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File Name: 09a0314p.06

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

ANGELA MONTGOMERY,
Plaintiff-Appellant,

v.

WYETH, fka American Home Products Corporation, AHP SUBSIDIARY HOLDING CORPORATION, fka Wyeth-Ayerst Laboratories Company; WYETH PHARMACEUTICALS, INC., fka Wyeth-Ayerst Pharmaceuticals, Inc.,
Defendants-Appellees.

No. 08-5701

Appeal from the United States District Court
for the Eastern District of Tennessee of Chattanooga.
No. 05-00323—Curtis L. Collier, District Judge.

Argued: January 14, 2009

Decided and Filed: August 28, 2009

Before: SUHRHEINRICH, GILMAN, and WHITE, Circuit Judges.

COUNSEL

ARGUED: Gregory J. Bubalo, BUBALO, HIESTAND & ROTMAN, PLC, Louisville, Kentucky, for Appellant. Michael T. Scott, REED SMITH LLP, Philadephia, Pennsylvania, for Appellees. **ON BRIEF:** Gregory J. Bubalo, D. Brian Rattliff, BUBALO, HIESTAND & ROTMAN, PLC, Louisville, Kentucky, Gregory F. Coleman, COLEMAN & EDWARDS, PSC, Knoxville, Tennessee, for Appellant. Michael T. Scott, REED SMITH LLP, Philadephia, Pennsylvania, Samuel L. Felker, BASS, BERRY & SIMS, Nashville, Tennessee, for Appellees. Michael D. Fishbein, LEVIN, FISHBEIN, SEDRAN & BERMAN, Philadelphia, Pennsylvania, for Amicus Curiae.

SUHRHEINRICH, J., delivered the opinion of the court, in which GILMAN, J., joined. WHITE, J. (pp. 20-23), delivered a separate opinion concurring in the affirmance.

OPINION

SUHRHEINRICH, Circuit Judge. Plaintiff Angela Montgomery sued Defendants Wyeth, Wyeth Pharmaceuticals, Inc., a wholly owned subsidiary of Wyeth, and AHP Subsidiary Holding Corporation, also a subsidiary of Wyeth, after she developed primary pulmonary hypertension ("PPH"), a serious, debilitating, and usually fatal disease, from ingesting "Fenphen,"a combination diet drug therapy that included Defendant Wyeth's diet drug, Pondimin.[1] The district court held that Montgomery's claim was barred by Tennessee's statute of repose, which requires that an action "be brought within one (1) year after the expiration of the anticipated life of the product." Tenn. Code Ann. § 29-28-103(a) ("TSOR").[2] Montgomery appeals.

[1]Pondimin was Wyeth's trade name for fenfluramine. As explained by the district court in the multidistrict litigation:

> Fenfluramine is an appetite suppressant that affects blood levels of the neurotransmitter, serotonin. Dexfenfluramine, the "d-isomer" of fenfluramine, is chemically related to fenfluramine and acts as an appetite suppressant by stimulating the release of serotonin from nerve cells in the brain and by reducing the reuptake of the released serotonin. In 1973, The United States Food and Drug Administration ("FDA") approved A.H. Robins, Inc.'s new drug application to market fenfluramine in the United States. . . .
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> Before 1989, A.H. Robins, Inc. was responsible for the marketing, sale and labeling of fenfluramine in the United States. In 1989, AHP acquired A.H. Robins. Following the acquisition, fenfluramine was marketed by AHP under the trade name "Pondimin." . . .
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> In 1992, a series of articles by Michael Weintraub, M.D., were published in the Journal of Clinical Pharmacology and Therapy, in which Dr. Weintraub advocated the use of fenfluramine together with the drug phentermine for weight loss management without the adverse side effects associated with the use of fenfluramine alone. This regimen popularly became known as "Fen-Phen." . . .
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> Dexfenfluramine, the chemical cousin of Pondimin, was developed by Les Laboratories Servier S.A. ("LLS") in France. The drug afforded the same anorexic effects as Pondimin without the need to add phentermine to ameliorate adverse side effects. Before 1994, the Lederle Division of American Cyanamid Company had the right, together with Interneuron Pharmaceuticals, Inc., to develop and promote dexfenfluramine in the United States under the trade name "Redux." In 1994, AHP acquired American Cyanamid. Following that acquisition, responsibility for the development and promotion of Redux in the United States in conjunction with Interneuron was assumed by AHP. Interneuron received approval to market Redux in the United States in mid-1996.

In re Diet Drugs, Nos. 1203, 99-20593, 2000 WL 1222042, at *1 (E.D. Pa. Aug. 28, 2000) ("PTO 1415").

[2]The products liability statute of repose provides as follows:

> Any action against a manufacturer or seller of a product for injury to person or property

I. Background

The FDA approved the sale of the Pondimin brand of fenfluramine 20 mg tablets as a prescription weight loss medication in 1973. Pondimin 20 mg tablets were manufactured in Richmond, Virginia, and distributed by Wyeth to pharmacies and wholesalers in 100-count and 500-count stock bottles. The expiration date for Pondimin 20 mg tablets was three years from the month of manufacture of each lot. The expiration date was printed on a label affixed to each stock bottle. Wyeth did not sell Pondimin 20 mg tablets directly to consumers. Instead the tablets were packaged by third parties. The product was withdrawn from the market in September 1997.

Montgomery began taking Pondimin in 1997. A Tennessee resident, Montgomery traveled to the Med-X Clinic in Fort Oglethorpe, Georgia, to receive treatment and prescriptions of Pondimin, which was not available in Tennessee at that time. Montgomery received her first treatment in January 1997 and went to Georgia at least eight times during 1997. Each time, she was evaluated by a Georgia physician. She was prescribed, and purchased, Pondimin on seven of those visits. Montgomery saw three doctors: Dr. Merton Sure, who has since died; Dr. David Hargett, who lost his medical license in January 2001; and Dr. Joyce Gray.

Pondimin became available in Tennessee as of March 26, 1997. Wyeth voluntarily withdrew Pondimin from the market on September 15, 1997, and did not manufacture, package, or distribute it after that time. Montgomery stopped using Pondimin in August 1997.

In December 1997, the Judicial Panel on Multidistrict Litigation established MDL No. 1203 in the Eastern District of Pennsylvania for consolidated proceedings

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> caused by its defective or unreasonably dangerous condition must be brought within the period fixed by §§ 28-3-104, 28-3-105, 28-3-202 and 47-2-725, but notwithstanding any exceptions to these provisions it must be brought within six years of the date of injury, in any event, the action must be brought within ten (10) years from the date on which the product was first purchased for use or consumption, *or within one (1) year after the expiration of the anticipated life of the product, whichever is the shorter*, except in the case of injury to minors whose action must be brought within a period of one (1) year after attaining the age of majority, whichever occurs sooner.

Tenn. Code Ann. § 29-28-103(a) (West 2008) (emphasis added).

relating to a wave of litigation involving Pondimin, Redux, and phentermine. *See In re Diet Drugs*, Nos. 1203, 99-20593, 2000 WL 1222042, at *1 (E.D. Pa. Aug. 28, 2000) ("PTO 1415"). On October 7, 1999, the numerous parties to the action reached an understanding of the principal terms of the settlement in a Memorandum of Understanding ("MOU"). *Id.* at *5. On October 12, 1999, a class action styled *Brown v. Wyeth* was filed on behalf of all users of Pondimin and Redux, in the Eastern District of Pennsylvania and became part of MDL 1203. *Id.*, at *19. Montgomery is a member of the *Brown* class. On November 18, 1999, the parties executed a Nationwide Class Action Settlement Agreement ("Settlement Agreement"), which included the *Brown* class members. On August 28, 2000, the district court entered PTO 1415, which certified the class and approved the Settlement Agreement. *See id.*

Montgomery was not diagnosed with PPH until April 2005. She filed the present action in Tennessee state court in October 2005, within six months after being diagnosed. The case was removed to the United States District Court for the Eastern District of Tennessee, transferred to the MDL for pretrial proceedings in February 2006, and then remanded to the district court in July 2007. Defendants moved for summary judgment, alleging that Montgomery's claim was barred by the TSOR because it had not been brought within one year of the expiration date of the product. The district court reluctantly agreed and granted summary judgment to Defendants on March 19, 2008. Specifically, the court concluded that the TSOR applied to Montgomery's claim under Tennessee's conflict-of-laws rules, the Settlement Agreement did not preserve her right to sue for PPH, Tennessee law rather than Georgia law applied, and Wyeth did not waive its statute of repose defense. *See Montgomery v. Wyeth*, 540 F. Supp. 2d 933 (E.D. Tenn. 2008). The court also denied Montgomery's Rule 59 motion to alter or amend judgment. This appeal followed.

II. Analysis

This Court reviews a district court's grant of summary judgment de novo. *Gribcheck v. Runyon*, 245 F.3d 547, 550 (6th Cir. 2001). Summary judgment is proper if "the pleadings, the discovery and disclosure materials on file, and any affidavits show

that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

A. Choice of Law

Montgomery argues that the district court erred in applying Tennessee law because the relevant choice-of-law principles dictate that Georgia law should govern. As noted, the district court held that the TSOR barred Montgomery's claim. There is a conflict because Georgia's statute of repose, which limits claims only after ten years, would not bar her claim. *See* Ga. Code Ann. § 51-1-11 (West 2008) (stating that "[n]o action shall be commenced pursuant to this subsection with respect to an injury after ten years from the date of the first sale for use or consumption of the personal property causing or otherwise bringing about the injury").

Because this is a diversity action, the law of the forum state, including the choice-of-law rules, apply. *Uhl v. Komatsu Forklift Co.*, 512 F.3d 294, 302 (6th Cir. 2008). Tennessee follows the "most significant relationship" approach of the Restatement (Second) of Conflict of Laws to choice-of-law questions. *Hataway v. McKinley*, 830 S.W.2d 53, 59 (Tenn. 1992). Under this approach, "the law of the state where the injury occurred will be applied unless some other state has a more significant relationship to the litigation." *Id.* at 59. [3] Tennessee adopted this position "because

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[3]The Restatement provides:

> § 145 The General Principle
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> (1) The rights and liabilities of the parties with respect to an issue in tort are determined by the local law of the state, which with respect to that issue, has the most significant relationship to the occurrence and the parties under the principles stated in § 6.

Hataway, 830 S.W.2d at 59 (quoting Restatement (Second) of Conflict of Laws § 145 (1971)).

> The relevant principles to consider are:
>
> (a) the needs of the interstate and international systems,
> (b) the relevant policies of the forum,
> (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue,
> (d) the protection of justified expectations,
> (e) the basic policies underlying the particular field of law,
> (f) certainty, predictability, and uniformity of result, and
> (g) ease in the determination and application of the law to be applied.

generally the law of the state where the injury occurred will have the most significant relationship to the litigation." *Id.* Thus, the most significant relationship "provides a 'default' rule whereby trial courts can apply the law of the place where the injury occurred when each state has an almost equal relationship to the litigation." *Id.*

Contacts to be considered in determining which state has the most significant relationship include (1) the place where the injury occurred, (2) the place where the conduct causing the injury occurred, (3) the domicile, residence, nationality, place of incorporation and place of business of the parties, and (4) the place where the relationship, if any, between the parties is centered. *Id.* at 59 (quoting § 145(2)).

The district court analyzed these four factors. First, the court noted that the place of injury is not obvious when the injury is a latent disease, like PPH, and that there is no Tennessee law for determining where a latent injury is suffered. However, the court also noted that there was no indication that Montgomery suffered from PPH in Georgia. The court therefore concluded that because she developed her injury while living in Tennessee, her place of injury is Tennessee. The court reasoned that this conclusion was consistent with the language of Tennessee's product liability statute of limitations, which states that a cause of action accrues when a plaintiff suffers her injury, not when she purchases the product. *See* Tenn. Code Ann. § 28-3-104(b)(1). Second, the district court determined that the conduct causing the injury occurred in Georgia because Montgomery bought Pondimin from a clinic in Georgia. The court noted that the drug was prescribed by Georgia doctors, and that she signed a consent form with a Georgia clinic. Furthermore, the Georgia doctors allegedly relied on false information from Wyeth. Third, the district court observed that Montgomery lived in Tennessee during the relevant periods and that Wyeth is incorporated in Delaware with its principal place of business in New Jersey. Lastly, the court determined that "the indirect relationship Plaintiff and Defendant had in Georgia weighs in favor of Georgia, but is weak." *See Montgomery v. Wyeth*, 540 F. Supp. 2d 933, 944 (E.D. Tenn. 2008).

Id. at 59 n.3 (quoting Restatement (Second) of Conflict of Laws § 6(2) (1971)).

Weighing these factors, the district court concluded that Tennessee had the most significant relationship because Tennessee was where Montgomery consumed the Pondimin and suffered her injury. By contrast, the only contact she had with Georgia was that she purchased the product from a third party there. *See id*. at 944-945.

On appeal, Montgomery claims that all the key events occurred in Georgia and that application of the TSOR does not promote any interest of the state of Tennessee. We agree with the district court that Tennessee has the most significant relationship to the parties and the occurrence at issue. Although it has not ruled on the issue of latent injury, the Tennessee Supreme Court has commented, in the context of adopting the discovery rule for malpractice actions, that where the "injury complained of, and the harmful effect thereof develops gradually over a period of time, the injury is 'sustained' . . . when the harmful effect first manifests itself and becomes physically ascertainable." *Teeters v. Curry*, 518 S.W.2d, 512, 517 (Tenn. 1974) (quoting *Layton v. Allen*, 246 A.2d 974, 978 (Del. 1968) (holding that a cause of action for medical malpractice accrues and the statute of limitations begins to run when the patient discovers or reasonably should have discovered the injury)). Further, based on the assertions in the complaint and evidence in the record, Tennessee has the most significant relationship to the parties and the occurrence because Tennessee is where Montgomery sustained her injury, Tennessee is her place of domicile and residence, Tennessee is where she intended to and did use almost all of her Pondimin tablets, and Tennessee is the state where she was diagnosed and treated for her injury. Wyeth also conducted business in Tennessee, where Pondimin was expected to be used by customers like Montgomery, and where it was in fact sold during most of the time Montgomery used it.[4] *Cf. Trahan v. E.R. Squibb & Sons, Inc.*, 567 F. Supp. 505 (M.D. Tenn. 1983) (applying the *lex loci* approach, holding that Tennessee law rather than North Carolina law applied to the plaintiff's claim against the defendant manufacturer of DES, although the plaintiff's mother ingested the drug

[4]Although Pondimin was banned for sale in Tennessee part of the time Montgomery was taking it, its *use* was always permitted. Tennessee residents were induced to obtain Pondimin through third-party advertising in Tennessee, and it was lawfully sold in at least 700 Tennessee pharmacies during most of the time Montgomery used it. It became legal to prescribe Fenphen in Tennessee on March 27, 1997, two months after Montgomery started taking Pondimin.

while pregnant in North Carolina, because the plaintiff moved to Tennessee, became pregnant, and was diagnosed with an incompetent cervix there).

Although Montgomery obtained Pondimin in Georgia, she received Pondimin from a third party. She took at most a few tablets there, and she does not claim to have suffered any symptoms in Georgia. None of the parties are current or former residents of Georgia. Montgomery alleges that her prescribing physicians received inadequate warnings from Wyeth in Georgia. However, there is no support in the record that her prescribing doctors reviewed Wyeth's inadequate warnings, relied on any other statements made by Wyeth, or were uninformed about the risks of Pondimin when they prescribed it to Montgomery in 1997. Thus, Montgomery's relationship with Wyeth is more significant in Tennessee, the state where she actually used the manufacturer's product and suffered the resulting injury, rather than Georgia, the state where she obtained the product through a third party.

Montgomery claims that all of the wrongful acts were consummated in Georgia because she was not fully informed of the risks at the prescribing clinic. She claims that she relied on her prescribing doctors at the Med-X Clinic to know the risks of Pondimin and she signed a consent form at the clinic stating that such consent was necessary pursuant to Georgia law and also that her treating physicians were licensed to practice in Georgia. She further claims that Wyeth did not adequately inform these doctors about the risks of its drugs. In support, she provides the testimony of Dr. Leon Lane, M.D., the Medical Director of Med-X Clinic at the time of her treatment. Dr. Lane testified that its consent form was inadequate because it was based on Wyeth's 1996 labeling, which did not highlight the risks for VHD and PPH. She also points out that the 1996 Physicians Desk Reference ("PDR"), which was sent to the Med-X Clinic, mentioned only four reported cases of pulmonary hypertension worldwide associated with Pondimin use and no cases of PPH, despite the fact that Wyeth was aware of more than fifty cases of PPH by May, 1996.

However, Montgomery offers no proof that either Dr. Shure or Dr. Hargett reviewed Wyeth's warnings or any other statements made by Wyeth. Dr. Lane did not

provide any evidence about the information Drs. Shure or Hargett had about Pondimin, and he did not work at the clinic when Dr. Hargett first prescribed Pondimin to Montgomery in June 1997. Dr. Lane offered no evidence relating to the Pondimin labeling in effect when Montgomery was prescribed Pondimin in 1997. Dr. Lane's testimony about the clinic's consent form is irrelevant because it did not contain any statements made by Wyeth and he did not draft it. In short, this evidence does not establish that Georgia's contacts are more significant than Tennessee's.

Our decision in *In re Bendictin Litig.*, 857 F.2d 290 (6th Cir. 1988), does not help Montgomery. As the district court noted, *Bendectin* applied Ohio law under Ohio choice-of-law rules because the drug was manufactured in Ohio, where the manufacturer also maintained its principal place of business. Pondimin was manufactured in Virginia, and the Wyeth entities maintain their principal places of business in Pennsylvania and New Jersey. *Bendectin* does not support the proposition that Georgia law should apply simply because the product was sold there.

In further support of its conclusion that Tennessee law should apply, the district court applied the choice-of-law principles from § 6 of the Restatement (Second) Conflict of Laws:

> [T]he principles in the Restatement . . . suggest Tennessee law should apply. Plaintiff argues Tennessee has an interest in compensating its resident and Georgia has an interest in regulating a product sold in its state. But this argument fails. Tennessee's interest is not in compensating its resident for harm done to her. Such an interest may be a good idea, but that is a decision for the General Assembly, not the Court. The policy of Tennessee as exemplified through its statute of repose is that residents who suffer from diseases with long incubation or latency periods are not entitled to recover for harms done to them. Although this statute is designed to limit product liability costs for manufacturers and sellers, it is not inapplicable merely because the product was not purchased in Tennessee. Pondimin was sold for a short period of time in Tennessee, and PPH is not the only latent disease for which the legislature decided not to create an exception. To the extent Tennessee wants to protect Pondimin's manufacturers and sellers from product liability costs, the statute advances that goal. And while Georgia does have an interest in regulating a product sold there, Tennessee has an

> interest in regulating a product used here; it chooses to effect that interest by strictly limiting the time that actions can be brought.

Montgomery, 540 F. Supp. 2d at 945. The court further noted that, while not dispositive, the parties had already relied exclusively on Tennessee law. *Id.*

Montgomery claims that the district court failed to consider whether the TSOR, as applied to *this case*, outweighed "relevant policies of other states and the relative interests of those states in the determination of the particular issue." Restatement (Second) of Conflict of Laws §§ 6(b) and (c). *See also* Restatement (Second) of Conflict of Laws, § 145, cmt. c (stating that "the interest of a state in having its tort rule applied in the determination of a particular issue will depend upon the purpose sought to be achieved by that rule and by the relation of the state to the occurrence and the parties"). She also asserts that Tennessee has no interest in a claim that is barred by Tennessee law. Thus, Montgomery contends that, as applied to this case, the TSOR does not advance Tennessee's interest in controlling insurance rates. Further, she notes that numerous authorities have noted that statutes like the TSOR do not actually lower insurance premiums, including this Court in *Kochins v. Linden-Alimak, Inc.*, 799 F.2d 1128, 1140 (6th Cir. 1986) (acknowledging that the legislative goals of the TSOR are not likely to be accomplished by the means selected based on the views of various authorities).

The primary flaw in Montgomery's argument is that it focuses on the outcome of applying Tennessee's statute of repose rather than on the significance of Tennessee's relationship to the parties and the place of injury as required by *Hataway*. Tennessee's choice-of-law analysis does not turn on whether a plaintiff has a viable claim in one state but not another. *See* Restatement (Second) of Conflict of Laws § 145, cmt. c ("A rule which exempts the actor from liability for harmful conduct is entitled to the same consideration in the choice-of-law process as a rule which imposes liability"; *see also Smith v. Priority Transp., Inc.*, No. 02A01-9203-CV-00074, 1993 WL 29021, at *3 (Tenn. Ct. App. Feb. 9, 1993) (holding that Mississippi law applied to a Mississippi resident's claim for retaliatory discharge from his job in Mississippi for filing a worker's compensation claim even though Mississippi did not recognize such a claim and

Tennessee did); *Cruz v. Ford Motor Co.*, 435 F. Supp. 2d 701, 707 (W.D. Tenn. 2006) (holding that Michigan law barring the plaintiff's claim for punitive damages applied, even though Tennessee would have allowed it).

As the Tennessee Supreme Court has recognized, the Tennessee products liability statute of repose "was enacted as an important and specific measure to address products liability actions." *Penley v. Honda Motor Co.*, 31 S.W.3d 181, 187 (Tenn. 2000); *see also Jones v. Five Star Eng'g Inc.*, 717 S.W.2d 882, 883 (Tenn. 1986) ("The statute in question was enacted after lengthy debates and full consideration by the General Assembly. In our opinion it represents a reasonable balancing of the conflicting interests and concerns with which the Legislature had to deal."). The preamble to Tennessee Products Liability Act ("TPLA") states:

> WHEREAS, The General Assembly finds and declares that the number of product liability suits and claims for damages and the amount of judgments, settlements and the expense of defending such suits have increased greatly in recent years, and because of these increases[,] the cost of product liability insurance was substantially increased.

Penley, 31 S.W.3d at 187 (quoting preamble). In *Penley*, the Tennessee Supreme Court explained:

> As the preamble to the TLPA indicates, the General Assembly perceived that uncertainty as to future liability increased the premiums for product liability insurance, which in turn increased the costs of production and ultimately consumer prices. The legislature considered the limitation of future liability to a reasonable and specific period to be one of the most important keys in solving the perceived products liability crisis.

Penley, 31 S.W.2d at 187.

We are not in a position to alter this policy decision of the state legislature. Indeed, this Court and the Tennessee Supreme Court have repeatedly upheld the constitutionality of the TSOR. *See Kochins*, 799 F.2d 1128; *Mathis v. Eli Lilly & Co.*, 719 F.2d 134 (6th Cir. 1983); *Hayes v. Gen. Motors Corp.*, No. 95-5713; 94 F.3d 644, 1996 WL 452916, *4 (6th Cir. Aug. 8, 1996) (unpublished per curiam); *Jones v. Five Star Eng'g, Inc.*, 717 S.W.2d 882 (Tenn. 1986); *Harmon v. Angus R. Jessup Assocs.*,

Inc., 619 S.W.2d 522 (Tenn. 1981); *Harrison v. Schrader*, 569 S.W.2d 822 (Tenn. 1978); *see also Spence v. Miles Lab., Inc.*, 810 F. Supp. 952, 960-61 (E.D. Tenn.1992), *aff'd*, 37 F.3d 1185 (6th Cir.1994); *Stutts v. Ford Motor Co.*, 574 F. Supp. 100 (M.D. Tenn. 1983). And this Court has rejected the criticisms made by Montgomery. *See Kochins*, 799 F.2d at 1139-40 (recognizing that evidence in support of fact that the statute actually reduced the cost of product liability insurance was lacking, but noting a rational basis existed between the TSOR and goals expressed in the preamble). Montgomery's claim that liability is more likely to be determined on a national basis ignores the fact that assessing liability based on the laws of each state would obviously be part of that calculation. In short, as the district court held, Tennessee has a strong interest is applying its statute of repose in products liability actions, even when that forecloses a claim by a Tennessee plaintiff.

In sum, although Georgia has an interest because Montgomery was prescribed Pondimin there, we agree with the district court's conclusion that Tennessee has the stronger interest for the purpose of the choice-of-law analysis. *Cf. Lemons v. Cloer*, 206 S.W.3d 60 (Tenn. Ct. App. 2006) (holding that Georgia had the more significant relationship to bus accident that occurred in Tennessee since all of the children on the bus were Georgia residents from a Georgia school district, even though Tennessee emergency and medical personnel responded to the accident and injured parties were taken to Tennessee hospitals).

B. Class Action

Montgomery also contends that the district court erred in applying the TSOR to dismiss this action. She argues that the TSOR was satisfied because she made a claim "for injury to person or property" as a member of the *Brown* class, which was certified before the TSOR would have barred her claim. She further claims that the class included both diagnosed and latent PPH claims and claimants, and that the PPH claims were fully preserved and remained subject to the retained jurisdiction of the MDL court. Finally she notes that she was enjoined from bringing this action until she satisfied the settlement definition of PPH and could not have filed this action any earlier.

Montgomery was a member of the *Brown* class, which was approved for settlement by the court responsible in MDL 1203. This class was certified to include "All persons . . . who ingested Pondimin." Upon settlement, the MDL court dismissed the class action, so the case is no longer pending. *See In re Diet Drugs*, PTO 1415, 2000 WL 1222042, at *71 (stating that "[t]he court hereby dismisses, with prejudice . . . the Third Amended Complaint in this action"). However, the *Brown* Class complaint expressly stated that PPH claims were not being asserted. The paragraph that defines the class clearly provides that "[t]he proposed class and subclasses do not include any claims based upon a diagnosis by a qualified physician of primary pulmonary hypertension ("PPH") suffered by a diet drug recipient."

The Settlement Agreement also expressly states that it does not include claims based on PPH: "Notwithstanding the foregoing, Settled Claims do not include claims based on PPH." *In re Diet Drugs*, PTO 1415, 2000 WL 1222042, at *31 (stating that "[u]nder the Settlement Agreement, claims based on PPH, including claims for compensatory, punitive, exemplary or multiple damages based on PPH are not 'settled claims'"); *In re Diet Drugs*, MDL 1203, NO. 04-23744, 2006 WL 1050289, at *1 (E.D. Pa. April 20, 2006) (stating that "[t]he Settlement Agreement exempts from the definition of 'settled claims' those claims based on PPH and allows a class member with this condition to sue Wyeth in the tort system").

At the same time, the Settlement Agreement "fully preserves" the rights of persons who have or develop PPH to sue. *See In re Diet Drugs*, PTO 1415, 2000 WL 1222042, at *31. The Settlement Agreement defines PPH, and limits a plaintiff from suing until she meets that definition.

Section VIII.B.1 of the Settlement Agreement, and PTO 1415, ¶ 11, retain the district court's continuing and exclusive jurisdiction over the action, including Defendants and the class members, to administer, supervise, interpret, and enforce the settlement in accordance with its terms and to enter such orders as necessary. *See In re Diet Drugs*, PTO 1415, 2000 WL 1222042, at *72, ¶ 11. PTO 2383, entered on February 26, 2002, authorizes the district court to enforce PTO 1415, including but not limited to

injunctive relief against any Class Member who has asserted a claim based on PPH, but whose medical condition does not meet the criteria set out in the Settlement Agreement.

The Settlement Agreement bars Wyeth from asserting a limitations defense "unless and until the condition of the Class Member meets the definition of PPH set forth" in the Settlement Agreement. The Settlement Agreement expressly provides:

> For purposes of any statute of limitations or similar time bar, the AHP Released Parties shall not assert that a Class Member actually had PPH unless and until the condition of the Class Member meets the definition of PPH set forth in Section I.46.
>
> In the event that a Class Member initiates a claim based on PPH, the AHP Released Parties shall not assert a defense based on "splitting" of claims, causes of action and/or parties by virtue of the fact that the Class Member is included in the Settlement, but the claim based on PPH is not a Settled Claim.

The first facet of Montgomery's argument–that any claim will suffice to preserve the cause of action–is unpersuasive. In requiring that an "action against the manufacturer . . . of a product for injury to person . . . caused by its defective or unreasonably dangerous condition" be "brought" within a certain time, § 29-28-103 does not suggest that *any* action against the manufacturer brought within the statute of repose preserves the ability to claim *different* injuries in the future. *See* Tenn. Code Ann. § 29-28-103. The straightforward reading of § 29-28-103 requires that an action for the injury for which a plaintiff seeks to recover be brought within the statute of repose.

Cronin v. Howe, 906 S.W.2d 910 (Tenn. 1995), does not support Montgomery's argument. In *Cronin*, the plaintiff's medical malpractice claim was timely filed and then dismissed without prejudice before it was refiled under the Tennessee savings statute, § 28-1-105(a) (providing that if an action is filed within the statute of limitations and a judgment of dismissal entered on any ground not concluding the right of action, the action may be refiled within one year of the dismissal). Under those circumstances, the Tennessee Supreme Court held that the applicable statute of repose did not bar the plaintiff's claim. Here, however, Montgomery did not file her PPH claim within the statute of repose, *cf. id.* at 914, and she did not refile her claim following dismissal of

the initial action within the one-year period allowed by any savings statute. *Cf. id.* at 911. In short, Montgomery never filed a timely claim for PPH and no savings statute is applicable. Although her class action claim was based on the use of Pondimin, the harm asserted was not PPH. She did not file that claim until 2005.

The second facet of Montgomery's argument–that the Settlement Agreement preserved her PPH claim–is also unpersuasive. As noted above, the Settlement Agreement expressly excludes claims for PPH. Thus, the Settlement Agreement did not purport to dismiss PPH claims because they were never asserted in the first place. Instead, the Settlement Agreement left the PPH claims unsettled and created limitations upon the defendants' ability to raise certain defenses when those claims were presented. While it precluded Wyeth from raising "statute of limitations or similar" defenses, or claim preclusion, it did not bar Wyeth from raising the statute of repose. By contrast, elsewhere, for those class members exercising certain opt-out rights and asserting valvular heart disease claims, the Settlement Agreement prevents Wyeth from asserting "any defense based on any statute of limitations or repose, the doctrine of laches, or any other defense predicated on failure to timely pursue the claim." As the district court noted, it is apparent that the drafters of the Settlement Agreement knew how to bar a statute of repose defense, but obviously did not include such a provision with respect to PPH claims. Thus, the Settlement Agreement limits Wyeth's ability to raise a statute of limitations defense or to claim that a Class Member actually had PPH such that her subsequent claim would be precluded, but it does not bar Wyeth from raising the statute of repose.[5]

Montgomery also complains that the Settlement Agreement prevented her from bringing a PPH claim before she had a confirmed PPH diagnosis as defined in the Settlement Agreement. However, as the district court explained:

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[5]Assuming that the Nationwide Settlement Agreement did not exist, any claim under Tennessee law relating to the use of Pondimin would be barred unless brought by September 2001. Had Montgomery opted out of the *Brown* class, she still would have had to comply with Tennessee's statute of repose. Had she opted out by the March 2000 deadline and brought suit after her diagnosis in 2005, her claim would still be barred by the statute of repose.

> That definition is a contractual provision in a freely-negotiated settlement about which all class members had notice and an opportunity to object. *In re Diet Drugs*, *MDL 1203 PTO 2623*, 2002 U.S. Dist. LEXIS 20323, *11 (E.D.Pa. Oct. 8, 2002). The settlement agreement gives class members with PPH "a right to the full and complete relief allowed by law." *In re Diet Drugs*, *MDL 1203 PTO 3085*, 2003 WL 22669132, *1, 2003 U.S. Dist. LEXIS 20221, *16 (E.D.Pa. Oct. 24, 2003). The problem for Plaintiff is the settlement agreement cannot change Tennessee substantive law. *See In re Diet Drugs*, *PTO 2623*, 2002 U.S. Dist. LEXIS 20323 at * 13 ("Any PPH claim, of course, will be subject to the substantive law and evidentiary and procedural rules of the place where the claim is being litigated.").
>
> Plaintiff complains the settlement agreement prevented her from asserting her PPH claim until the PPH definition was met. The parties contractually agreed as to the administration of PPH claims, but could not create a substantive claim that is barred by Tennessee law. Furthermore, the PPH definition was articulated by leading medical experts and has never been challenged as inaccurate. *In re Diet Drugs, PTO 3085*, 2003 WL 22669132, at *2, 2003 U.S. Dist. LEXIS 20221 at *17; *In re Diet Drugs, PTO 2623*, 2002 U.S. Dist. LEXIS 20323 at *11. "If anything, the definition is more generous to claimants than it might otherwise have been." *In re Diet Drugs, PTO 3085*, 2003 WL 22669132 at *2, 2003 U.S. Dist. LEXIS 20221 at * 17. Therefore, the settlement agreement is not what prevented Plaintiff from asserting her right to sue for PPH. The prohibition is that she developed PPH after the statute of repose period.

Montgomery, 540 F. Supp. 2d at 941. Although the result is harsh in this case, it derives from both the contractual arrangements of the nationwide Settlement Agreement and the state law of Tennessee, namely the severe one-year statute of repose for products liability actions. It did not result from any legal error by the district court.

C. Expiration Date

Montgomery also claims that the district court misapplied the TSOR because there were no expiration dates on the product dispensed to her. Defendants acknowledge that Montgomery did not get the pills in their original packaging because they were repackaged by the distributor who bought them from Wyeth and sold them to Montgomery.

The "anticipated life of the product" is the "expiration date placed on the product by the manufacturer when required by law but shall not commence until the date the product was first purchased for use or consumption." Tenn. Code Ann. § 29-28-102.[6] As the district court observed, Wyeth stopped manufacturing Pondimin on September 2, 1997. Wyeth offered uncontested evidence that packaging for Pondimin contained the expiration dates as required by law, and those expiration dates were three years from the date of manufacture. Thus, the expirations were at the latest September 2000. Montgomery filed this case in October 2005. Because the undisputed evidence establishes that all Pondimin tablets had an expiration date of five or more years before Montgomery brought this suit, there is no genuine issue of material fact as to the expiration date for purposes of applying the TSOR.

Contrary to Montgomery's assertion, the TSOR does not require that the purchaser have knowledge of the expiration date, but conditions the anticipated life of the product on the expiration date imposed by the manufacturer. This reading of the statute is consistent with the legislative intent. As this Court has noted, the statute of repose operates when "parties may be ignorant about the particular time limitations involved. Thus, a delay, even without knowledge of the hazard involved in the delay, may preclude the bringing of an otherwise meritorious claim." *Mathis*, 719 F.2d at 140 (holding that the application of ten-year limitation in TSOR does not violate a party's due process rights). However harsh the result, this is a decision of the Tennessee legislature. "Statutes of limitation find their justification in necessity and convenience rather than logic. . . . They represent a *public policy* about the privilege to litigate." *Id.* (quoting *Chase Sec. Corp. v. Donaldson*, 325 U.S. 304, 314 (1945)).

Our decision in *Spence v. Miles Lab.*, 37 F.3d 1185 (6th Cir.1994), is virtually identical. There we held the product liability claim was barred by the statute of repose

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[6]Tenn Code Ann. § 29-28-102 provides in pertinent part:

(1) "Anticipated life." The anticipated life of a product shall be determined by the expiration date placed on the product by the manufacturer when required by law but shall not commence until the date the product was first purchased for use or consumption[.]

Tenn. Code Ann. § 29-28-102 (West 2008).

because the expiration date on a package of blood (which was infected with AIDS and was transferred to the plaintiff) was June 5, 1987, and the plaintiff had filed his product liability claim more than one year after that date, despite the fact that he filed his action less than one year after discovering he had AIDS. *Id*. at 1188, 1190. As the district court held, *Spence* controls the result in this case.

D. Waiver

Last, Montgomery contends that the district court erred in finding that Defendants had not waived their statute of repose defense. Montgomery argues that Defendants did not raise it in their Answer and waited more than thirty-two months after the action was filed to assert it.

The district court ruled that Defendants sufficiently pleaded the statute of repose defense because their Answer states that "Plaintiff's causes of action are barred in whole or in part by the applicable statutes of limitations and repose," and their affirmative defenses include the "defenses of the Tennessee Products Liability Act of 1978, as codified in [Tenn. Code Ann.] §§ 29-28-101 through 108." (Court File No. 8, pp. 2 & 32).

We agree. The Federal Rules of Civil Procedure do not require a heightened pleading standard for a statute of repose defense. Rule 8(b)(1) provides generally that "[i]n responding to a pleading, a party must . . . state in short and plain terms its defenses to each claim." Rule 8(d)(1) requires that averments in pleadings be "simple, concise, and direct," and that "[n]o technical form is required." Fed. R. Civ. P. 8(b)(1). *Cf. Conley v. Gibson*, 355 U.S. 41, 47 (1957) (stating that a plaintiff must simply "give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests"). It also states that a party may state as many defenses as it has, regardless of consistency. Fed. R. Civ. P. 8(d)(3).

The averments cited above satisfy this standard. The TSOR is codified at subsection 29-28-103, and is plainly one of the defenses asserted. Thus, it cannot be

said that Wyeth waived the defense when it both presented it in its Answer and then filed its motion for summary judgment before the dispositive motion deadline.[7]

III. Conclusion

For the foregoing reasons, as well as those in the district court's thorough and thoughtful opinion, the judgment of the district court is **AFFIRMED**.

[7] As noted by the district court, even if Defendants had not relied on the statute of repose in their answer, the TSOR was probably not a waivable affirmative defense under Tennessee law. Although federal law governs procedural rules, including when waiver occurs, state law defines the nature of defenses. *Roskam Baking Co., Inc. v. Lanham Mach. Co.*, 288 F.3d 895, 901 (6th Cir. 2002). The Tennessee Supreme Court has held that, unlike a statute of limitations, a statute of repose is substantive rather than procedural. A statute of limitations nullifies a party's remedy, but a statute of repose extinguishes both the right and the remedy. *See Cronin*, 906 S.W.2d at 913 (agreeing that statutes of repose are substantive as opposed to procedural). However, as the district court also noted, in 2006, Tennessee Rule of Civil Procedure 8.03 was amended to add the statute of repose as an affirmative defense that must be pleaded in an answer. *Cf. Roskam*, 288 F.3d at 902 (concluding that Michigan's statute of repose for product liability actions was substantive rather than procedural; noting that the Michigan Court Rules do not include statute of repose in nonexhaustive list of affirmative defenses). As the district court also noted, because Defendants' answer asserted the statute of repose, we need not decide whether Tenn. R. Civ. P. 8.03 would apply retroactively. *See Wyeth*, 540 F. Supp. 2d at 942 n.7.

CONCURRING IN THE AFFIRMANCE

WHITE, Circuit Judge, concurring. Reluctantly, I concur in the affirmance. I write separately to further address the Multidistrict Litigation (MDL) settlement (Settlement Agreement), and to observe that the Eastern District of Pennsylvania would have been much better suited to decide this motion.

As the majority explained, the Judicial Panel on Multidistrict Litigation (JPML) established MDL 1203 in the Eastern District of Pennsylvania. The instant case was initially transferred to the MDL court and that court oversaw pretrial proceedings in this case before remanding it back to the Eastern District of Tennessee in July 2007. On January 14, 2008, Wyeth moved for summary judgment based on the Tennessee statute of repose (TSOR). In addition to her arguments that Wyeth had waived the TSOR defense by failing to timely assert it and that Georgia law should apply, Montgomery argued that her PPH claim was preserved by the MDL and Settlement Agreement.

Montgomery was a plaintiff in the MDL.[1] The complaint in that action was filed within the time allowed by the TSOR. While PPH claims were not "settled claims," they were clearly part of the litigation until settlement, and the MDL court expressly exercised jurisdiction over those claims in approving the settlement.[2] Further the Settlement Agreement defined PPH and addressed the rights of PPH claimants. Thus, any assessment of the timeliness of Montgomery's PPH claim necessitates an examination of the nationwide Class Action Settlement Agreement, approved by the Pennsylvania court.

[1]The Settlement Class included "All persons . . . who ingested Pondimin and/or Redux" except those whose claims had previously been resolved through litigation or settlement. (ROA, Vol. 6, at 1028.)

[2]Pretrial Order 1415 stated: "The court has jurisdiction over the subject matter of this action with respect to all claims, and has jurisdiction over all parties to this action, including all members of the settlement class and subclasses defined below." *In re Diet Drugs*, Nos. 1203, 99-20593, 2000 WL 1222042, at *69 (E.D. Pa. Aug. 28, 2000).

Both the Settlement Agreement and Pretrial Order (PTO) 1415 state that the Eastern District of Pennsylvania "retains continuing and exclusive jurisdiction over this action and each of the Parties . . . to administer, supervise, interpret and enforce the Settlement in accordance with its terms." *In re Diet Drugs*, Nos. 1203, 99-20593, 2000 WL 1222042, at *72 (E.D. Pa. Aug. 28, 2000). Although it can be argued that Wyeth's motion is based on a statute unique to Tennessee, the primacy of the interpretation and effect of the Settlement Agreement and PTO 1415 in resolving the issue is apparent. For this reason, Wyeth should have moved for summary judgment during the pretrial proceedings in Pennsylvania. *See Humphreys v. Tann*, 487 F.2d 666, 667-68 (6th Cir. 1973) (holding that a MDL transferee court has authority to hear motions for summary judgment as part of pretrial proceedings); *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 38 (D. D.C. 2007) (noting that the transferee court's "familiarity with the issues in this case – a case which by now encompasses a voluminous docket – as well as the many related issues in the other cases in this MDL, indicates that it would be much more efficient to proceed to summary judgment motions in this Court rather than to ask the transferor court to play catch-up"); *Kaiser Indus. Corp. v. Wheeling- Pittsburgh Steel Corp.*, 328 F. Supp. 365, 370-71 (D. Del. 1971) (looking at the relevant legislative history and concluding that Congress intended "to grant to the transferee district court under §1407 the power to pass upon all pretrial motions including motions to dismiss, motions for judgment on the pleadings, or motions for summary judgment"); *see also* 28 U.S.C. § 1407(a) ("Each action so transferred shall be remanded by the panel at or before the conclusion of such pretrial proceedings to the district from which it was transferred unless it shall have been previously terminated . . . ."). *But cf. In re Accutane Prods. Liab. Litig.*, 560 F. Supp. 2d 1370, 1370-71 (J.P.M.L. 2008) (vacating a transfer order that would consolidate the case as part of a MDL because the pending motion for summary judgment involved issues of state law unique to the plaintiff).

In opposing Wyeth's motion for summary judgment, Montgomery asserted that her PPH claim was preserved by the commencement of the MDL and also by the Settlement Agreement. While the former assertion is easily addressed as a pure question

of Tennessee law, the latter requires an interpretation of the Settlement Agreement in light of the MDL proceedings.

Regarding the former assertion, I do not agree with the majority that the MDL did not commence an action within the TSOR. As stated above, Montgomery was a member of the class, the action was brought within the TSOR, and the court expressly exercised jurisdiction over all claims. The fact that PPH claims were not settled does not alter these facts. Nevertheless, I cannot agree with Montgomery's essential assertion that the PPH claims were pending before the Eastern District of Pennsylvania after the dismissal of the MDL. While the MDL court retained jurisdiction to "administer, supervise, interpret and enforce" the Settlement Agreement, such jurisdiction was retained "[w]ithout affecting the finality of this Final Order and Judgment in any way," and PTO 1415 dismissed the Third Amended Complaint. *In re Diet Drugs*, Nos. 1203, 99-20593, 2000 WL 1222042, at *71-72. Thus, unless the Settlement Agreement itself preserved Montgomery's claim, it is barred because it was not re-filed within the TSOR.

In opposing application of the TSOR to bar her claim, Montgomery argued that under the Settlement Agreement 1) PPH claims were expressly preserved for future litigation; 2) Wyeth agreed not to assert the statute of limitations defense or argue that a plaintiff split her claims; and 3) any conclusion otherwise would conflict with the class notice she received. Montgomery argues that the class notice led PPH plaintiffs to believe that if they satisfied the agreed-upon definition of PPH, their rights would be unaffected by the Settlement Agreement. However, the Settlement Agreement barred PPH plaintiffs from bringing a claim until they satisfied the definition of PPH contained therein, which, in Montgomery's case, was after the TSOR ran. Therefore, the only way Montgomery's claim remains unaffected by the Settlement Agreement, as represented in the class notice, is if the Agreement is interpreted to bar Wyeth's assertion of the TSOR defense. Montgomery further argued that the intent of the MDL was to treat all cases uniformly, settle non-PPH claims, and preserve PPH claims for future litigation under an agreed-upon definition, in exchange for which Wyeth agreed not to assert a time bar.

All these arguments are plausible, and the MDL court might have agreed with one or all of them. In any event, on this record, neither the district court nor this court is in a position to put the gloss on the Settlement Agreement that Montgomery urges upon us, because such a gloss is rooted in the context, rather than the language, of the Settlement Agreement. On the other hand, the MDL court would have been within its retained authority to do so.

While Montgomery complained below that Wyeth "inexplicably failed" to make "its motion while this action was pending in the MDL," she never asked the court to transfer the case back to the MDL court for interpretation of the Settlement Agreement, nor has she argued on appeal that the district court erred in failing to do so, or in interpreting the Settlement Agreement itself. I am therefore constrained to concur in the affirmance.

Lastly, I do not agree with the majority's conclusion that "Montgomery's relationship with Wyeth is more significant in Tennessee," and agree with the district court's determination that that relationship was centered in Georgia. Nevertheless, I also agree with the district court's conclusion that the Tennessee courts would apply the TSOR because Montgomery consumed the Pondimin and suffered her injury in Tennessee.