

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS : MDL DOCKET NO. 1203
(PHENTERMINE, FENFLURAMINE, :
DEXFENFLURAMINE) PRODUCTS :
LIABILITY LITIGATION :
: :
THIS DOCUMENT RELATES TO: :
: :
SHEILA BROWN, et al. :
: :
v. :
: :
AMERICAN HOME PRODUCTS :
CORPORATION : CIVIL ACTION NO. 99-20593

MEMORANDUM AND PRETRIAL ORDER NO. 3065

Bartle, J.

October 10, 2003

Wyeth has moved to enforce the Nationwide Class Action Settlement Agreement ("Settlement Agreement") in this diet drug litigation against three class members who have filed lawsuits against it in the state courts in Texas. The actions are entitled: (1) Jerry Coffey, Individually and as a Representative of the Estate of Cynthia Cappel, Deceased, et al. v. Wyeth, et al.,¹ Case No. E-167,334, pending in the District Court of Jefferson County, Texas; (2) Rita Dix, et al. v. Wyeth, et al., Case No. 03-02-01014-CV pending in the District Court of Montgomery County, Texas; and (3) Donna Allan Franz v. Wyeth, et

1. The original plaintiff Cynthia Cappel has died since the institution of her lawsuit and her executor has been substituted. For ease of reference, we will continue to refer to her as the plaintiff.

al., Case No. 49,594, pending in the District Court of Galveston County, Texas.

These class members aver that they suffer from a fatal disease known as primary pulmonary hypertension ("PPH") as a result of ingesting Pondimin and/or Redux which Wyeth or one of its predecessors manufactured and sold. It is undisputed that at the state court trials, which are imminent, these three plaintiffs intend to offer evidence not only about PPH but also about other conditions that were allegedly caused by these drugs. Wyeth argues that interjecting this latter evidence will violate the Settlement Agreement and Pretrial Order ("PTO") 1415 and requests that we enjoin the plaintiffs from doing so. See In re Prudential Insur. Co. of Am. Sales Practice Litig., 261 F.2d 355 (3d Cir. 2001).

The court approved the Settlement Agreement on August 28, 2000, after extensive and thorough notice to the class and after an exhaustive Fairness Hearing conducted in May, 2000. The class consists of the millions of persons in the United States who ingested Pondimin and/or Redux and their associated claimants. Memorandum and PTO 1415 at 43. All class members were afforded the opportunity to exercise an initial opt-out from the class by March 30, 2000. See PTO 1050, Official Court Notice § 4.D.

The Settlement Agreement provides for various benefits to be paid to class members by the AHP Settlement Trust ("Trust") funded by Wyeth. Under certain conditions, a class member with

valvular heart disease ("VHD") may exercise an intermediate, back-end, or financial security opt-out. While still remaining a part of the class, persons who are so-called downstream opt-outs forego certain benefits from the Trust and may sue Wyeth in the tort system. In return for Wyeth's waiving the statute of limitations, downstream opt-outs may seek compensatory but not punitive damages. The Settlement Agreement, however, provides no direct monetary benefits from the Trust for PPH victims. In return, as will be seen below, PPH victims may sue Wyeth for both compensatory and punitive damages without regard to the exercise of any opt-out.

Except for those who have elected to pursue a downstream opt-out, the court-approved Settlement Agreement prohibits any class member from suing Wyeth, a released party, with respect to "settled claims," which are broadly defined as:

any and all claims, including assigned claims, whether known or unknown, asserted or unasserted, regardless of the legal theory, existing now or arising in the future by any or all members of the Settlement Class arising out of or relating to the purchase, use, manufacture, sale, dispensing, distribution, promotion, marketing, clinical investigation, administration, regulatory approval, prescription, ingestion, and labeling of Pondimin® and/or Redux™, alone or in combination with any other substance, including, without limitation, any other drug, dietary supplement, herb, or botanical. These "Settled Claims" include, without limitation and by way of example, all claims for damages or remedies of whatever kind or character, known or unknown, that are now recognized by law or that may be created or recognized in the future by statute,

regulation, judicial decision, or in any other manner, for:

- a. personal injury and/or bodily injury, damage, death, fear of disease or injury, mental or physical pain or suffering, emotional or mental harm, or loss of enjoyment of life;
- b. compensatory damages, punitive, exemplary, statutory and other multiple damages or penalties of any kind;
- c. loss of wages, income, earnings, and earning capacity, medical expenses, doctor, hospital, nursing, and drug bills;
- d. loss of support, services, consortium, companionship, society or affection, or damage to familial relations, by spouses, parents, children, other relatives or "significant others" of Settlement Class Members;
- e. consumer fraud, refunds, unfair business practices, deceptive trade practices, Unfair and Deceptive Acts and Practices ("UDAP"), and other similar claims whether arising under statute, regulation, or judicial decision;
- f. wrongful death and survival actions;
- g. medical screening and monitoring, injunctive and declaratory relief;
- h. economic or business losses or disgorgement of profits arising out of personal injury; and
- i. prejudgment or post-judgment interest.

Settlement Agreement § I.53. See also, § I.48; PTO 1415, ¶ 7.

The definition of "settled claims," however, carves out an important exception for the claim of any class member suffering from PPH. The Settlement Agreement specifically provides that "[n]otwithstanding the foregoing, Settled Claims do not include claims based on PPH, including claims for compensatory, punitive, exemplary or multiple damages based on PPH" Settlement Agreement § I.53. To avoid the otherwise inevitable disputes over what constitutes PPH, the Settlement Agreement carefully and specifically defines the term. Settlement Agreement § I.46. Because PPH is a defined term, we have a responsibility under the Settlement Agreement to make sure that the threshold for a PPH claim has been met before a lawsuit against Wyeth may be filed. See PTO 1415 at 66-70; PTO 2383.

Thus, a person diagnosed with PPH, as described in the Settlement Agreement, may sue Wyeth in the tort system regardless of any opt-out decision. Unlike persons with VHD who exercise a downstream opt-out, persons with PPH may seek both compensatory and punitive damages, whether or not they have opted-out, since, as noted above, the Trust provides no direct monetary benefits for them. The carve-out, as set forth in the language of the Settlement Agreement, is limited to claims "based on PPH."

The three plaintiffs, who are class members suing Wyeth for damages resulting from PPH, concede they will seek to introduce evidence at trial not only about PPH but also about VHD and possibly other conditions which are admittedly "settled claims," even though they do not claim to be suffering from any

of these other conditions. These plaintiffs contend that such evidence is either relevant or necessary to prove a defective design or failure to warn case with respect to Pondimin or Redux. Wyeth seeks to prohibit this effort as a breach of the Settlement Agreement. Obviously, there will be no chance for this court to intervene to prevent any violation once the state trials begin.

The Settlement Agreement is a contract which this court approved in August, 2000 and which we have authority to enforce. See PTO 1415; Prudential, 261 F.2d at 367-68. In order to resolve the issue before us, we must first glean the intent of the parties from the words of the Settlement Agreement and, to the extent necessary, from the surrounding circumstances. See Bohler-Uddeholm Am., Inc. v. Ellwood Group, Inc., 247 F.3d 79 (3d Cir. 2001); Restatement (Second) of Contracts § 202 (1981).

Wyeth reads the Settlement Agreement as enunciating a blanket rule that only evidence related to PPH itself may be used to prove a claim based on PPH because non-opt-out class members have released as "settled claims" everything else, including claims of VHD. According to Wyeth, the PPH exception will swallow the release and render it meaningless if class members may introduce evidence of VHD into a PPH trial. At the extreme, a trial could be mostly about VHD and Wyeth's conduct related thereto and very little about PPH.

The PPH carve-out in the Settlement Agreement recognizes that PPH cases are different not only in kind but also in degree from cases involving VHD. It is undisputed that PPH,

unlike VHD, is always or virtually always a fatal disease. As described by my able predecessor Judge Louis C. Bechtle in PTO 1415, "PPH is a relentlessly progressive disease that leads to death in virtually all circumstances.... the diagnosis [of PPH] is accompanied by enormous psychological trauma to the patient because it is a virtual death sentence." PTO 1415 at 38. In contrast to class members with VHD who have a limited downstream opt-out right to sue only for compensatory damages, individuals may sue Wyeth for both compensatory and punitive damages whenever they are diagnosed with PPH. This expansive right for PPH victims to sue is particularly significant since, as noted previously, the Settlement Agreement provides no option for them to receive direct benefits from the Trust. Thus, the relatively small number of persons with PPH are treated more generously than other class members because of the traumatic and ultimately deadly consequences they face.

The parties certainly understood at the time they entered into the Settlement Agreement that, due to the size of the class, lawsuits based on PPH would be filed in many different states. The parties were well aware that the law of negligence and strict liability for a defective product or for failure to warn varies to some degree from jurisdiction to jurisdiction. They also knew that a claim based on PPH must necessarily mean a claim based on evidence, for there can be no viable claim without evidence. Just as the substantive law may differ from state to state, it follows that evidence relevant or necessary to

establish such a claim may differ from state to state. The Settlement Agreement, we must not forget, reads broadly, "[n]otwithstanding the foregoing, Settled Claims do not include claims based on PPH" Settlement Agreement § I.53. Thus, despite any release of settled claims, there is no release of PPH claims. Since there is no release of PPH claims, there cannot be a release with respect to the evidence relevant or necessary to prove a PPH claim, for any contractual restriction on the evidence would be a contractual restriction on the claim itself.

Our reading of the Settlement Agreement is bolstered by Memorandum and PTO 1415, in which Judge Bechtle analyzed the terms of the Settlement Agreement before approving it. In the course of his discussion, he wrote, "Although the Settlement Agreement does not provide any direct benefits for PPH, it fully preserves the rights of class members to recover against AHP [Wyeth] if they have or develop PPH as a result of taking Pondimin and/or Redux." PTO 1415 at 70 (emphasis added). The Settlement Agreement can only "fully preserve[] the rights of class members to recover" for PPH if they have the right to prove their claims without contractual restrictions limiting the evidence on which they may rely.

To the extent any ambiguity can be said to exist in the Settlement Agreement, the notice sent to class members in the spring of 2000 about the proposed settlement confirms our analysis. Included in the packet of materials comprising the notice was a color brochure described as "A Class Member's Guide

to the Diet Drug Litigation Settlement" (the "Guide"). The words "Official Court Notice" in bold letters were imprinted on the front. On page fourteen of the Guide was the statement "If you have a PPH claim, as defined in the Settlement Agreement, you may pursue that claim in court outside of this Settlement, whether or not you Opt-Out." Thus, class members were told that their rights to sue for a PPH claim would be the same whether or not they exercised an initial opt-out. By exercising an initial opt-out, a class member would no longer be a part of the settlement and would not be bound by any contractual limitations with respect to settled claims. Since an initial opt-out plaintiff could introduce evidence of VHD in a lawsuit involving PPH if allowed by state law, class members such as the three plaintiffs here who did not initially opt out must have the same opportunity.

The contractual language used by the parties, viewed within the four corners of the Settlement Agreement as well as in light of all the surrounding circumstances, cannot reasonably be interpreted to restrict the evidence otherwise available to prove a PPH claim in a court of law. It could not have been the intent of the parties to undermine or possibly eliminate by contract an otherwise valid PPH claim. Consequently, we find that the proper construction of the Settlement Agreement allows class members to offer evidence of settled claims to prove a claim based on PPH to the extent allowed under evidentiary rules of the jurisdiction in which their lawsuits are being tried.

We emphasize that the result we reach does not mean that anything goes. Nor does it mean that we are deciding that Texas law requires or even permits such evidence in the cases of the three class members before us.² 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. In some states, evidence of other conditions will be excluded either as not relevant or because unfair prejudice outweighs the probative value. In other states, such evidence may be admitted in whole or in part, with or without cautionary instructions, under one or more theories of recovery.

It is important to emphasize that proof in any PPH case will also be subject to the due process requirements of the federal Constitution on the issue of punitive damages. In State Farm Mutual Auto Insurance Company v. Campbell, 123 S. Ct. 1513 (2003), the plaintiff instituted a bad faith claim in the Utah state court against his automobile insurer after it refused to pay a verdict against him. The Supreme Court held that the punitive damage award of \$145 million on top of a compensatory damage award of \$1 million violated due process. The trial court

2. At least in a failure to warn case, it appears that Texas law may not permit the introduction of evidence concerning conditions other than PPH. In In re Norplant Contraceptive Products Liability Litigation, No. MDL 1038, 1997 WL 81094 (E.D. Tex. Feb. 21, 1997), the United States District Court for the Eastern District of Texas held that "[t]he question of the adequacy of the warnings must be confined to consideration of whether the warnings were sufficient to inform the plaintiff of the risk of the particular condition or disease which allegedly caused his injury or death."

had admitted evidence of State Farm's willful conduct unrelated to the particular claim involved. The Supreme Court explained:

A defendant's dissimilar acts, independent from the acts upon which liability was premised, may not serve as the basis for punitive damages. A defendant should be punished for the conduct that harmed the plaintiff, not for being an unsavory individual or business. Due process does not permit courts, in the calculation of punitive damages, to adjudicate the merits of other parties' hypothetical claims against the defendant under the guise of the reprehensibility analysis.

Id. at 1523.

We appreciate Wyeth's concerns about the dangers that a PPH case could be transformed, chameleon-like, into a VHD case without curbs on the evidence used to establish liability or damages. Nonetheless, all parties must rely on the presiding judge to control the trial in accordance with state law and due process. Our role here is simply to enforce the terms of the Settlement Agreement and to enjoin the class members and other parties, as well as their counsel, only when it is necessary to prevent a violation of the bargain the parties struck. See PTO 1415; Prudential, 261 F.2d at 364. The words of the Settlement Agreement, as well as the surrounding circumstances, lead to the same result. The Settlement Agreement contains no prohibition against the use of evidence of settled claims to prove a claim based on PPH. See PTO 1415 at 66-68. Rather, any limitations must depend on state law and due process.

Plaintiffs are not in breach of the Settlement Agreement. Accordingly, we will deny Wyeth's motion.

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PRETRIAL ORDER NO. 3065

AND NOW, this 10th day of October, 2003, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the motion of Wyeth to enforce the Nationwide Class Action Settlement Agreement against the class members in the cases of Jerry Coffey, Individually and as a Representative of the Estate of Cynthia Cappel, Deceased, et al. v. Wyeth, et al. (Case No. E-167,334, District Court of Jefferson County, Texas), Rita Dix, et al. v. Wyeth, et al. (Case No. 03-02-01014-CV, District Court of Montgomery County, Texas), and Donna Allan Franz v. Wyeth, et al. (Case No. 49,594, Court of Galveston County, Texas) is DENIED.

BY THE COURT:

Lawrence Bartle
J.