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
ANNETTE KERR, et al.	:	
v.	:	
ED R. STEWART, et al.	:	CIVIL ACTION NO. 03-20014

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, J. March , 2004

Wyeth has filed a motion challenging the eligibility of two class members, Annette Kerr and Roberta Raines,[1] to exercise an intermediate opt-out under the Nationwide Class Action Settlement involving the diet drugs, Pondimin and Redux. A person who is an intermediate opt-out may file a lawsuit for damages against Wyeth but may not seek "punitive, exemplary or any multiple damages." See Settlement Agreement § IV.D.3.c. The action of Ms. Kerr and Ms. Raines was transferred here from the United States District Court for the Western District of Oklahoma for pretrial proceedings in accordance with the multidistrict litigation process. See 28 U.S.C. § 1407.

1. The docket spells her last name as "Raines." In the briefs before us, the parties refer to her as Roberta "Rains." Not knowing which is correct and with apologies if we are in error, we will continue to use the spelling as it appears on the docket.

In order to be eligible to exercise an intermediate opt-out, a person must be "diagnosed by a Qualified Physician as FDA Positive." See Settlement Agreement § IV.D.3.a. The Settlement Agreement has two definitions of "FDA Positive." The one applicable to Ms. Kerr and Ms. Raines is as follows:

> With respect to a diagnosis based on an Echocardiogram conducted after September 30, 1999, FDA Positive is defined as mild or greater regurgitation of the aortic valve of the heart and/or moderate or greater regurgitation of the mitral valve of the heart as these levels are defined in Singh (1999) and measured by an echocardiographic examination performed and evaluated by qualified medical personnel following the protocol as outlined in Feigenbaum (1994) or Weyman (1994).

Settlement Agreement § I.22.b (internal footnotes omitted). Both class members rely on the echocardiogram readings of Dr. Joshua Penn, a board-certified cardiologist, that they are FDA Positive. It is undisputed that he is not and has not been involved in their treatment.

Wyeth first contends that the findings and conclusions of Dr. Penn do not constitute a diagnosis under the Settlement Agreement.[2] Wyeth argues that Dr. Penn and i-Cardio, his mobile echocardiography company which performed the echocardiograms on Ms. Kerr and Ms. Raines, are engaged in "an assembly-line echocardiogram reading process." Wyeth maintains that because Dr. Penn never met or examined Ms. Kerr or Ms. Raines, his

---

2. Wyeth does not challenge Dr. Penn as a "qualified physician," which under the Settlement Agreement means "a board-certified or a board-eligible cardiologist." See Settlement Agreement § I.48.

readings of their echocardiograms were not diagnoses as required under the Settlement Agreement. According to Wyeth's supporting brief, "the act of rendering a diagnosis under the Settlement Agreement is inextricably linked to the treatment of a patient. Wyeth elaborates, "In other words, the Settlement Agreement requires that the physician evaluating the echocardiogram be involved in the medical care of the patient." We disagree.

Wyeth's reading of the word diagnosis is far too narrow. In addition to the definition of FDA Positive applicable here, the Settlement Agreement contains another definition when the diagnosis is based on an echocardiogram conducted on or before September 30, 1999. This definition states, "... FDA Positive is a condition in which the Cardiologist interpreting the Echocardiogram, in the ordinary course of medical treatment, has issued a written report which clearly states that the individual has mild or greater regurgitation of the aortic valve and/or moderate or greater regurgitation of the mitral valve; ...." (emphasis added). Settlement Agreement § I.22.a. While these earlier diagnoses require that the cardiologist must have been acting "in the ordinary course of medical treatment," these crucial words are omitted in the definition of FDA Positive relevant to the diagnoses of Ms. Kerr and Ms. Raines. This omission can only be read as eliminating such a requirement for them.

There is simply nothing in the Settlement Agreement to suggest that a diagnosis based on a post-September 30, 1999

echocardiogram has anything other than its ordinary meaning. In Clites v. Jones & Laughlin Steel Co., 663 F.2d 14 (3d Cir. 1981), our Court of Appeals spoke about the diagnosis made by a pathologist as a result of an autopsy. Clearly, a diagnosis made after a person has died is not linked to a patient's treatment or medical care. In Flanagan v. Labe, 690 A.2d 183 (Pa. 1997), a medical malpractice action, the Pennsylvania Supreme Court enunciated the meaning of "medical diagnosis" in accordance with "common and approved usage" as follows:

> A medical diagnosis is commonly understood to be an identification of a disease based on its signs and symptoms. See Random House Dictionary (2d ed. unabridged 1987) (defining diagnosis for medical purposes as "the process of determining by examination the nature and circumstances of a diseased condition"); Webster's Third New International Dictionary (unabridged 1976) (defining "medical" as "concerned with physicians or the practice of medicine" and defining "diagnosis" as "the art or act of identifying a disease from its signs and symptoms"). See also Commonwealth v. Green, 251 Pa. Super. 318, 323, 380 A.2d 798, 801 (1977) ("Medical diagnosis ... entails a 'conclusion concerning a condition not visible but reflected circumstantially by the existence of other visible and known symptoms.' Paxos v. Jarka Corp., 314 Pa. 148, 153-154, 171 A. 468, 471 (1934).").

Flanagan, 690 A.2d at 186.

We agree with the class members that Dr. Penn made a diagnosis as that term is used in common and approved usage and thus as used in the Settlement Agreement. He identified the medical condition of Ms. Kerr and Ms. Raines as FDA Positive by reading their echocardiograms. It is not necessary that Dr. Penn

render a diagnosis for the purpose of treating or providing medical care to the person whose condition he seeks to evaluate.

Of course, whether Dr. Penn properly identified Ms. Kerr and Ms. Raines as FDA Positive is an entirely different matter. Wyeth vigorously contends that his readings are wrong and that accordingly these two class members are not eligible to exercise an intermediate opt-out. Wyeth relies on its expert, Dr. Miguel Quinones, who has extensive experience in echocardiography.

Preliminarily, we must decide whether this eligibility issue should be decided here or by the transferor court after the case is returned to it for trial. While the meaning of diagnosis is of significance to all class members seeking to opt out, the question of whether Ms. Kerr and Ms. Raines are FDA Positive is fact specific. We are being asked to resolve highly contested and individualized medical questions related to two class members. While a decision in this regard goes to the question of their eligibility to opt out, it also goes to the merits of the controversy, that is, whether these class members may recover damages from Wyeth in their lawsuit. If we should decide the issue against them, they are out of court not only because of ineligibility to opt out but also because they are deemed not to be FDA Positive.

The Settlement Agreement provides that if a class member as an intermediate opt-out initiates a lawsuit, Wyeth "shall have the right to challenge, in such lawsuit only, whether

the opt-out was timely and proper, including whether the class member was eligible to exercise such an opt-out right." See Settlement Agreement § IV.D.3.c.

In Pretrial Order ("PTO") No. 2654, we had before us the question whether this court or a state court where an opt-out case was pending should decide the question of eligibility to opt-out. Because the Settlement Agreement stated that the issue was to be decided "in such lawsuit only," we held that it was a matter for the state court where the lawsuit was pending. While we also concluded that eligibility to opt-out was a threshold issue, we left it to the state court as to when and how that issue should be determined. Here we are dealing with an opt-out action transferred from the United States District Court for the Western District of Oklahoma as part of the multidistrict litigation process.

Wyeth cites to PTO No. 2984 in which this court urged the MDL panel not to dissolve this MDL 1203. In that PTO, we referred to the need for consistency in the application of detailed medical criteria for eligibility to opt out. We did not imply that we would decide all fact specific issues of opt-out eligibility. Unlike other matters under the Settlement Agreement, eligibility to opt out is to be decided "in such lawsuit only." This language clearly allows for the transferee court to defer to the transferor court in appropriate circumstances. We will continue to rule on matters of general applicability where consistency is necessary as we have done

here. On the other hand, the transferor court seems to be the more fitting forum to decide the contested factual issues of a medical nature with respect to the eligibility of Ms. Kerr and Ms. Raines to opt out.

Accordingly, we will deny without prejudice Wyeth's motion challenging the eligibility of Annette Kerr and Roberta Raines to exercise an intermediate opt-out.

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
ANNETTE KERR, et al.	:	
v.	:	
ED R. STEWART, et al.	:	CIVIL ACTION NO. 03-20014

PRETRIAL ORDER NO._____

AND NOW, this day of March, 2004, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the motion of Wyeth challenging the eligibility of class members Annette Kerr and Roberta Raines to exercise an intermediate opt-out right (Document #7) is DENIED without prejudice.

BY THE COURT:

_____
J.