any event, there is no rational justification for extending the third-party-fraud theory to cover physical injuries resulting from prescription-drug usage. The majority's observation that "[p]rescription medication is heavily regulated by the FDA" (Slip op. 46) cuts against, not in favor of, its novel liability theory. The fact that

pharmaceuticals (and manufacturers' statements about them) are subject to such careful regulation by an expert federal agency charged with ensuring consumer safety is a reason to limit the third-party-fraud theory, not expand it.

II. The Majority Opinion Misapprehends The Supreme Court's Recent Mensing Decision And Overlooks Unanimous Post-Mensing Precedent.

The majority opinion focuses heavily on the Supreme Court's recent Mensing decision, which it reads to absolve generic drug manufacturers of any responsibility for their products' labeling and to immunize them from tort liability.[1] But whatever Mensing portends for generic manufacturers, it provides no basis for the majority opinion's dramatic expansion of Alabama tort law to create an unprecedented cause of action against brand-name manufacturers.

A. Courts Have Unanimously Rejected The View That Mensing Supports Innovator Liability.

Since Mensing, generic-ingesting plaintiffs have repeatedly asserted (as the majority here seemed to conclude) that because federal law preempts claims against generic

[1] It is not at all clear that Mensing does so. To this day, the Weekses continue to pursue claims against the manufacturers of Mr. Weeks's generic metoclopramide, contending that they survive Mensing. See ECF No. 149 at 16-21. And in fact, numerous courts have allowed claims against generic manufacturers to proceed post-Mensing. See **Appendix D**.

manufacturers, courts must recognize a state-law remedy against brand-name manufacturers, lest generic-ingesting plaintiffs be left with no one to sue. All 16 courts to address that contention — including three U.S. Courts of Appeals — have expressly rejected it, holding instead that Mensing has "no effect" on brand-name manufacturers' state-law duties. See, e.g., Demahy v. Schwarz Pharma, Inc., 702 F.3d 177, 184 (5th Cir. 2012); see also **Appendix C**. This Court stands completely alone in concluding otherwise.

B. Mensing Itself Undermines The Majority's Adoption Of Innovator Liability.

Far from supporting the majority opinion's adoption of innovator liability, Mensing flatly undermines it. The Supreme Court's opinion there makes clear that its holding — that federal law preempts certain claims against generic manufacturers — does not justify the expansion of state-law duties owed by brand-name manufacturers.

In the decision under review in Mensing, the Eighth Circuit had concluded — consistent with the above-described national consensus — that as a matter of state law, brand-name drug manufacturers may not be held liable to generic-ingesting plaintiffs. See 588 F.3d at 612–14. In light of that settled state-law rule, Justice Sotomayor voiced the

same policy concern that underlies the majority opinion here — namely, that by holding that federal law preempts claims against generic manufacturers, the Court was leaving users of generic drugs with "no right to sue." 131 S. Ct. at 2592. The Court acknowledged the generic consumers' "unfortunate hand" but, exercising judicial restraint, left any potential fix to the political branches: "Congress and the FDA retain the authority to change the law and regulations if they so desire." Id. at 2581–82.

If perceived unfairness to generic-ingesting plaintiffs "is not a problem for the [U.S. Supreme] Court to correct," then "a fortiori, it is not a matter for this or any state court to correct." Dissent 4–5. Indeed, this Court has said repeatedly that its duty is "to say what the law is, not to say what it should be," e.g., Ex parte Pfizer, Inc., 746 So. 2d 960, 964 (Ala. 1999), and that "questions of propriety, wisdom, necessity, utility, and expediency" are properly left to the political process, Densmore v. Jefferson Cnty., 813 So. 2d 844, 850 (Ala. 2001). The majority opinion here violates those baseline principles.

C. Post-Decision Developments Further Undermine The Majority's Reliance On Mensing.

The majority's reliance on Mensing is problematic in

yet another respect — one that has arisen since this Court issued its decision. As already noted, FDA recently confirmed that it "is considering a regulatory change that would allow generic manufacturers, like brand-name manufacturers, to change their labeling in appropriate circumstances," thereby overruling Mensing and "eliminat[ing] preemption of failure-to-warn claims against generic-drug manufacturers." See supra at ii–iii, 3.

The sand is thus shifting beneath the Court's feet; the regulatory assumptions underlying the majority's rationale may soon change. Accordingly, rather than distorting settled law to saddle manufacturers with indefinite liability for their competitors' products, the Court should defer to the appropriate policymaking bodies, which may yet provide "an answer that yields a just result for both plaintiffs and defendants in cases such as this." Dissent 1.

III. By Disregarding Key Precedents And Unexpectedly Saddling The Brand-Name Defendants With Open-Ended Liability, The Majority Opinion Violates Due Process.

The Due Process Clause forbids state courts to alter state law in ways that are "unexpected and indefensible." Bouie v. City of Columbia, 378 U.S. 347, 354 (1964). With respect, the majority opinion does just that.

First, without even acknowledging key cases, the majority implicitly overruled settled Alabama law and imposed tort liability without proof of either a duty-creating relationship or product identification — and did so without warning, or even an opportunity to be heard at oral argument. Second, the majority compounded its error by concluding that Mensing — which in **2011** altered the then-prevailing understanding that generic manufacturers could unilaterally strengthen the warnings in their products' labels — should somehow be read to retroactively render Mr. Weeks's **pre-2011** injuries more "foreseeable" to the brand-name defendants. Slip op. 41–42. Finally, based on this series of unexplained decisions, the majority opinion unexpectedly — and unfairly — saddles brand-name drug manufacturers with open-ended liability for products they did not make, thereby thrusting them "into the role of insurers" of the entire prescription-drug market. Barnes v. Kerr Corp., 418 F.3d 583, 590 (6th Cir. 2005).

"The Due Process Clause ... is a central limitation upon the exercise of judicial power." Stop the Beach Renourishment, Inc. v. Fla. Dep't of Envtl. Prot., 130 S. Ct. 2592, 2614 (2010) (Kennedy, J., concurring). The "usual

due process constraint is that courts cannot abandon settled principles." Id. at 2515–16 (citing, e.g., Bouie, 378 U.S. at 354). Accordingly, "a judicial decision that eliminates or substantially changes established property rights, which are a legitimate expectation of the owner, is 'arbitrary or irrational' under the Due Process Clause." Id. at 2615 (quoting Lingle v. Chevron U.S.A., Inc., 544 U.S. 528, 542 (2005)).[2]

At the very least, if the Court insists on establishing a "new rule of law" that fundamentally changes settled expectations — based on an assumption about the regulatory landscape that may well be changing — it should clarify that the rule applies only prospectively. Ex parte Ward, 46 So. 3d 898, 902 (Ala. 2010); accord, e.g., Griffin v. Unocal Corp., 990 So. 2d 291, 293 (Ala. 2008).

IV. At A Minimum, The Court Should Grant Rehearing And Hold Oral Argument.

For reasons already explained, the Court should at a minimum hear oral argument before so dramatically altering Alabama tort law. See supra at i–iii.

[2] See also Gibson v. Am. Cyanamid Co., 719 F. Supp. 2d 1031 (E.D. Wis. 2010) ("risk-contribution" theory violated due process by imposing retroactive liability without proof of causation, thereby disrupting settled expectations).

CONCLUSION

This Court should grant the Application for Rehearing, withdraw its opinion, and answer the certified question in the negative. In the alternative, the Court should hear oral argument. At the very least, the Court should clarify that its decision applies only prospectively.

Respectfully submitted,

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FDA Mulls Dramatic Shift In Generic-Drug Labeling Regs

By **Greg Ryan**

Law360, New York (February 11, 2013, 6:02 PM ET) -- The U.S. Food and Drug Administration is considering allowing generic-drug makers to change a product's safety warning, the agency confirmed Monday, a move that would dismantle the requirement that labeling for generic drugs follow that of their brand-name counterparts.

The U.S. Department of Justice indicated the FDA was mulling such a move in a footnote in an amicus curiae brief it filed with the Supreme Court in January. The brief supported Mutual Pharmaceutical Co. Inc. in its appeal of a First Circuit decision that found design defect claims against the company, a generic-drug maker, are not preempted by federal law.

In confirming the FDA is contemplating altering the regulations, agency spokeswoman Sandy Walsh told Law360 that a change "would allow generic manufacturers, like brand-name manufacturers, to change their labeling in appropriate circumstances."

There have been calls for the agency to empower generics makers to change their drugs' labeling since the Supreme Court issued its Pliva v. Mensing decision in June 2011. The high court held in that case that because federal law dictates that generic-drug labeling match brand-name labeling, state-law failure-to-warn claims against generics makers are preempted.

Since the decision, plaintiffs have been largely unsuccessful in their lawsuits seeking to hold generics makers liable for injuries alleged caused by drugs. The most notable exception has been the First Circuit ruling, handed down in May in a case known as Bartlett.

In its brief to the Supreme Court, the DOJ said the regulatory change under consideration "could eliminate preemption of failure-to-warn claims against generic-drug manufacturers."

Walsh declined to elaborate on any potential changes, other than to say the public would have the opportunity to comment on any proposal. She did not give a timetable for a decision by the agency.

Robert Pollock, a senior adviser at Lachman Consultants and a former acting deputy director of the FDA Office of Generic Drugs, said the footnote marked "the first real indication I've seen in any public document that the FDA appears to be moving in that direction."

"As I was scrolling through it, I noticed the footnote and the hair on the back of my neck

stood up a little bit," he said.

Depending on how it shaped the regulation, the FDA could allow different generic versions of the same drug to have different warnings, creating confusion over liability in the case of an injury, according to Pollock.

The consumer group Public Citizen filed a citizen petition asking the agency to allow generics makers to change their labels in August 2011, shortly after Mensing was decided. Generic drugs dominate the marketplace, and the safety of their many users are threatened by manufacturers' lack of responsibility for updating their labeling with new risk information, the petition said.

To date, the FDA's only substantive response to the group has been its acknowledgment in March that it had not reached a decision on the petition because "it raises complex issues requiring extensive review and analysis by agency officials."

Georgetown University law professor Brian Wolfman, a signatory to the petition, said Monday that the placement of the footnote in the DOJ's brief showed the FDA's commitment to giving the idea a full vetting.

"I don't think the solicitor general would say that unless they were giving it serious consideration, because to do anything else would be seriously misleading," Wolfman said.

Wolfman said the FDA could make sure any changes to a drug's labeling initiated by one generic manufacturer were reflected in the labeling for other versions of the drug.

Democratic lawmakers led by Sen. Patrick Leahy of Vermont introduced legislation in both houses of Congress in April that would have allowed generics makers to independently change their labels. Neither bill left committee, however, and neither has been reintroduced in the new Congress.

The Generic Pharmaceutical Association opposed the legislation, arguing in part that it would erode consumers' trust that generic drugs are equivalent to brand-name drugs. A GPhA spokeswoman said Monday that the organization would reserve comment on any potential FDA regulation until it had been made public.

--Editing by Katherine Rautenberg.

APPENDIX B

APPENDIX B

Courts nationwide have overwhelmingly rejected the innovator-liability theory in cases brought by plaintiffs alleging the same types of claims asserted here (i.e., fraud, misrepresentation, suppression, and failure to warn).

DECISIONS THAT HAVE REJECTED INNOVATOR LIABILITY

1. Washington v. Medicis Pharm. Corp., No. 3:12-cv-00126, 2013 WL 496063 (S.D. Miss. Feb. 7, 2013) (Mississippi law).

2. Nicely v. Wyeth, Inc., No. 11SL-CC04757, slip op. (Mo. Cir. Ct. Jan. 24, 2013) (Kentucky law).

3. Gardley-Starks v. Pfizer, Inc., __ F. Supp. 2d __, 2013 WL 139900 (N.D. Miss. Jan. 10, 2013) (Mississippi law).

4. Willis v. Alaven Pharm. LLC, No. 9:11-cv-00094, 2013 WL 414526 (E.D. Tex. Feb. 4, 2013), adopting Report and Recommendation of U.S. Magistrate Judge, 2013 WL 414514 (E.D. Tex. Jan. 8, 2013) (Texas law).

5. Demahy v. Schwarz Pharma, Inc., 702 F.3d 177 (5th Cir. 2012), pet. for reh'g denied (Dec. 7, 2012) (Louisiana law).

6. Hogue v. Pfizer, Inc., __ F. Supp. 2d __, 2012 WL 4466609 (S.D. Ohio Sept. 27, 2012) (Ohio law).

7. Del Valle v. Pliva, Inc., No. 11-CV-113, 2012 WL 4747259 (S.D. Tex. Sept. 12, 2012), adopting Report and Recommendation of U.S. Magistrate Judge (S.D. Tex. Aug. 8, 2012), appeal pending, No. 12-41148 (5th Cir.) (Texas law).

8. In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig., No. 2:11-md-02226-DCR, 2012 WL 3984871 (Sept. 10, 2012) ("Darvocet IV") (dismissing claims under the law of 9 states, including Florida, Georgia, Michigan, Mississippi, New Hampshire, Oklahoma, South Carolina, Tennessee, and Texas, but allowing claims under California law to proceed).

9. Baymiller v. Ranbaxy Pharm., Inc., __ F. Supp. 2d __, 2012 WL 3929768 (D. Nev. Sept. 6, 2012) (Nevada law).

10. Phares v. Actavis-Elizabeth LLC, __ F. Supp. 2d __, 2012 WL 3779227 (S.D. Tex. Aug. 30, 2012) (Texas law).

11. In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig., No. 2:11-MD-02226-DCR, 2012 WL 3610237 (E.D. Ky. Aug. 21, 2012) ("Darvocet III") (dismissing claims under the law of 8 states, including Arkansas, Connecticut, Georgia, Kentucky, Louisiana, Massachusetts, Oklahoma, and West Virginia).

12. Eckhardt v. Qualitest Pharm. Inc., __ F. Supp. 2d __, 2012 WL 3600194 (S.D. Tex. Aug. 9, 2012), appeal pending, No. 13-40151 (5th Cir.) (Texas law).

13. Strayhorn v. Wyeth Pharm., Inc., 882 F. Supp. 2d 1020 (W.D. Tenn. 2012), appeal pending, No. 12-6195 (6th Cir.) (Tennessee law).

14. Lashley v. Pfizer, Inc., 877 F. Supp. 2d 466 (S.D. Miss. 2012), appeal pending, No. 12-60861 (5th Cir.) (Mississippi law).

15. Coundouris v. Wyeth, No. ATL-L-1940-10, 2012 WL 2401776 (N.J. Super. Ct. Law Div. June 26, 2012) (New Jersey law).

16. Phelps v. Wyeth, Inc., 857 F. Supp. 2d 1114 (D. Or. 2012), adopting Report and Recommendation of U.S. Magistrate Judge, 2012 WL 1021084 (D. Or. Feb. 24, 2012) (Oregon law); see also Phelps v. Wyeth, Inc., No. 09-cv-6168, 2010 WL 2553619 (D. Or. May 28, 2010), findings and recommendation adopted by No. 09-cv-6168, 2010 WL 2553614 (D. Or. June 21, 2010) (Oregon law).

17. Guarino v. Wyeth LLC, No. 8:10-cv-2885-T-30TGW, 2012 WL 1138631 (M.D. Fla. Apr. 3, 2012), appeal pending, No. 12-13263-DD (11th Cir.) (Florida law).

18. In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig., No. 2:11-MD-02226-DCR, 2012 WL 767595 (E.D. Ky. Mar. 7, 2012) ("Darvocet II") (dismissing claims under the law of 14 states, including Arkansas, Connecticut,

Georgia, Indiana, Kentucky, Louisiana, Massachusetts, Mississippi, New Jersey, New York, Oklahoma, Pennsylvania, Tennessee, and Texas).

19. In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig., 856 F. Supp. 2d 904 (E.D. Ky. 2012) ("Darvocet I") (dismissing claims under the law of 18 states, including Arkansas, Georgia, Indiana, Kentucky, Louisiana, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, New Jersey, New York, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, and Texas).

20. Metz v. Wyeth LLC, 830 F. Supp. 2d 1291 (M.D. Fla. 2011), appeal pending, No. 12-13321-B (11th Cir.) (Florida law).

21. Smith v. Wyeth, Inc., 657 F.3d 420 (6th Cir. 2011), pet. for reh'g en banc denied (Nov. 22, 2011), pet. for cert. denied (Apr. 30, 2012) (Kentucky law).

22. Bell v. Pfizer, Inc., No. 5:10-cv-00101, 2011 WL 904161 (E.D. Ark. Mar. 16, 2011) (Arkansas law).

23. Overton v. Wyeth, Inc., No. CA 10-0491, 2011 WL 1343392 (S.D. Ala. Mar. 15, 2011), report and recommendation adopted by No. CA 10-0491, 2011 WL 1343391 (S.D. Ala. Apr. 7, 2011) (Alabama law).

24. Simpson v. Wyeth, Inc., No. 7:10-cv-01771, 2010 WL 5485812 (N.D. Ala. Dec. 9, 2010), report and recommendation adopted by No. 7:10-cv-01771, 2011 WL 10607 (N.D. Ala. Jan. 4, 2011) (Alabama law).

25. Gross v. Pfizer, Inc., No. 10-cv-00110, 2010 WL 4485774 (D. Md. Nov. 9, 2010) (Maryland law).

26. Cooper v. Wyeth, Inc., No. 09-CV-929, 2010 WL 4318816 (M.D. La. Oct. 26, 2010) (Louisiana law).

27. Fullington v. Pfizer, Inc., No. 4:10-cv-00236, 2010 WL 3632747 (E.D. Ark. Sept. 17, 2010) (Arkansas law).

28. Johnson v. Teva Pharm. USA, Inc., No. 2:10-cv-404, 2010 WL 3271934 (W.D. La. Aug. 16, 2010), appeal pending, No. 12-31011 (5th Cir.) (Louisiana law).

29. Fisher v. Pelstring, No. 4:09-cv-00252, 2010 WL 2998474 (D.S.C. July 28, 2010) (South Carolina law).

30. Neal v. Teva Pharm. USA, Inc., No. 09-CV-1027, 2010 WL 2640170 (W.D. Ark. July 1, 2010) (Arkansas law).

31. Mosley v. Wyeth, Inc., 719 F. Supp. 2d 1340 (S.D. Ala. 2010) (Alabama law).

32. Craig v. Pfizer, Inc., No. 3:10-cv-00227, 2010 WL 2649545 (W.D. La. May 26, 2010), report and recommendation adopted by No. 3:10-cv-00227, 2010 WL 2649544 (W.D. La. June 29, 2010) (Texas law).

33. Negron v. Teva Pharm. USA, Inc., No. 09-16519, 2010 WL 8357563 (Tex. Dist. Ct. May 7, 2010) (Texas law).

34. Finnicum v. Wyeth, Inc., 708 F. Supp. 2d 616 (E.D. Tex. 2010) (Texas law).

35. Howe v. Wyeth, Inc., No. 8:09-CV-610, 2010 WL 1708857 (M.D. Fla. Apr. 26, 2010) (Florida law).

36. Hardy v. Wyeth, Inc., No. 9:09-CV-152, 2010 WL 1049588 (E.D. Tex. Mar. 8, 2010), report and recommendation adopted by No. 9:09-CV-152, 2010 WL 1222183 (E.D. Tex. Mar. 29, 2010) (Texas law).

37. Couick v. Wyeth, Inc., 691 F. Supp. 2d 643 (W.D.N.C. 2010) (North Carolina law).

38. Levine v. Wyeth Inc., 684 F. Supp. 2d 1338 (M.D. Fla. 2010) (Florida law).

39. Washington v. Wyeth, Inc., No. 3:09-CV-01343, 2010 WL 450351 (W.D. La. Feb. 8, 2010) (Louisiana law).

40. Dietrich v. Wyeth, Inc., No. 50-2009-CA-021586, 2009 WL 4924722 (Fla. Cir. Ct. Dec. 21, 2009) (Florida law).

41. Mensing v. Wyeth, Inc., 588 F.3d 603 (8th Cir. 2009), rev'd on other grounds sub nom. PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011), reinstated in relevant part, 658 F.3d 867 (8th Cir. 2011) (Minnesota law).

42. Morris v. Wyeth, Inc., No. 09-cv-0854, 2009 WL 4064103 (W.D. La. Nov. 23, 2009) (Louisiana law).

43. Meade v. Parsley, No. 2:09-cv-0038, 2009 WL 3806716 (S.D. W. Va. Nov. 13, 2009) (West Virginia law).

44. Burke v. Wyeth, Inc., Civ. No. G-09-82, 2009 WL 3698480 (S.D. Tex. Oct. 29, 2009) (Texas law).

45. Stoddard v. Wyeth, Inc., 630 F. Supp. 2d 631 (E.D.N.C. 2009) (North Carolina law).

46. Fields v. Wyeth, Inc., 613 F. Supp. 2d 1056 (W.D. Ark. 2009) (Arkansas law).

47. Moretti v. Wyeth, Inc., No. 2:08-CV-00396, 2009 WL 749532 (D. Nev. Mar. 20, 2009), appeal pending, No. 12-16334 (9th Cir.) (Nevada law).

48. Schrock v. Wyeth, Inc., 601 F. Supp. 2d 1262 (W.D. Okla. 2009), appeal pending, No. 12-6078 (10th Cir.) (Oklahoma law).

49. Cousins v. Wyeth Pharm., Inc., No. 3:08-CV-0310-N, 2009 WL 648703 (N.D. Tex. Mar. 10, 2009) (Texas law).

50. Huck v. Trimark Physicians Grp., No. LACV018947, 2009 WL 3760458 (Iowa Dist. Ct. Feb. 27, 2009), appeal pending, No. 12-0596 (Iowa Ct. App.) (Iowa law).

51. Mensing v. Wyeth, Inc., No. 07-3919, 2008 WL 4724286 (D. Minn. Oct. 27, 2008), aff'd, 588 F.3d 603 (8th Cir. 2009) (Minnesota law).

52. Westerlund v. Wyeth, Inc., No. MID-2174-05, 2008 WL 5592753 (N.J. Super. Ct. Law Div. Oct. 20, 2008) (New Jersey law).

53. Buchanan v. Wyeth Pharm., Inc., No. CV-2007-900065, 2008 WL 7136137 (Ala. Cir. Ct. Oct. 20, 2008) (Alabama law).

54. Wilson v. Wyeth, Inc., No. 3:07-CV-378, 2008 WL 2677049 (W.D. Ky. June 30, 2008), aff'd, 657 F.3d 420 (6th Cir. 2011) (Kentucky law).

55. Smith v. Wyeth, Inc., No. 5:07-CV-18, 2008 WL 2677051 (W.D. Ky. June 30, 2008), aff'd, 657 F.3d 420 (6th Cir. 2011) (Kentucky law).

56. Morris v. Wyeth, Inc., No. 1:07-CV-176, 2008 WL 2677048 (W.D. Ky. June 30, 2008), aff'd, 657 F.3d 420 (6th Cir. 2011) (Kentucky law).

57. Stanley v. Wyeth, Inc., 991 So. 2d 31 (La. Ct. App. 2008) (Louisiana law).

58. Pustejovsky v. Wyeth, Inc., No. 4:07-CV-103-Y, 2008 WL 1314902 (N.D. Tex. Apr. 3, 2008) (Texas law).

59. Swicegood v. Pliva, Inc., 543 F. Supp. 2d 1351 (N.D. Ga. 2008) (Georgia law).

60. Green v. Wyeth Pharm., Inc., No. CV06-3917, 2007 WL 6428717 (Ala. Cir. Ct. May 14, 2007) (Alabama law).

61. Barnhill v. Teva Pharm. USA, Inc., No. 06-cv-0282, 2007 WL 5787186 (S.D. Ala. Apr. 24, 2007) (Alabama law).

62. Sharp v. Leichus, 952 So. 2d 555 (Fla. Dist. Ct. App. 2007) (Florida law).

63. Rossi v. Hoffman-LaRoche, No. ATL-L-690-05, 2007 WL 7632318 (N.J. Super. Ct. Law Div. Jan. 3, 2007) (New Jersey).

64. Leblanc v. Wyeth, Inc., No. Civ. A 04-0611, 2006 WL 2883030 (W.D. La. Oct. 5, 2006) (Louisiana law).

65. Goldych v. Eli Lilly & Co., No. 5:04-CV-1477, 2006 WL 2038436 (N.D.N.Y. July 19, 2006) (New York law).

66. Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514 (E.D. Pa. 2006), aff'd in pertinent part and rev'd in other part, 521 F.3d 253 (3d Cir. 2008), vacated and remanded, 129 S. Ct. 1578 (2009) (Pennsylvania law).

67. Possa v. Eli Lilly & Co., No. 05-cv-1307-JJB-SCR, 2006 WL 6393160 (M.D. La. May 10, 2006) (Louisiana law).

68. Sharp v. Leichus, No. 04-CA-643, 2006 WL 515532 (Fla. Cir. Ct. Feb. 17, 2006), aff'd per curiam, 952 So. 2d 555 (Fla. Dist. Ct. App. 2007) (Florida law).

69. Tarver v. Wyeth, No. Civ. A. 3-04-2036, 2006 WL 1517546 (W.D. La. Jan. 26, 2006) (Louisiana law).

70. Tarver v. Wyeth, No. Civ. A. 3-04-2036, 2005 WL 4052382 (W.D. La. June 7, 2005) (Louisiana law).

71. Kelly v. Wyeth, No. 03-CV-3314, 2005 WL 4056740 (Super. Ct. Mass. May 6, 2005) (Massachusetts law).

72. Reynolds v. Anton, No. 01A-76719-3, 2004 WL 5000272 (Ga. Super. Ct. Oct. 28, 2004) (Georgia law).

73. Sheeks v. Am. Home Prods. Corp., No. 02CV337, 2004 WL 4056060 (Colo. Dist. Ct. Oct. 15, 2004) (Colorado law).

74. Sloan v. Wyeth, No. MRS-L-1183-04, 2004 WL 5767103 (N.J. Super. Ct. Oct. 13, 2004) (New Jersey law).

75. Block v. Wyeth, Inc., 3:02-CV-1077, 2003 WL 203067 (N.D. Tex. Jan. 28, 2003) (Texas law).

76. Beutella v. A.H. Robins Co., Inc., No. 980502372, 2001 WL 35669202 (Utah Dist. Ct. Dec. 10, 2001) (Utah law).

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

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

DECISIONS THAT HAVE ADOPTED INNOVATOR LIABILITY

1. Wyeth, Inc. v. Weeks, __ So. 3d __, 2013 WL 135753 (Ala. Jan. 11, 2013).

2. Kellogg v. Wyeth, 762 F. Supp. 2d 694 (D. Vt. 2010) (denying summary judgment under Vermont law).

3. Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008) (denying summary judgment under California law).

APPENDIX C

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Every court to address the question has squarely held that the U.S. Supreme Court's recent decision in PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011), does not justify innovator liability.

1. Nicely v. Wyeth, Inc., No. 11SL-CC04757, slip op. (Mo. Cir. Ct. Jan. 24, 2013) (rejecting the argument that neither Mensing nor this Court's decision in Weeks changed Kentucky law regarding claims asserted against brand-name drug manufacturers by generic-ingesting plaintiffs).

2. Gardley-Starks v. Pfizer, Inc., __ F. Supp. 2d __, 2013 WL 139900 (N.D. Miss. Jan. 10, 2013) (rejecting the argument that Mensing changed Mississippi law regarding claims asserted against brand-name drug manufacturers by generic-ingesting plaintiffs).

3. Demahy v. Schwarz Pharma, Inc., 702 F.3d 177, 184 (5th Cir. 2012), pet. for reh'g denied (Dec. 7, 2012) (Mensing "does not impose on name-brand manufacturers a duty of care to customers using generic products.... [T]he Supreme Court's decision in Mensing had no effect on Louisiana state law ....").

4. Hogue v. Pfizer, Inc., __ F. Supp. 2d __, 2012 WL 4466609, at *5 (S.D. Ohio Sept. 27, 2012) ("[T]he Mensing decision has no bearing whatsoever on the issue whether the Brand Defendants may be held liable under Ohio Product liability law for injuries arising from the ingestion of generic metoclopramide they did not manufacture.").

5. Dietrich v. Wyeth, Inc., No. 50-2009-CA-021586, slip op. at 4 (Fla. Cir. Ct. Sept. 4, 2012) ("[E]very court to address this question ... has rejected the argument that Mensing changes state law principles relating to name brand manufacturer liability.").

6. Phares v. Actavis-Elizabeth LLC, __ F. Supp. 2d __, 2012 WL 3779227, at *10 (S.D. Tex. Aug. 30, 2012) ("Mensing does not affect the principles underlying

Texas products liability law and the Court is not persuaded by Plaintiff's attempts to convince the Court otherwise.").

7. Coundouris v. Wyeth, No. ATL-L-1940-10, 2012 WL 2401776, at *4 (N.J. Super. Ct. Law Div. June 26, 2012) (Mensing "does not change New Jersey law ... [and does] not address or impact the issue currently before this Court — namely, whether a brand-name manufacturer owes a duty to a patient who ingested a drug that the brand-name manufacturer did not make or sell.").

8. Phelps v. Wyeth, Inc., 857 F. Supp. 2d 1114, 1119 (D. Or. 2012) (Mensing "does not overrule Foster's holding regarding the liability of name-brand manufacturers" and "does not overturn the central holding in Foster").

9. Guarino v. Wyeth LLC, No. 8:10-cv-2885-T-30TGW, 2012 WL 1138631, at *2 (M.D. Fla. Apr. 3, 2012) (rejecting the argument that Mensing somehow "warranted a change in how Florida law is applied to producers of brand name pharmaceuticals").

10. Huck v. Trimark Physicians Grp., No. LACV018947, slip op. at 2 (Iowa Dist. Ct. Jan. 6, 2012) ("The Mensing case does nothing to expressly expand liability to the manufacturer of a branded drug that did not manufacture or supply the actual drug ingested.").

11. Fullington v. Pfizer, Inc., 4:10-cv-00236-JLH, 2011 WL 6153608, at *6 (E.D. Ark. Dec. 12, 2011) ("Nothing in Mensing purported to overrule [the governing] principle of state law, nor would the United States Supreme Court have the authority to overrule such a principle of state law in the absence of a conflict between state law and federal law.").

12. Metz v. Wyeth LLC, 830 F. Supp. 2d 1291, 1294 (M.D. Fla. 2011) (concluding that dicta in pre-Mensing cases about generic preemption "does not compel the conclusion that Mensing changed Florida law").

13. Morris v. Wyeth, Inc., No. 3:09-cv-00854, 2011 WL 4975317 (W.D. La. Oct. 19, 2011) ("[T]he Mensing decision and the current application of the [Louisiana

Product Liability Act] have made it clear that parties injured by generic drugs have no recourse against brand name manufacturers ....").

14. Mensing v. Wyeth, Inc., 658 F.3d 867 (8th Cir. 2011) (reinstating the portion of its opinion affirming judgment in favor of the brand-name manufacturers).

15. Smith v. Wyeth, Inc., 657 F.3d 420 (6th Cir. 2011), pet. for reh'g en banc denied (Nov. 22, 2011), pet. for cert. denied (Apr. 30, 2012) (rejecting the argument made in supplemental briefing that Mensing overturned Foster).

16. Gross v. Pfizer, Inc., No. 8:10-cv-00110-AW, 2011 WL 4005266, at *2 (D. Md. Sept. 7, 2011) ("The Supreme Court's holding in Mensing neither created nor abrogated any duty under Maryland law [i.e., the same law that applied in Foster] with regard to brand-name manufacturers ....").

APPENDIX D

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Even after the U.S. Supreme Court held in PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011), that federal law preempts state-law failure-to-warn claims against generic drug manufacturers, numerous courts have allowed labeling-based claims against those manufacturers to proceed.

1. Stoddard v. PLIVA USA, Inc., No. 4:08-cv-173, slip op. (E.D.N.C. Jan. 30, 2013), ECF No. 131.

2. Arters v. Sandoz, Inc., __ F. Supp. 2d __, 2013 WL 308768 (S.D. Ohio Jan. 25, 2013).

3. Acree v. Watson Pharm., Inc., No. 10-C-7812, 2012 WL 5306296 (N.D. Ill. Oct. 26, 2012).

4. In re Prempro Prods. Liab. Litig., No. 4:03-CV-1507, 2012 WL 3985752 (E.D. Ark. Sept. 11, 2012).

5. Whitener v. PLIVA, Inc., No. 10-1552, 2012 WL 1995795 (E.D. La. June 4, 2012).

6. In re Reglan/Metoclopramide Cases, No. CJC-10-004631, order and transcript (Cal. Super. Ct. May 21, 2012).

7. In re Reglan Litig., No. 289, 2012 WL 1613329 (N.J. Super. Ct. Law. Div. May 4, 2012).

8. Fosamax/Alendronate Sodium Drug Cases, No. JCCP 4664, slip op. (Cal. Super. Ct. May 3, 2012).

9. Bartlett v. Mut. Pharm. Co., Inc., 678 F.3d 30 (1st Cir. 2012), cert. granted, 133 S. Ct. 694 (Nov. 30, 2012).

10. Cooper v. Wyeth, Inc., No. 09-929-JJB, 2012 WL 733846 (M.D. La. Mar. 6, 2012).

11. Lyman v. Pfizer, Inc., No. 2:09-cv-262, 2012 WL 368675 (D. Vt. Feb. 3, 2012); see also Lyman v. Pfizer, Inc., No. 2:09-cv-262, 2012 WL 2970627 (D. Vt. July 20, 2012).

12. Couick v. Wyeth, Inc., No. 3:09-cv-210, 2012 WL 79670 (W.D.N.C. Jan. 11, 2012).

13. Fisher v. Pelstring, 817 F. Supp. 2d 791, 805, 821, 834–45 (D.S.C. 2011).

14. Hutchinson v. Endoscopy Ctr. of S. Nev., LLC, No. A562216, 2011 WL 9378975 (Nev. Dist. Ct. Sept. 16, 2011).

15. Brasley-Thrash v. Teva Pharm. USA, Inc., No. 10-00031-KD-N, 2011 WL 4025734 (S.D. Ala. Sept. 12, 2011).

16. Keck v. Endoscopy Ctr. of S. Nev., LLC, No. A575837, 2011 WL 3921690 (Nev. Dist. Ct. Aug. 19, 2011).

17. Sacks v. Endoscopy Ctr. of S. Nev., LLC, No. 08A572315, 2011 WL 4915174 (Nev. Dist Ct. July 28, 2011).