

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 : CIVIL ACTION NO. 99-20593  
CORPORATION :

MEMORANDUM AND PRETRIAL ORDER NO.

3088

Bartle, J.

October 30, 2003

Wyeth has filed a motion to enjoin plaintiff class members and their counsel in the cases of Eichmiller v. American Home Products Corp., Civil Action No. 2002CV52077 (Fulton County, Georgia), Cook, et al. v. Wyeth, Cause No. 2002-21 (Hinds County, Mississippi), and Caldwell v. American Home Products Corp., No. 2002-113-CV3 (Jones County, Mississippi) from introducing evidence at trial related to the "four cases label" for the diet drug Pondimin and to the "black box warning" for the diet drug Redux for the years 1995 and 1996. Wyeth contends the introduction of such proof would violate the Nationwide Class Action Settlement Agreement ("Settlement Agreement") in this multidistrict litigation.

Under the Settlement Agreement, approved in Pretrial Order ("PTO") 1415, class members who are suffering from left-

sided valvular heart disease ("VHD") may exercise either an immediate or back-end opt-out under certain conditions. By exercising such a downstream opt-out, as plaintiffs have done here, they may sue Wyeth in the tort system for compensatory damages. However, the Settlement Agreement forbids them from suing Wyeth for punitive, exemplary, or multiple damages. See Settlement Agreement §§ IV.D.3.C and IV.D.4.C.

Underlying Wyeth's motion is its effort to prevent any mention of primary pulmonary hypertension ("PPH"), a progressive disease which is virtually always fatal. In a number of previous pretrial orders, we have enjoined plaintiffs and their counsel in other lawsuits from introducing such evidence because it was clearly designed to inflame the jury to award punitive damages. See PTO 2680. The plaintiffs here allege that they are suffering from VHD and not from PPH. Consequently, any effort to inject PPH into their trials can only be for the purpose of obtaining punitive damages, in fact if not in name. See PTO 2828. Because the offer of such evidence would clearly be in breach of the Settlement Agreement, we have authority to prevent plaintiffs from doing so. See In re Prudential Insur. Co. of Am. Sales Practice Litig., 261 F.2d 355 (3d Cir. 2001). Any procedural, evidentiary, or substantial rule of law of any state must yield to the terms of the Settlement Agreement and specifically its punitive damages exclusion. See PTO 2818; PTO 2680.

The "four cases label" for the diet drug Pondimin stated:

There have been four causes [sic] of pulmonary hypertension reported in association with fenfluramine use. Two cases were apparently reversible after discontinuation of fenfluramine, but evidence of pulmonary hypertension recurred in one of these patients upon rechallenge with fenfluramine. A third patient was initially improved with nifedipine treatment, but was noted to have increased pulmonary arterial pressure again at a four month follow up visit. Finally, an irreversible and fatal case of pulmonary hypertension has been reported in a patient who had seven 1-month courses of fenfluramine in the twelve years prior to death. Patients taking fenfluramine should be advised to report immediately any deterioration in exercise tolerance.

Pulmonary hypertension ("PH") is a quite common phenomenon in the general population and should not be confused with the fatal disease known as PPH. PH, which involves an elevation in pulmonary artery pressure, is a symptom caused by various conditions, including high blood pressure. PH can also be secondary to VHD.

While the four cases label uses the term PH rather than the term PPH, a review of the record as well as the wording of the four cases label itself demonstrates that it is describing PPH. The four cases referred to in the label were actually cases of PPH. The plaintiff in Caldwell, supra, concedes as much in her answer to an interrogatory. Clearly the references to PH are not to PH secondary to VHD.

The "black box warning" concerns the warning label the Food and Drug Administration ("FDA") was considering in 1995 and 1996 in connection with the approval of the diet drug Redux and whether the warning should be enclosed within a black border,

that is, a black box. There can be no doubt, and plaintiffs do not really challenge, that the discussions with the FDA during this time period centered on a warning for PPH and not PH secondary to VHD.

At the time we entered PTO 2828, we did not have enough information to decide the issue now before the court. Thus, we deferred to the trial judge to determine whether evidence involving the four cases label and the black box warning related to PH or to PPH. Now, having a more complete record, we are convinced that issues of "the four cases label" and "the black box warning" concern PPH, and not PH or even PH secondary to VHD.<sup>1</sup>

We made it quite clear in PTO 2828, as well as other PTO's, and we reiterate here that class members and their counsel may not make any reference, directly or indirectly, to PPH at any trial where class members are suing Wyeth for VHD. Likewise, they may not mention PH, except as a secondary condition to VHD. We now rule that these prohibitions specifically prevent reference to evidence related to the "four cases label" for Pondimin and evidence related to the "black box warning" in 1995 and 1996 for Redux. The offer and introduction of such proof

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1. If a plaintiff were allowed to introduce evidence, however spurious, that the four cases label is about PH secondary to VHD and not about PPH, Wyeth would face the necessity of introducing truthful evidence that it really is about PPH. A plaintiff would thus have achieved indirectly what the Settlement Agreement forbids, that is, the introduction of the inflammatory issue of PPH into a case involving VHD.

would violate the provisions of the Settlement Agreement against claims for punitive, exemplary, or multiple damages.

We will grant Wyeth's motion and enter the attached injunction.

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AMERICAN HOME PRODUCTS :  
CORPORATION : CIVIL ACTION NO. 99-20593

PRETRIAL ORDER NO. 3088

AND NOW, this 30<sup>th</sup> day of October, 2003, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that:

(1) the plaintiffs and their agents, attorneys, and derivative claimants are ENJOINED in the cases of Eichmiller v. American Home Products Corp., Civil Action No. 2002CV52077 (Fulton County, Georgia), Cook, et al. v. Wyeth, Cause No. 2002-21 (Hinds County, Mississippi), and Caldwell v. American Home Products Corp., No. 2002-113-CV3 (Jones County, Mississippi) from introducing any evidence, making any statement before or argument to the court or jury, related directly or indirectly to:

(a) punitive, exemplary or multiple damages,  
however described;

(b) malicious, wanton or other similar conduct of Wyeth, however described;

(c) any medical condition of plaintiffs caused by Wyeth other than left-sided mitral valve regurgitation or pulmonary hypertension secondary to mitral valve regurgitation;

(d) Wyeth's profits, size or financial condition;

(e) the amount or size of Wyeth's sales of diet drugs or other products;

(f) Wyeth's marketing or promotion of diet drugs to the extent that Wyeth placed marketing or promotion ahead of health or safety concerns;

(g) any deception or any destruction, hiding, overwriting, or deliberate miscoding of documents or information by Wyeth;

(h) any involvement by Wyeth in the ghostwriting of articles;

(i) primary pulmonary hypertension;

(j) neurotoxicity;

(k) any other disease, illness or condition or persons suffering from any other disease, illness or condition caused by Redux or Pondimin except for left-sided valvular heart disease or pulmonary hypertension secondary to left-sided valvular heart disease; and

(1) the "four cases label" for Pondimin  
and the "black box warning" for Redux in 1995  
and 1996; and

(2) the parties shall deliver forthwith to the state  
trial judges a copy of this Memorandum and Pretrial Order.

BY THE COURT:

Lawrence Bartle  
J.