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
THIS DOCUMENT RELATES TO:	:	
KATHRYN A. DECKER	:	
v.	:	
WYETH	:	CIVIL ACTION NO. 99-20593

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J. November 30, 2007

Before this court is the motion of defendant Wyeth[1] to enforce the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") against plaintiff Kathryn A. Decker and to enjoin her from continuing a state court action she has initiated against it. The Settlement Agreement was approved by this court as part of our continuing jurisdiction over Multi-District Litigation No. 1203 involving the diet drugs Pondimin and Redux. See Pretrial Order ("PTO") No. 1415 (Aug. 28, 2000).

Ms. Decker has sued Indevus Pharmaceuticals, Inc., Wyeth, Wyeth Pharmaceuticals, Inc., and Boehringer Ingelhelm Pharmaceuticals, Inc. in the Superior Court of Massachusetts for Middlesex County. She alleges that she suffers from primary

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

pulmonary hypertension ("PPH") as a result of ingesting dexfenfluramine, which was sold under the brand name Redux. Decker v. Indevus Pharm., No. 06-4461 (Mass. Super. Ct.).

In PTO No. 1415 this court approved the Settlement Agreement. Paragraph 7 of PTO 1415 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.

PTO No. 1415.

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 third prong is in controversy here. It provides: "Conditions known to cause pulmonary hypertension including ... portal hypertension, ... have been ruled out by a Board-Certified Pulmonologist as the cause of the person's pulmonary hypertension." Settlement Agreement § I.46(a)(3).

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).

In the present motion, Wyeth argues that Ms. Decker does not satisfy the definition of PPH under the Settlement Agreement and therefore cannot pursue her state court action. Time is of the essence here, as the Massachusetts Superior Court has set Ms. Decker's case for trial on January 3, 2008.

Ms. Decker purportedly was prescribed and ingested Redux from June 1996 until December 1996. On June 29, 2006 Ms. Decker was admitted to the hospital after fainting and, as a result, was put through a gamut of tests by a number of physicians.

Ms. Decker was diagnosed with PPH by Drs. James White and Amit Singh, Ms. Decker's treating pulmonologist and cardiologist, respectively.[2] At the time of diagnosis, both Drs. White and Singh attributed her PPH to her 1996 diet drug use. In a letter to Dr. Neil Shallish, Ms. Decker's primary care physician, Dr. White wrote, "Mrs. Decker is a 54-year old female with pulmonary arterial hypertension. At this point, it is likely related to her Redux use nine years past ...." (Pl.'s

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2. Ms. Decker's medical records state that she was diagnosed with pulmonary arterial hypertension ("PAH"). Today, PPH is commonly known as PAH. That was not the case at the time the Settlement Agreement was drafted. For clarity, we will refer to Ms. Decker's diagnosis as PPH, the terminology used in the Settlement Agreement.

Resp., Ex. B). Dr. Singh also wrote Dr. Shallish, stating, "Mrs. Decker ... is ... unfortunately afflicted with significant pulmonary hypertension felt due to prior anorectic agent use, i.e., Redux." (Pl.'s Resp., Ex. C).

Ms. Decker subsequently underwent an endoscopy, ordered by Dr. Brent Lemberg, her gastroenterologist and hepatologist. As a result of the endoscopy, performed on August 31, 2006, Dr. Lemberg diagnosed Ms. Decker with gastric antral vascular ectasia ("GAVE"), a disease of the stomach. A biopsy of Ms. Decker's liver showed that she also had Stage 3 primary biliary cirrhosis.

At Dr. White's direction Ms. Decker underwent a liver catheterization on February 14, 2007. The test showed that Ms. Decker had "significant portal hypertension." (Wyeth Ex. 12). Dr. Lemberg has testified that Ms. Decker's primary biliary cirrhosis caused her portal hypertension. (Wyeth Ex. 9, Lemberg Dep. pp. 36-37, June 5, 2007).

Wyeth argues that Ms. Decker's doctors have failed to rule out portal hypertension as the cause of her PPH and have merely offered conclusory opinions that her PPH was caused by diet drugs. We disagree. Dr. White testified at his deposition that "[t]o the best of [his] medical opinion," neither Ms. Decker's primary biliary cirrhosis nor her portal hypertension is the cause of her PPH. (Pl.'s Resp. Ex. H, White Dep. 63:15-63:19, June 4, 2007). Ms. Decker's retained expert, Dr. Harold I. Palevsky, has testified that Redux is "likely the cause or a significant contributing factor" to her PPH. (Pl.'s Resp.

Ex. L., Palevsky Dep. 17:15-17:19, Sept. 24, 2007). In a supplemental declaration Dr. Palevsky further clarified his opinion, stating: "All possible causes of Mrs. Decker's [PPH] have been ruled out as capable of explaining her [PPH] with the sole exception of her ingestion of Redux for six (6) months. Accordingly, I have so ruled out conditions including ... portal hypertension ...." (Pl.'s Resp. Ex. M).

Wyeth maintains that the opinions of Drs. White and Palevsky are not grounded in a reasonable scientific basis. We agree that all expert opinions regarding a PPH diagnosis must have a reasonable scientific basis. On the record before us, it is not the role of this court to make this determination. We simply must decide whether a genuine issue of material fact remains.

According to the deposition transcripts and other exhibits before us, Drs. White and Palevsky have opined that Redux caused Ms. Decker's PPH. This situation is not, as Wyeth argues, analogous to PTO No. 2912 (July 2, 2003). In that case the plaintiff's expert retreated from her conclusion ruling out connective tissue disease, another alternative cause of PPH under the Settlement Agreement, when presented with new medical information at her deposition. Under those circumstances we concluded that connective tissue disease had not been rule out.[3]

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3. It is of note that this court vacated PTO No. 2912 after the plaintiff's expert conducted another review of plaintiff's medical records and submitted a letter stating, "I have, in fact, ruled out (continued...)

Here, Drs. White and Palevsky are both aware that Ms. Decker has portal hypertension but nevertheless opine that Redux caused her PPH. Wyeth is free to question the soundness of those conclusions but the determination as to whether they are correct properly lies with the state trial court.

Accordingly, because genuine issues of material fact exist, the motion of Wyeth to enforce the Settlement Agreement will be denied.

3.(...continued)
connective tissue disease ...." PTO No. 3066 (Oct. 10, 2003).

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PRETRIAL ORDER NO.

AND NOW, on this 30th day of November, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the motion of Wyeth to enforce the Settlement Agreement under Pretrial Order No. 1415 against class member Kathryn A. Decker is DENIED.

BY THE COURT:

/s/ Harvey Bartle III
C.J.