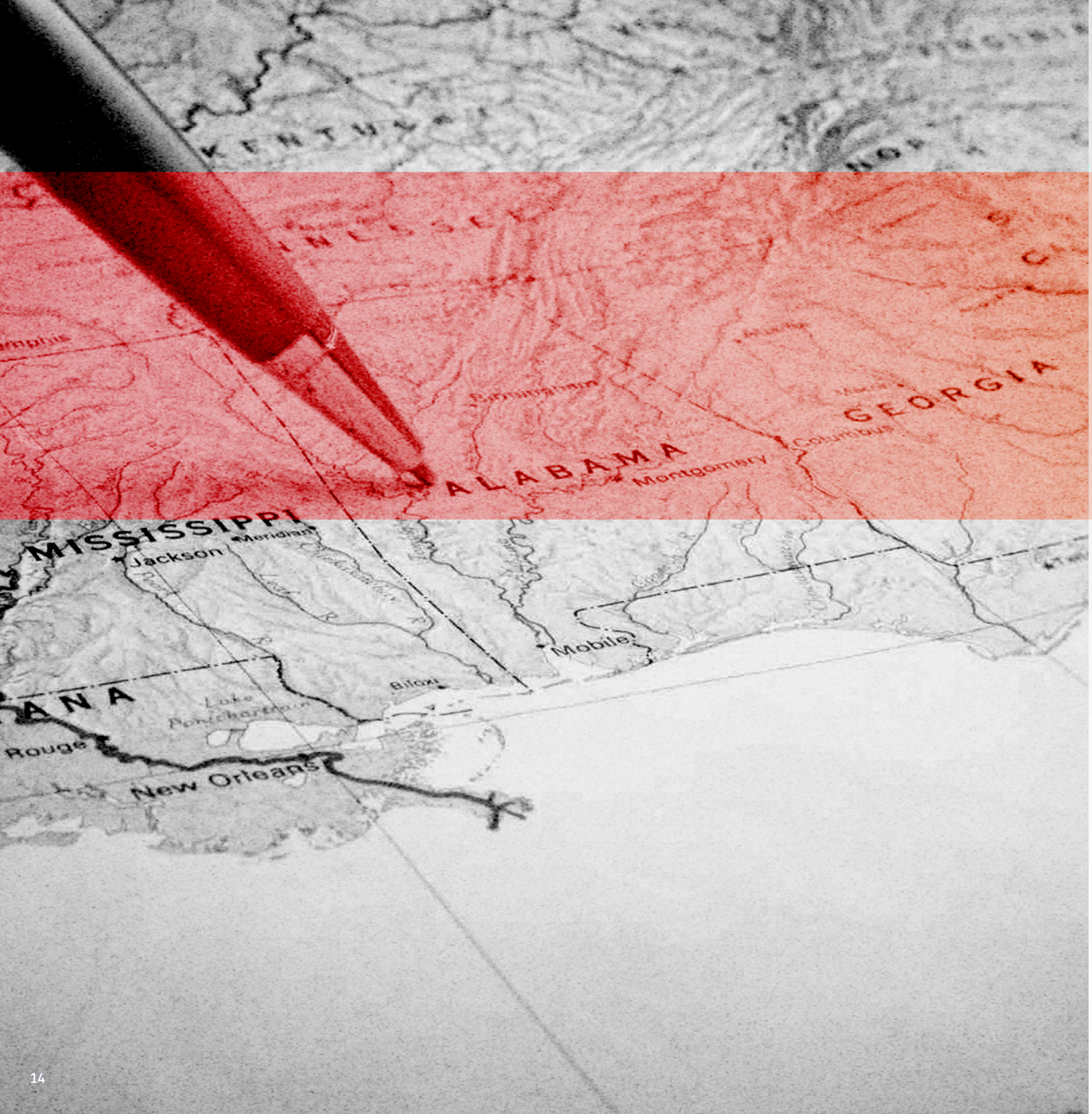


ALABAMA NO LONGER AN OUTLIER STATE:

LEGISLATURE SAYS "NO" TO INNOVATOR LIABILITY

I. INTRODUCTION

Since the United States Supreme Court's decision in *Pliva, Inc. v. Mensing*[1], the plaintiffs' bar has been feverishly searching for an alternate theory of recovery when the claimant took a generic prescription drug. One of those alternate theories is "innovator liability," which posits that the brand manufacturer should be liable for injuries caused by the generic equivalent even if the claimant did not ingest the brand manufacturer's product. Plaintiffs rationalize that because the FDA requires the generic manufacturer to copy the brand's label and warnings, the brand manufacturer should be liable.

The innovator theory contravenes a principal foundation of product liability law: that a manufacturer is not liable for injuries resulting from use of another manufacturer's product. Indeed, the logic is undeniable – if a manufacturer did not make the product, it cannot be liable for damages allegedly caused by its use.

In the context of pharmaceutical litigation, this foundational rule was set forth in *Foster v. American Home Products*,[2] which required product identification – a direct evidentiary link between the allegedly harmful product and the allegedly liable defendant-manufacturer.[3] The Foster court reasoned that making brand-name drug manufacturers liable for generic manufacturers' activities was unfair and stretched the boundaries of legal foreseeability in product liability law.[4]

The innovator theory contravenes a principal foundation of product liability law: that a brand-name manufacturer is not liable for injuries resulting from use of another manufacturer's product.

This established law took a step backward with the first mention of innovator liability in *Conte v. Wyeth, Inc.*[5] In *Conte*, the court concluded that *Foster*'s analysis was flawed because it did not consider concurrent liability, rationalizing that it was reasonable to require brand-name manufacturers to put correct information on their labels or be held liable for its failure to warn.[6] The *Conte* court held that it would not protect the brand-name manufacturer from foreseeable injuries caused by its allegedly inadequate warnings that the generic manufacturers are required to replicate.[7]

In addition to California, Alabama and Vermont are the only other jurisdictions to apply the innovator liability theory to hold a brand-name manufacturer liable for misstatement or omission for an injury caused by a generic drug manufactured by a different company.[8] However, Alabama recently took swift action to curtail the potential Pandora's box of litigation created by the *Wyeth v. Weeks* decision. In doing so, the Alabama legislature reduced the number of innovator liability states to just two, a considerable minority to the number of states addressing the issue and holding otherwise.[9]

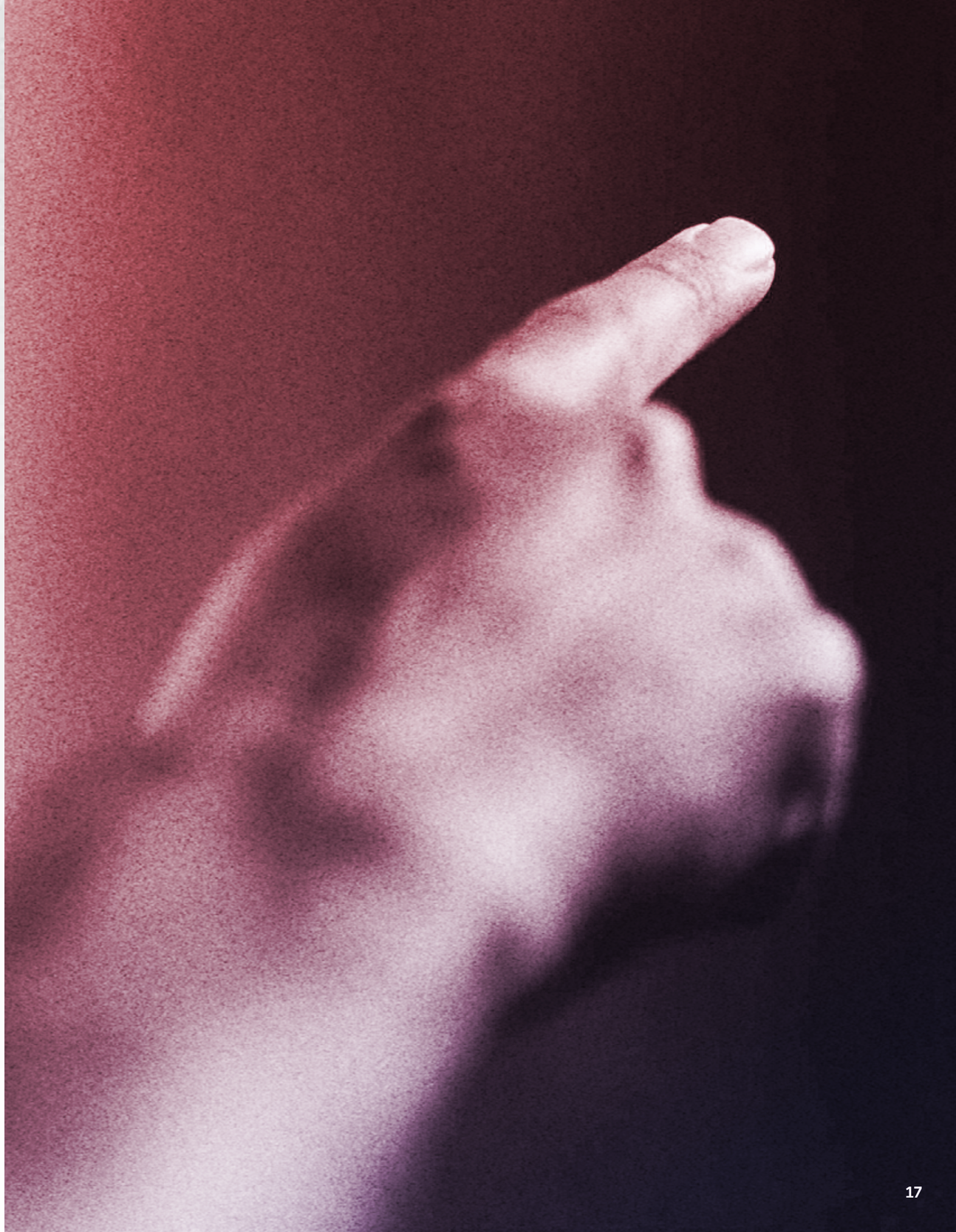
II. WEEKS: THE "WORST PRESCRIPTION DRUG/MEDICAL DEVICE DECISION OF 2014"

In our July 2013 *Pro Te* article, "*What Do California, Vermont and Alabama Have In Common*?,"[10] we reported on what had been deemed the "worst prescription drug/medical device decision of 2014."[11] To recap, in *Wyeth, Inc. v. Weeks*, the Alabama Supreme Court allowed a plaintiff claiming injury from a generic product to maintain a misrepresentation claim against the brand manufacturer. The original *Weeks* decision garnered widespread negative press, thus causing the Alabama Supreme Court to reconsider its original opinion, *en banc*.

At rehearing, Wyeth argued – supported by the majority of states – that it had no relationship with the Weeks plaintiffs and, thus, it owed them no duty to warn. However, the Alabama Supreme Court emphatically rejected this notion and admonished Wyeth's argument, holding:

> Wyeth's argument completely ignores the nature of prescription medication. The Weekses cannot obtain Reglan or any other prescription medication directly from a prescription-drug manufacturer. The only way for a consumer to obtain a prescription medication is for a physician or other medical professional authorized to write prescriptions (i.e. a learned intermediary) to prescribe the medication to his or her patient. When the warning to the prescribing health-care professional is inadequate, however, the manufacturer is directly liable to the patient for damage resulting from that failure. [12]

Although one would think – as the majority of states have previously held – that the above rationale would prevent brand-name manufacturer liability in the case of generic ingestion, the Supreme Court rejected such a conclusion, rationalizing:



> The substitution of a generic drug for its brand-name equivalent is not fatal to Weekses' claim because the Weekses are not claiming that the drug Danny ingested was defective; instead, the Weekses' claim is that Wyeth fraudulently misrepresented or suppressed information concerning the way the drug was to be taken and, as discussed, the FDA mandates that the warning on a generic-drug label be the same as the warning on the brand-name-drug label and only the brand-name manufacturer may make unilateral changes to the label.[13]

The Alabama Supreme Court again relied heavily on the United States Supreme Court's holding in *Mensing*, noting that "the Supreme Court in PLIVA held that it would have been impossible for the generic manufacturers to change their warning labels without violating the federal requirement that the warning on the generic drug must match the warning on the brand-name version, preempting failure-to-warn claims against generic manufacturers."[14] The *Weeks* Court thus emphasized the FDA's role in drug labeling and restrictions placed upon generic manufacturers, remarking "FDA regulations require that a generic manufacturer's labeling[15] for a prescription drug be exactly the same as the brand-name manufacturer's labeling." In further justification of its holding, the Alabama Supreme Court rationalized that:

> it is not fundamentally unfair to hold the brand-name manufacturer liable for warnings on a product it did not produce because the manufacturing process is irrelevant to misrepresentation theories based, not on manufacturing defects in the product itself, but on information and warning deficiencies, when those alleged misrepresentations were drafted by the brand-name manufacturer and merely repeated, as allowed by the FDA, by the generic manufacturer. [16]

Justice Parker, relying on Justice Murdock's 2013 dissent in *Weeks*, stressed the potentially grave consequences of the court's dissolution of bedrock legal principles of duty and privity, noting:

> [n]othing in federal legislation or regulations at issue here requires this Court to ignore, modify, or override our bedrock legal principles of duty and privity with regard to the originator of a pharmaceutical drug and a consumer who has not consumed a drug manufactured by the originator of the drug. [17]

As recognized by the United States Supreme Court, while a consumer may be left without a remedy absent a legislative change, "it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre."[18]

The *Conte* court held that it would not protect the brand-name manufacturer from foreseeable injuries caused by its allegedly inadequate warnings that the generic manufacturers are required to replicate.

III. THE ALABAMA LEGISLATURE TO THE RESCUE

Despite the Alabama Supreme Court's refusal to alter the Weeks decision, innovator liability will not stand in the State of Alabama. Less than one year after Weeks, the Alabama Legislature passed Act No. 2015-106 (S.B. 80), effectively abolishing innovator liability in the State of Alabama. Originally introduced in the Alabama Senate, Act No. 2015-106 passed the Alabama House of Representatives on April 28, 2015. With Governor Robert Bentley signing the bill into law on May 1, 2015, Act No. 2015-106 returned Alabama to the majority of states disallowing innovator liability in cases involving generic ingestion.

While the statute will not take effect until November 1, 2015, it states in part:

> Section 1. In any civil action for personal injury, death, or property damage caused by a product, regardless of the type of claims alleged or the theory of liability asserted, the *plaintiff must prove, among other elements, that the defendant designed, manufactured, sold, or leased the particular product the use of which is alleged to have caused the injury on which the claim is based, and not a similar or equivalent product.* Designers, manufacturers, sellers, or lessors of products not identified as having been used, ingested, or encountered by an allegedly injured party may not be held liable for any alleged injury. A person, firm, corporation, association, partnership, or other legal or business entity whose design is copied or otherwise used by a manufacturer without the designer's express authorization is not subject to liability for personal injury, death, or property damage caused by the manufacturer's product, even if use of the design is foreseeable. [19] (emphasis added).

Theoretically, under this statutory approach, liability is limited to entities that "manufactured, sold, or leased" the product at issue, and may not be imposed on those whose original product design is later copied.

Theoretically, under this statutory approach, liability is limited to entities that "manufactured, sold, or leased" the product at issue, and may not be imposed on those whose original product design is later copied.

On its face, Act No. 2015-106 makes no mention of pharmaceutical drug products or brand versus generic manufacturers. Instead, the statute applies more broadly to "[d]esigners, manufacturers, sellers, or lessors of products." Regardless, brand-name pharmaceutical manufacturers will likely sleep easier knowing innovator liability is no longer a viable claim in Alabama.

I. CONCLUSION

Under Alabama Act No. 2015-106, brand-name drug manufacturers may no longer be held liable under Alabama law for misrepresentations in cases where the plaintiff never ingested the brand drug product. Alabama legislatively re-joined the majority of states disallowing innovator liability. Only time will tell if California and Vermont will follow suit.

APPENDIX OF CASES DECLINING INNOVATOR LIABILITY

ARKANSAS LAW

- *Fullington v. Pfizer, Inc.*, 720 F.3d 739 (8th Cir. 2013).
- *Bell v. Pfizer, Inc.*, 716 F.3d 1087 (8th Cir. 2013).
- *Neal v. Teva Pharm. USA, Inc.*, No. 09-CV-1027, 2010 WL 2640170 (W.D. Ark. July 1, 2010).
- *Fields v. Wyeth, Inc.*, 613 F. Supp. 2d 1056 (W.D. Ark. 2009).

COLORADO LAW

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

FLORIDA LAW

- *Metz v. Wyeth, L.L.C.*, 525 F. App'x 893 (11th Cir. 2013).
- *Guarino v. Wyeth, L.L.C.*, 719 F.3d 1245 (11th Cir. 2013).
- *Howe v. Wyeth, Inc.*, No. 8:09-CV-610, 2010 WL 1708857 (M.D. Fla. Apr. 26, 2010).
- *Levine v. Wyeth Inc.*, 684 F. Supp. 2d 1338 (M.D. Fla. 2010).
- *Dietrich v. Wyeth, Inc.*, No. 50-2009-CA-021586, 2009 WL 4924722 (Fla. Cir. Ct. Dec. 21, 2009).
- *Sharp v. Leichus*, 952 So. 2d 555 (Fla. Dist. Ct. App. 2007).

GEORGIA LAW

- *Dement v. Alaven Pharm., LLC*, No. 10-EV-009036-3, 2014 WL 2404289 (Ga. Super. Ct. May 27, 2014).
- *Tanner v. Alaven Pham., LLC*, No. 10-EV-009036-4, 2014 WL 2404287 (Ga. Super. Ct. May 27, 2014).
- *Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351 (N.D. Ga. 2008).
- *Reynolds v. Anton*, No. 01A-76719-3, 2004 WL 5000272 (Ga. Super. Ct. Oct. 28, 2004).

INDIANA LAW

- *Stewart v. Sanofi Aventis U.S.*, L.L.C., 15 F. Supp. 3d 1151 (N.D. Ala. 2014).
- *Scott v. Elsevier Inc.*, No. 11-04445, slip op. (Mass. Super. Ct. Aug. 11, 2014).
- *Short v. Eli Lilly & Co.*, No. 49D12-0601-CT-2187, 2009 WL 9867531 (Ind. Super. Ct. Mar. 25, 2009).

IOWA LAW

- *Huck v. Wyeth, Inc.*, 850 N.W.2d 353 (Iowa 2014).

KENTUCKY LAW

- *Nicely v. Wyeth, Inc.*, 451 S.W.3d 694 (Mo. Ct. App. 2014).
- *Franzman v. Wyeth*, Inc., 451 S.W.3d 676 (Mo. Ct. App. 2014).
- *White v. Elsevier Inc.*, No. 11-04441, slip op. (Mass. Super. Ct. July 26, 2013).
- *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).
- *Wilson v. Wyeth, Inc.*, No. 3:07-CV-378, 2008 WL 2677049 (W.D. Ky. June 30, 2008), *aff'd sub nom. Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011).
- *Morris v. Wyeth, Inc.*, No. L07-CV-176, 2008 WL 2677048 (W.D. Ky. June 30, 2008), *aff'd sub nom. Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011).

LOUISIANA LAW

- *Whitener v. Pliva, Inc.*, 606 F. App'x 762 (5th Cir. 2015).
- *Johnson v. Teva Pharms. USA*, Inc., 758 F.3d 605 (5th Cir. 2014).
- *Demahy v. Schwarz Pharm., Inc.*, 702 F.3d 177 (5th Cir. 2012), *pet. for reh'g denied* (Dec. 7, 2012), *cert. denied* (Oct. 7, 2013).
- *Stanley v. Wyeth, Inc.*, 991 So. 2d 31 (La. Ct. App. 2008).

MARYLAND LAW

- *Gross v. Pfizer, Inc.*, No. 10-cv-00110, 2010 WL 4485774 (D. Md. Nov. 9, 2010).
- *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165 (4th Cir. 1994).

MASSACHUSETTS LAW

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

MISSISSIPPI LAW

- *Lashley v. Pfizer, Inc.*, 750 F.3d 470 (5th Cir. 2014).
- *Washington v. Medicis Pharm. Corp.*, No. 3:12-cv-00126, 2013 WL 496063 (S.D. Miss. Feb. 7, 2013).
- *Gardley-Starks v. Pfizer, Inc.*, 917 F. Supp. 2d 597 (N.D. Miss. 2013).

MINNESOTA LAW

- *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), re-instated in relevant part, 658 F.3d 867 (8th Cir. 2011).
- *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342 (Minn. Ct. App. 2001).

NEVADA LAW

- *Moretti v. Wyeth, Inc.*, 579 F. App'x 563 (9th Cir. 2014).
- *Baymiller v. Ranbaxy Pharms.*, Inc., 894 F. Supp. 2d 1302 (D. Nev. 2012).

NEW JERSEY LAW

- *Coundouris v. Wyeth*, No. ATL-L-1940-10, 2012 WL 2401776 (N.J. Super. Ct. Law Div. June 26, 2012).
- *Westerlund v. Wyeth*, Inc., No. MID-2174-05, 2008 WL 5592753 (N.J. Super. Ct. Law Div. Oct. 20, 2008).
- *Rossi v. Hoffman-LaRoche*, No. ATL-L-690-05, 2007 WL 7632318 (N.J. Super. Ct. Law Div. Jan. 3, 2007).
- *Sloan v. Wyeth*, No. MRS-L-1183-04, 2004 WL 5767103 (N.J. Super. Ct. Oct. 13, 2004).

NEW YORK LAW

- *Weese v. Pfizer*, Inc., No. 153742/12, slip op. (N.Y. Sup. Ct. Oct. 8, 2013).
- *Goldych v. Eli Lilly & Co.*, No. 5:04-CV-1477, 2006 WL 2038436 (N.D.N.Y. July 19, 2006).

NORTH CAROLINA LAW

- *Couick v. Wyeth, Inc.*, 691 F. Supp. 2d 643 (W.D.N.C. 2010).
- *Stoddard v. Wyeth, Inc.*, 630 F. Supp. 2d 631 (E.D.N.C. 2009).

OHIO LAW

- *Hendricks v. Pharmacia Corp.*, No. 2:12-cv-00613, ECF No. 47, Report and Recommendation of U.S. Magistrate Judge (S.D. Ohio June 4, 2014).
- *Hogue v. Pfizer, Inc.*, 893 F. Supp. 2d 914 (S.D. Ohio 2012).

OKLAHOMA LAW

- *Cardinal v. Elsevier Inc.*, No. 11-04442, slip op. (Mass. Super. Ct. Aug. 11, 2014).
- *Schrock v. Wyeth, Inc.*, 727 F.3d 1273 (10th Cir. 2013).

OREGON LAW

- *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); *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).

PENNSYLVANIA LAW

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

SOUTH CAROLINA LAW

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

TENNESSEE LAW

- *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378 (6th Cir. 2013).

TEXAS LAW

- *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674 (5th Cir. 2014).
- *Willis v. Schwarz-Pharm., Inc.,* 62 F. Supp. 3d 560 (E.D. Tex. July 23, 2014), adopting Report and Recommendation of U.S. Magistrate Judge (E.D. Tex. June 26, 2014).
- *Del Valle v. Teva Pharm. USA, Inc.*, 750 F.3d 470 (5th Cir. 2014).
- *Phares v. Actavis-Elizabeth L.L.C.*, 892 F. Supp. 2d 835 (S.D. Tex. 2012).
- *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).
- *Negron v. Teva Pharm. USA, Inc.*, No. 09-16519, 2010 WL 8357563 (Tex. Dist. Ct. May 7, 2010).
- *Finnicum v. Wyeth, Inc.*, 708 F. Supp. 2d 616 (E.D. Tex. 2010).
- *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).
- *Burke v. Wyeth, Inc.*, Civil No. G-09-82, 2009 WL 3698480 (S.D. Tex. Oct. 29, 2009).
- *Cousins v. Wyeth Pharm.*, Inc., No. 3:08-CV-0310-N, 2009 WL 648703 (N.D. Tex. Mar. 10, 2009).
- *Pustejovsky v. Wyeth, Inc.*, No. 4:07-CV-103-Y, 2008 WL 1314902 (N.D. Tex. Apr. 3, 2008).
- *Block v. Wyeth, Inc.*, 3:02-CV-1077, 2003 WL 203067 (N.D. Tex. Jan. 28, 2003).

UTAH LAW

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

WEST VIRGINIA LAW

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

MULTIPLE STATES' LAW

- *Germain v. Teva Pharms., USA, Inc. (In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig)*, 756 F.3d 917 (6th Cir. 2014) (68 appeals involving 22 different states' laws).
- *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.,* No. 2:11-MD-02226-DCR, 2013 WL 5184129 (E.D. Ky. July 29, 2013) (dismissing claims under Georgia and Texas law).
- *Esposito v. Lilly (In re Darvocet),* 856 F. Supp. 2d 904 (E.D. Ky. 2012) (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).
- *In re Darvocet, Damon & Propoxyphene Prods. Liab. Litig.,* No. 2:11-md-02226-DCR, 2012 WL 3984871 (E.D. Ky. Sept. 10, 2012) (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).
- *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.,* No. 2:11-md-02226-DCR, 2012 WL 3610237 (E D. Ky. Aug. 21, 2012) (dismissing claims under the law of 8 states, including Arkansas, Connecticut, Georgia, Kentucky, Louisiana, Massachusetts, Oklahoma and West Virginia).
- *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.,* No. 2:11-MD-02226-DCR, 2012 WL 767595 (ED. Ky. Mar. 7, 2012) (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). ■

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1. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, *reh'g denied*, 132 S. Ct. 55 (2011).
2. 29 F.3d 165 (4th Cir. 1994).
3. *Id.*
4. *Id.* at 170-71.
5. 168 Cal. App. 4th 89 (2008).
6. *Id.* at 109.
7. *Id.* at 110.
8. *Wyeth, Inc. v. Weeks*, 2013 Ala. Lexis 2, *59 (Ala. Jan. 17, 2013); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010).
9. The appendix lists 102 judicial decisions, applying the law of 30 states, holding that a brand-name drug manufacturer is not liable for injuries caused by a competitor's generic equivalent.
10. "What Do California, Vermont and Alabama Have In Common?" Pro Te: Solutio, Vol. 6 No. 3 (September 2013).
11. http://druganddevicelaw.blogspot.com/2014/12/thumbs-down-worst-prescription.html.
12. *Weeks*, 159 So. 3d at 673-674.
13. *Id.* at 674.
14. *Id.* at 677.
15. *Id.*
16. *Id.*
17. *Id.* at 684.
18. *Id.* (citing *Cuomo v. Clearing House Assn., L.L.C.*, 557 U.S. 519, 556 (2009)).
19. Act No. 2015-106.

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