

SUPERIOR COURT OF NEW JERSEY  
BERGEN COUNTY  
HON. CHARLES J. WALSH, J.S.C.  
MASTER DOCKET NO.: BER-L-13379-04MT  
DOCKET NO.: BER-L-545-04MT

***IN RE: DIET DRUG LITIGATION  
FREDA REED v. WYETH CORPORATION***

MOVANT: FREDA REED

MOVANT'S ATTORNEY: CORY, WATSON, CROWDER & DEGARIS (JON C. CONLIN, ESQ. APPEARING)

OPPONENT: WYETH CORPORATION

OPPONENT'S ATTORNEYS: PORZIO, BROMBERG & NEWMAN (THOMAS J. O'GRADY, ESQ., APPEARING) AND ARNOLD & PORTER (ANAND AGNESHWAR, ESQ., APPEARING)

LETTER OPINION: NOVEMBER 15, 2004

This matter is before the Court on a motion by Freda Reed ("Reed") seeking an order precluding Wyeth Corporation ("Wyeth") from challenging Reed's contention that she has FDA Positive mitral regurgitation. For the reasons that follow, the Court finds that Wyeth may challenge Reed's contention that she has FDA Positive mitral regurgitation even if it concedes that Reed has FDA Positive aortic regurgitation.

The facts underlying this motion are straightforward and uncontested. Reed's right to opt-out of Multidistrict Litigation 1203 ("MDL 1203") is governed by the Class Action Settlement ("CAS").<sup>1</sup> Under the CAS, certain class members who satisfy specific medical criteria and procedural requirements are entitled to exercise an IOO, and thereafter bring a lawsuit against Wyeth.

Section IV.D.3.a of the CAS defines the eligibility criteria for IOOs . These are as follows:

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<sup>1</sup> The procedural history and the mechanism for asserting eligibility challenges is discussed in *In Re: Diet Drug Litigation*, BER-L-7718-03 (Law Div. April 13, 2004) slip op.

**Eligibility:** All Diet Drug Recipients (other than those who have entered into AIO Individual Agreements pursuant to the Accelerated Implementation Option) who are not members of Subclasses 2(a), 2(b) or 3, *and who have been diagnosed by a Qualified Physician<sup>2</sup> as FDA Positive by an Echocardiogram* performed between the commencement of Diet Drug use and the end of the Screening Period, and their associated Representative and/or Derivative Claimants, are eligible to exercise a right to Intermediate Opt-Out....

CAS § IV.D.3.a (emphasis added).

The CAS gives Wyeth the right to contest the eligibility of each plaintiff to make an IOO:

If, at any time after a Class Member exercises an Intermediate Opt-Out right, the Class Member initiates a lawsuit seeking to pursue a Settled Claim against AHP or any other Released Party, the Released Party 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....*

CAS § IV.D.3.c (emphasis added).

The CAS defines FDA Positive by specifying both the requisite levels of regurgitation for each valve at issue (either aortic or mitral) and the methodologies under which the echocardiograms must be performed.

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*

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<sup>2</sup> According to the CAS, “Qualified Physician shall mean a Board-Certified or Board-Eligible Cardiologist.” CAS § I.47.

*personnel following the protocol as outlined in Feigenbaum (1994) or Weyman (1994).*

CAS § I.22.b (citations omitted) (emphasis added).

FDA Positive, as defined, contains two standards: one quantitative and one methodological. First, the quantitative measurements that constitute FDA Positive heart valve regurgitation are as follows:

Aortic Valve – Mild or greater regurgitation, defined as regurgitant jet diameter in the parasternal long-axis view (or in the apical long-axis view, if the parasternal long-axis view is unavailable), equal to or greater than ten percent (10%) of the outflow tract diameter (JH/LVOTH).

Mitral-Valve – Moderate or greater regurgitation, defined as regurgitant jet area in any apical view equal to or greater than twenty percent (20%) of the left atrial area (RJA/LAA).

CAS § I.22.b.

The CAS requires that specific criteria be used in determining whether these levels of valvular regurgitation are present. J.P. Singh, et al. *Prevalence and Clinical Determinants of Mitral, Tricuspid, and Aortic Regurgitation (The Framingham Heart Study)*, 83 Am J. Cardiology 897, 898 (1999) (“Singh”).

Second, the CAS specifies that to meet the FDA Positive standard, the echocardiograms be performed and evaluated by “qualified medical personnel” in accordance with the methodology set forth in two (2) referenced texts – Harvey Feigenbaum, **ECHOCARDIOGRAPHY** (5<sup>th</sup> ed. 1994) (“Feigenbaum Text”) and Arthur Weyman, **PRINCIPLES AND PRACTICES OF ECHOCARDIOGRAPHY** (2d ed. 1994) (“Weyman Text”).

Reed is an IOO and has relied on a December 23, 2002 echocardiogram interpreted by John P. Orchard M.D. to establish her FDA Positive status. Dr. Orchard claims that Reed has both FDA Positive mitral and aortic regurgitation. In June 2004, Wyeth challenged Reed’s claim that she had FDA Positive mitral regurgitation but did not challenge Reed’s claim that she had FDA Positive aortic regurgitation. Reed claims that the CAS does not permit an eligibility challenge

which will, if successful, not return the opt-out candidate to the class. The Court disagrees.

Normal contract principles apply with respect to the construction of the provisions of class action settlement agreements under federal law. *In re Cendant Corp. PRIDES Litig*, 233 F.3d 188, 193 (3d Cir. 2000) (basic contract principles apply to class action settlement agreements); *Plymouth Mut. Life Ins. Co. v. Illinois Mid-Continent Life Ins. Co. of Chicago, Illinois*, 378 F.2d 389, 391 (3d Cir. 1967) (applying the basic contract principles in construing settlement agreements). New Jersey cases reach the same conclusion. *See, e.g., Pascarella v. Bruck*, 190 N.J. Super. 118, 124-125 (App. Div. 1983) (“An agreement to settle a lawsuit is a contract which, like all contracts, may be freely entered into and which a court, absent a demonstration if found or other compelling circumstances, should honor and enforce it as it does other contracts”).

The paramount principle in contract construction is effectuation of the parties’ intentions. *Constitution Bank v. Kalinowski*, 38 F. Supp. 2d 384, 385 (E.D. Pa. 1999). “A contract is to be enforced so as to give effect to the reasonable expectations created by the parties in entering into the bargain.” *Walther & Cie v. U.S. Fidelity & Guaranty Co.*, 397 F. Supp. 937, 941 (M.D. Pa. 1975). If the objective of the parties is ascertainable it should be given the greatest consideration. **RESTATEMENT (SECOND) OF CONTRACTS**, § 202. Hence, the proper interpretation of an agreement “requires consideration of the situation of the parties, the attendant circumstances and the ends they [seek] to achieve.” *Constitution Bank v. Kalinowski*, 38 F. Supp. 2d at 387; **RESTATEMENT (SECOND) OF CONTRACTS**, § 202. And, a contractual interpretation which gives a reasonable meaning to all the terms of the agreement is preferred to an interpretation which leaves a part of the agreement unreasonable or unfulfilled. *See, e.g., Arnold M. Diamond, Inc. v. Gulf Coast Trailing Company*, 180 F.3d 518, 522 (3d Cir. 1999), citing **RESTATEMENT (SECOND) OF CONTRACTS**, § 203; *New Castle County Delaware v. National Union Fire Ins. Co. of Pittsburgh, Pa.*, 174 F.3d 338, 349 (3d Cir. 1999); *Tamarind Resort Assocs. v. Gov’t of Virgin Islands*, 138 F.3d 107, 111 (3d Cir. 1998).

The central aim of the CAS is to secure compensation for those class members with valve disease, while at the same time assuring that Wyeth is able to effectively insist that unqualified IOOs not be able to institute litigation against it. To effectuate these objectives, the CAS details the medical criteria -- i.e., FDA Positive -- which must be satisfied to successfully opt-out. And, Wyeth has reserved to itself the right in the case of each IOO “to challenge ... whether the opt-out was timely and proper,

*including whether the Class Member was eligible to exercise such an opt-out right....”* CAS § IV.D.3.c as to IOOs (emphasis added).

The CAS tellingly provides here that:

A Class Member who timely and properly exercises and Intermediate Opt-Out right may pursue all of his or her Settled Claims ... but may only assert a claim ... based on the heart valve ... which was diagnosed by a Qualified Physician as FDA Positive.

CAS § IV.D.3.c. Accordingly, one who exercises an IOO can only pursue claims that arise from that FDA Positive heart valve.<sup>3</sup> Memorandum and Pretrial Order No. 1415, *In Re: Diet Drugs (Phentermine, Fenfluramin, Dexfenfluramine), Product Liability Litigation*, MDL No. 1203, (E.D. Pa. August 28, 2000) (“PTO 1415”), enjoins any class member exercising an IOO, such as Reed, from pursuing any other Settled Claims. *See* PTO 1415 ¶ 6. In other words, a class member only is permitted to seek damages for Settled Claims relating to a FDA Positive heart valve.

The Court finds that Wyeth may challenge the propriety of a class member’s eligibility to sue based on each valve independently, regardless of whether the condition of the other valve is conceded to be FDA Positive by Wyeth. Any other result would permit an IOO to pursue Settled Claims as to one valve by virtue of an FDA diagnosis in the other, directly violating PTO 1415 ¶ 6 (“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 AHP ... any and all Settled Claims which the class member had, has or may have in the future in any federal, state or territorial court.”).<sup>4</sup>

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<sup>3</sup> The CAS defines the term Settled Claims to include:

any and all claims, including assigned claims, whether known, or unknown, asserted or unasserted, regardless of the legal theory, existing now and arising in the future 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.

CAS I.53.

<sup>4</sup> Reed claims that she may present evidence at trial of injury to the non-FDA Positive mitral valve, to the extent such injury may implicate and support allegations of damage to the FDA Positive aortic valve and that as a valid IOO she may assert *any* claim for damages that naturally flows from injury to the FDA Positive valve. Counsel arguing the motion for

For these reasons then, the Court denies Reed's motion and will permit Wyeth to challenge her eligibility to make a mitral valve claim even where it concedes she has a valid IOO based on the condition of her aortic valve. An Order is entered with this Letter Opinion.

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Reed notes that: "Plaintiff does not dispute, however, that the CAS provides that an Intermediate Opt-Out (IOO) plaintiff may 'only assert a claim against AHP Released Parties and/or the Non-AHP Released Parties based on the heart valve of the relevant Diet Drug Recipient which was diagnosed by a Qualified Physician as FDA Positive....'"

The Court does not intend to rule on whether evidence involving Reed's mitral valve may ever be relevant in the trial of this case. Needless to say, however, the Court will be on guard if efforts to introduce such evidence turns out to be a pretext to enhance Reed's damages claims.