

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

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

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

May 28, 2008

Before this court is the appeal of plaintiff, Nancy Cochran ("Cochran"), challenging Report and Recommendation No. 60 of the Special Master.

Defendant Wyeth¹ filed a motion to enforce the Diet Drug Nationwide Class Action Settlement Agreement against Cochran and to enjoin her from continuing a state court action she has initiated against it. The Settlement Agreement was approved by this court in Pretrial Order ("PTO") No. 1415 (Aug. 28, 2000) as part of our continuing jurisdiction over Multi-District Litigation No. 1203 involving the diet drugs Pondimin and Redux. Pursuant to Pretrial Order ("PTO") No. 2383 (Feb. 26, 2002) the motion was referred to the Special Master for consideration. The

1. Prior to March 11, 2002 Wyeth was known as American Home Products.

Special Master has recommended to this court that we grant Wyeth's motion and order Cochran to dismiss her current action against Wyeth.

Cochran has sued Wyeth, Wyeth Pharmaceuticals, Inc. f/k/a Wyeth-Ayerst Pharmaceuticals, Inc., Wyeth Pharmaceuticals Division of Wyeth f/k/a Wyeth-Ayerst Laboratories, Division of American Home Products Corp., and Wyeth-Ayerst Laboratories, Co. in the Court of Common Pleas of Philadelphia County, Pennsylvania. She alleges that she suffers from primary pulmonary hypertension ("PPH")² as a result of ingesting dexfenfluramine, which was sold under the brand name Redux, from November, 1996 until August, 1997.

Cochran has undergone ten echocardiograms since 2002. The first was performed on August 9, 2002. The resulting echocardiogram report, signed by Janice Frost, M.D., found that Cochran had mitral regurgitation graded 1+, that is, mild mitral regurgitation.³ Cochran had a second echocardiogram on October 3, 2002. Dr. Frost concluded that the echocardiogram showed mitral regurgitation graded 2+, that is, moderate mitral valve regurgitation. Cochran obtained a legal review of the

2. Today, PPH is commonly known in the medical community as pulmonary arterial hypertension ("PAH"). This was not the case at the time the Settlement Agreement was drafted. For consistency, we will refer to "PPH" throughout this memorandum as it is the term used in the Settlement Agreement.

3. There is an inconsistency in Dr. Frost's report. Page 1 states that plaintiff's mitral regurgitation was graded 1+ or mild but page 2 states that it was graded 2. It is unclear which is correct.

echocardiogram from Timothy Hanlon, M.D. Dr. Hanlon opined that the echocardiogram did not "demonstrate[] what [he] would call moderate mitral regurgitation" but "[u]tilizing the criteria that you have defined, this patient would fall into the moderate range, but it is my opinion that the degree of mitral regurgitation is more on the mild side, for what that is worth." Pl.'s Appeal, Ex. 2.

On January 22, 2003 Cochran underwent a right heart catheterization, which found her mean pulmonary artery pressure to be 25 mmHg at rest and 42 mmHg with exercise and her mean wedge pressure to be 15 mmHg at rest and 18 mmHg with exercise. After Cochran's right heart catheterization, her physician, Jeffrey Edelman, M.D., a Board-Certified Pulmonologist, prescribed calcium channel blockers to her "as treatment for systemic hypertension with the hope that this therapy might also be beneficial in the setting of underlying pulmonary hypertension." Defs.' Mot., Ex. H. Thereafter, Cochran underwent eight additional echocardiograms, all of which showed her mitral valve regurgitation to be trace or mild.

As set forth above, this court approved the Settlement Agreement in PTO No. 1415. Paragraph 7 of that pretrial order provides:

The court hereby bars and enjoins all class members who have not, or do not, timely and properly exercise an Initial, Intermediate, Back-End or Financial Insecurity Opt-Out right from asserting, and/or continuing to prosecute against [Wyeth] or any other Released Party any and all Settled Claims

which the class member had, has or may have in the future in any federal, state or territorial court.

Under the Settlement Agreement, PPH is excluded from the definition of Settled Claims, and therefore PPH claims are not subject to the release and bar provisions of the Settlement Agreement. Settlement Agreement § VII.B. The definition of PPH under the terms of the Settlement Agreement, however, is rigorous. Plaintiffs claiming a diagnosis of PPH must satisfy a three part definition. Only the second and third prongs of the definition are in controversy here. They provide:

For a diagnosis based on examinations and clinical findings prior to death:

...

(2) Medical records which demonstrate that the following conditions have been excluded by the following results:

- (a) Echocardiogram demonstrating no primary cardiac disease including, but not limited to, shunts, valvular disease (other than tricuspid or pulmonary valvular insufficiency as a result of PPH or trivial, clinically insignificant left-sided valvular regurgitation), and congenital heart disease (other than patent foramen ovale);

...

(3) Conditions known to cause pulmonary hypertension including connective tissue disease known to be causally related to pulmonary hypertension, toxin induced lung disease known to be causally related to pulmonary hypertension, portal hypertension, significant obstructive sleep apnea, interstitial fibrosis (such as silicosis, asbestosis, and granulomatous disease) defined as greater than mild patchy

interstitial lung disease, and familial causes, have been ruled out by a Board-Certified Cardiologist or Board-Certified Pulmonologist as the cause of the person's pulmonary hypertension.

Settlement Agreement § I.46(a).

We have previously stated that PTO No. 1415 requires "this court to decide if there is a genuine issue of material fact as to whether plaintiff suffers from PPH. If no such issue exists, this court will enjoin the plaintiff from going forward. Otherwise, it is a matter for the trial court." PTO No. 3699 at 4 (July 6, 2004); see also PTO No. 7553 at 2-3 (Nov. 30, 2007).

In its motion to enforce the injunction provision in PTO No. 1415 ¶7, Wyeth argued that Cochran did not satisfy Parts 2(a) and 3 of the PPH definition. Both parties fully briefed Wyeth's motion. Subsequently, the Special Master held a teleconference with the parties, after which an additional round of briefing ensued. Numerous arguments were raised by both sides and ultimately the Special Master recommended that Cochran did not meet Part 2(a) of the PPH definition. In considering the medical record Cochran had provided, the Special Master stated:

Part 2(a) of the PPH definition is silent with respect to the weighing of the conflicting evidence in determining whether a plaintiff has demonstrated that he or she does not have primary cardiac disease. The parties' intent, however, requires that only plaintiffs with legitimate PPH claims be permitted to pursue their claims against Wyeth. In my view, under Part 2(a), this means that it is a plaintiff's burden to produce objective evidence proving that he or she does not have primary cardiac disease.

Report and Recommendation No. 60 at 13-14.

The Special Master concluded that Cochran's October 3, 2002 echocardiogram and her January 22, 2003 right heart catheterization demonstrate primary cardiac disease. In his view, "[p]laintiff has failed to provide a reasonable explanation regarding the disqualifying tests, which would provide a basis for allowing her claims to proceed." Id. at 14-15.

The October 3, 2002 echocardiogram is the echocardiogram from which Dr. Frost opined that Cochran had moderate mitral valve regurgitation. Primary cardiac disease, as defined under the Settlement Agreement, includes moderate mitral valve regurgitation, a type of valvular disease. See Settlement Agreement § I.46(a)(2). The Special Master concluded that the October 3, 2002 echocardiogram therefore prevented Cochran from satisfying the definition of PPH under the Settlement Agreement, since the PPH definition requires an echocardiogram "demonstrating no primary cardiac disease." He also noted that the eight post-October 3, 2002 echocardiograms were done after Cochran began taking calcium channel blockers to treat her high blood pressure. Thus, "[t]o the extent that her blood pressure dropped after starting this new treatment" the Special Master believed it "would be inappropriate to allow [p]laintiff to rely on these echocardiograms" Id. at 15.

In addition, the Special Master cited Cochran's January 22, 2003 right heart catheterization as disqualifying her from the definition of PPH under the Settlement Agreement. He

pointed to Report and Recommendation No. 27⁴ in which he stated that a normal pulmonary capillary wedge pressure, both at rest and with exercise, demonstrate that a plaintiff's regurgitation is trivial or clinically insignificant under Part 2(a). Since Cochran's pulmonary capillary wedge pressure was elevated with exercise, the Special Master wrote that based upon that test "[p]laintiff's moderate mitral regurgitation cannot be deemed trivial and clinically insignificant." Report and Recommendation No. 60 at 14.

Cochran filed a timely appeal to this court, in which she raises several issues. She relies heavily on the expert report of Harold I. Palevsky, M.D. in which he opined that "the mitral regurgitation does not/cannot account for the majority of the pulmonary hypertension directly measured at [the January 23, 2003] catheterization." Pl.'s Appeal, Ex. 1. Cochran also maintains that there is a genuine issue of material fact whether her October 3, 2002 echocardiogram showed moderate mitral regurgitation because of the conflicting opinions of Drs. Frost and Hanlon. Finally, Cochran contends that Part 2(a) of the PPH definition does not require that her mean wedge pressure be normal at rest and with exercise.

In response, Wyeth maintains that Cochran cannot satisfy Part 2(a) of the definition of PPH because her October 3,

4. We note that Report and Recommendation No. 27 was never approved by this court. The case with which it was concerned settled before the appeal was heard here.

2002 echocardiogram shows moderate mitral regurgitation. Wyeth also contends that the opinions of Drs. Palevsky and Hanlon are unavailing. Finally, Wyeth argues that Cochran is not required under the Settlement Agreement to demonstrate that her mean wedge pressure is normal at rest and with exercise but merely is precluded from relying on that narrow exception to Part 2(a) of the PPH definition as articulated in Report and Recommendation No. 27 because her mean wedge pressure was elevated with exercise.

As stated above, the Settlement Agreement requires putative PPH plaintiffs to provide "[m]edical records which demonstrate that the following conditions have been excluded by the following results ... echocardiogram demonstrating no primary cardiac disease" Settlement Agreement § I.46.a(2)(a). We agree with Wyeth and the Special Master that "it is a plaintiff's burden to produce objective evidence proving that he or she does not have primary cardiac disease." Report and Recommendation No. 60 at 13-14.

The real nub of this appeal is determining the affect of Cochran's October 3, 2002 echocardiogram on her ability to satisfy Part 2(a) of the definition of PPH under the Settlement Agreement given that her medical records contain nine other echocardiograms that state her mitral valve regurgitation is trace or mild. Cochran's medical records present us with what is arguably an ambiguity in the Settlement Agreement definition. It is silent regarding how conflicting echocardiograms should be

weighed. Wyeth advocates a definition where one echocardiogram showing moderate mitral regurgitation, that is, primary cardiac disease, disqualifies the putative PPH plaintiff from the Settlement Agreement definition. That is not, however, the plain reading of the Settlement Agreement. The Settlement Agreement merely requires a putative PPH plaintiff to provide an echocardiogram that excludes primary cardiac disease. Cochran has done that here, at least eight times over. Although Wyeth argues that the eight echocardiograms performed after she began taking calcium channel blockers do not accurately depict her true level of regurgitation, that is not a matter this court can resolve based on the record at this stage of the proceedings. Accordingly, a genuine issue of material fact remains regarding whether Cochran has satisfied Part 2(a) of the definition of PPH under the Settlement Agreement. It is therefore unnecessary for this court to reach the other arguments of Cochran and Wyeth regarding Part 2(a) of the PPH definition under the Settlement Agreement.

The Special Master did not reach the question whether Cochran has satisfied Part 3 of the PPH definition. Since we have concluded that a genuine issue of material fact remains regarding whether Cochran has satisfied Part 2(a) we must also consider Part 3. Wyeth, in its motion to enforce the Settlement Agreement, argued that Cochran had not demonstrated that "significant obstructive sleep apnea" had been ruled out as the cause of her pulmonary hypertension by a polysomnograph, a

particular kind of sleep study. Unlike under Part 2(a) of the definition, the Settlement Agreement does not specify what tests must be used to rule out the conditions listed in Part (3). It simply says the listed conditions must be ruled out by a "Board-Certified Cardiologist or Board-Certified Pulmonologist." Settlement Agreement § I.46.a(3). Cochran submitted a PPH Checklist completed by Dr. Edelman in which he attests that "significant obstructive sleep apnea" was ruled out by an overnight oximetry performed on September 26, 2002.

Wyeth maintains that Dr. Edelman admitted in his deposition that he did not rule out "significant obstructive sleep apnea." Wyeth's argument misconstrues Dr. Edelman's testimony:

- Q. You do have to rule out sleep apnea, don't you, for an evaluation of pulmonary arterial hypertension?
- A. I think you have to consider the diagnosis. I don't think that any of the guidelines say that every patient should have polysomnography.
- Q. Have you ruled it out?
- A. Have we ruled out sleep apnea here? Has she had polysomnography?
- Q. No.
- A. No. She certainly had – you know, she had an overnight oximetry which showed virtually no desaturation which would be very uncharacteristic of the severe sleep apnea that is likely to be limited but associated with pulmonary hypertension.

Wyeth's Mot. to Enforce, Ex. G, Deposition Tr. at 144, June 21, 2007.

There is a difference between sleep apnea and "significant obstructive sleep apnea." Dr. Edelman has attested and testified that he has ruled out significant obstructive sleep apnea through Cochran's overnight oximetry. The Settlement Agreement does not require that a polysomnography be performed, and we will not impose such a requirement in contravention of its terms.

Genuine issues of material fact remain regarding whether Cochran has satisfied the definition of PPH as set forth in § I.46 of the Settlement. Accordingly, we will not adopt Report and Recommendation No. 60 of the Special Master and will not enforce PTO No. 1415 against class member Nancy Cochran.

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KATHRYN A. DECKER	:	
	:	
v.	:	
	:	
WYETH	:	CIVIL ACTION NO. 99-20593
	:	

PRETRIAL ORDER NO.

AND NOW, on this 28th day of May, 2008, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that:

(1) Report and Recommendation No. 60 of the Special Master is NOT ADOPTED; and

(2) the motion of Wyeth to enforce the Settlement Agreement under Pretrial Order No. 1415 against class member Nancy Cochran is DENIED.

BY THE COURT:

/s/ Harvey Bartle III

C.J.