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IN RE: DIET DRUG LITIGATION :  
: SUPERIOR COURT OF NEW JERSEY  
: LAW DIVISION: BERGEN COUNTY  
: MASTER DOCKET NO.: BER-L-7718-03  
: Civil Action  
:  
: **OPINION**  
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Decided: April 13, 2004

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Anita R. Hotchkiss, Esq., Porzio, Bromberg & Newman, P.C. and Peter T. Grossi, Jr, Esq. and Daniel Waldman, Esq., of Arnold & Porter, LLP, appearing on behalf of defendant Wyeth Corporation.

**Walsh, J.S.C.**

This matter is before the Court on a motion filed by Wyeth Corporation, as the successor to American Home Products Corporation (“AHP”) and each of its former subsidiaries, affiliates and divisions (collectively “Wyeth or defendants”) seeking the appointment of an expert or experts to aid in the Court’s evaluation of the eligibility of certain Group I plaintiffs to exercise intermediate or back-end opt-

outs of the Nationwide Class Action Settlement (“CAS”) with AHP. The CAS brought to a close much of the nationwide class action where allegations were made that Pondimin® and/or Redux® (collectively “phen-fen”) <sup>1</sup> caused injuries to the heart valves of individuals taking one or both of these drugs in order to lose weight. Wyeth, in this motion, also seeks to bar 53 of the 182 Group I plaintiffs - - about 29% of them - - from pursuing their lawsuits in the New Jersey courts because it claims that they have failed to meet the criteria necessary to exercise an Intermediate Opt-Out (“IOO”) or Back-End Opt-Out (“BEOO”) under the CAS.<sup>2</sup>

Plaintiffs, through their Co-Liaison Counsel, Williams, Cuker & Berezofsky, and Wilentz, Goldman & Spitzer, P.A. oppose Wyeth’s motion claiming that the CAS restricts “Wyeth to limited challenges regarding plaintiffs’ opt-out eligibility.” According to plaintiffs, “Wyeth ... [only] is allowed to challenge whether the plaintiff submitted written notice pursuant to the [CAS], whether the plaintiff was diagnosed as FDA Positive<sup>3</sup> based on a timely echocardiogram, and whether the diagnosing physician had the requisite qualifications.” According to

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<sup>1</sup> The common name for Pondimin® is fenfluramine and the common name for Redux® is dexfenfluramine. Phen-fen is a combination drug product containing phentermine and either fenfluramine or dexfenfluramine.

<sup>2</sup> There are as of the date of this Opinion over 3400 IOO or BEOO cases filed in New Jersey and consolidated for case management before this Court by the Chief Justice of the New Jersey Supreme Court through Order dated July 17, 2003. By Case Management Order 2 (“CMO2”) the Court directed that cases filed by September 29, 2003 be placed in Group I for discovery purposes. There are now 12 groups each of approximately 300 cases with different discovery start dates. The timetable for each group provides for a date on which Wyeth must challenge the IOO and BEOO opt-outs. Thereafter the Court will permit such challenges only where exceptional circumstances are shown. See *Vitti v. Brown*, 359 N.J. 40 (Law Div. 2003) for a definition of and a thorough discussion of exceptional circumstances in the context of pretrial discovery.

<sup>3</sup> FDA Positive is a term of art defined in the CAS and will be discussed at length later in this Opinion.

the plaintiffs, any opt-out challenges by Wyeth, while permitted as a threshold matter, should be confined to the question of whether a plaintiff timely submitted information attesting to his or her FDA Positive status and whether a qualified physician made a diagnosis of aortic or mitral valve regurgitation following the enumerated criteria in the CAS. Further, since the threshold determination to be made by this Court under this view would be rather mechanical, the plaintiffs argue that no experts need be appointed by the Court to assist it.

For the reasons that follow, the Court finds that Wyeth is entitled to pursue a more searching inquiry than that suggested by plaintiffs. Wyeth, as a threshold matter, may challenge whether each plaintiff has satisfied the time limits and physician qualifications necessary to opt-out as described in the CAS. If these minimums are satisfied, the Court finds that the technician's performance of and/or the physician's evaluation of the echocardiogram supporting the IOO or BEOO must also be medically reasonable. In short, Wyeth will not be bound by the determination by a plaintiff's physician that he or she is FDA Positive, but may challenge the medical reasonableness of that conclusion. Such a hearing will follow the format used to access challenges made to the scientific methodology used by expert witnesses in tort and other cases and discussed in *Kemp ex rel. Wright v. State*, 174 N.J. 412 (2002); *Landrigan v. Celotex Corp.*, 127 N.J. 404 (1992); and *Rubanick v. Witco Chem. Corp.*, 125 N.J. 421 (1991). Thus Wyeth, in

order to disqualify a plaintiff from pursuing an IOO or BEOO will bear the burden of establishing by a preponderance of the evidence that the performance and/or evaluation of the echocardiogram supporting the opt-out was medically unreasonable.

The Court also grants Wyeth's motion for the appointment of an expert or experts to aid it in determining the propriety of Wyeth's challenges. The selection of the expert will follow the format established in this Opinion. Finally, the procedure outlined in this Opinion will be followed in determining how Wyeth may challenge the right of any IOO and BEOO before this Court.

## I

Two (2) drugs, both appetite suppressants, fenfluramine – marketed as Pondimin® – and dexfenfluramine – marketed as Redux®, were widely sold in the United States prior to 1997. In 1997, data surfaced suggesting a link between the use of these drugs and valvular heart disease. In July 1997, the United States Food and Drug Administration (“FDA”) issued a public health advisory and in September 1997, AHP removed both drugs from the market.

In the wake of the Pondimin® and Redux® market withdrawals, some 18,000 individual lawsuits and over 100 putative class actions were filed in the federal and state courts. In December 1997, the Judicial Panel for Multidistrict Litigation transferred all the federal actions to the United States District Court for

the Eastern District of Pennsylvania, creating Multidistrict Litigation 1203 (“MDL 1203”). See *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Products Liability Litigation*, 282 F.3d 220, 226-227 (3d Cir. 2000).

As a result of discussions between AHP and plaintiffs in the various federal and state actions, a tentative settlement anticipating a nationwide class was reached in November 1999. The proposed class included all persons in the United States, as well as their representatives and dependents, who had taken either or both Pondimin® and Redux®. The global settlement contemplated different kinds of relief, including medical care, medical screening, and payment for a variety of defined injuries, including injuries to mitral and/or aortic valves of the potential class members. The injuries covered in the settlement and the anticipated payments for them were set out in a matrix (“matrix benefits”). The cost to AHP in order to fund the settlement totaled \$3.75 billion. In August 2000 after a comprehensive notice program and fairness hearing, Judge Louis C. Bechtel of the MDL Court approved the CAS, Memorandum and Pretrial Order No. 1415, *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Products Liability Litigation, MDL No. 1203* (E.D. Pa. August 28, 2000) (“PTO 1415”). The CAS received “Final Judicial Approval” on January 3, 2002, when all appeals were resolved or exhausted.

The focus of this Opinion is on the rights of each plaintiff and Wyeth respectively where a plaintiff is diagnosed as FDA Positive after September 30, 1999, has opted-out of the CAS and has initiated a lawsuit in the New Jersey courts.<sup>4</sup> Under the CAS, certain class members who satisfy specific medical criteria and procedural requirements are entitled to exercise either an IOO or BEOO, and thereafter bring a lawsuit against Wyeth and others as defined in the CAS.

Section IV.D.3.a of the CAS defines eligibility for IOOs and Section IV.4.a defines eligibility for BEOOs. Both provisions address the medical criteria for exercising opt-outs under the CAS:

**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>5</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....

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**Eligibility:** (1) As to Matrix-Level claims based upon valvular regurgitation, all Diet Drug Recipients (other

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<sup>4</sup> Under the CAS, an individual could be diagnosed as FDA Positive after September 30, 1999 only in accordance with the FDA Positive definition in CAS § I.22.b. An IOO could be exercised during the “Screening Period.” CAS § I. 49. A BEOO is permitted if that plaintiff reaches a Matrix Level Condition after September 30, 1999 but before the Matrix Payment Cut-Off Date. CAS § IV.4.a.1.

<sup>5</sup> According to the CAS, “Qualified Physician shall mean a Board-Certified or Board-Eligible Cardiologist.” CAS § I.47.

than those who have entered into AIO Individual Agreements pursuant to the Accelerated Implementation Option) *who have been diagnosed by a Qualified Physician as FDA Positive or as having Mild Mitral Regurgitation by an Echocardiogram* performed between the commencement of Diet Drug use and the end of the Screening Period, and who reach a Matrix-Level condition after September 30, 1999, but before the Matrix Payment cut-Off Date, and their associated Representative and/or Derivative claimants, may exercise a Back-End Opt-Out right, provided that the Class Member has registered or is deemed to have registered for settlement benefits by Date 2....

CAS § IV.D.3.a; CAS § IV.4.a. (emphasis added)

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

If, at any time after a Class Member exercises an Intermediate .... [or Back-End] 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; § IV.D.4.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 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”).

Wyeth insists that it has the right to challenge both the qualifications of the physician interpreting the echocardiogram supporting the opt-out, as well as whether the echocardiogram is FDA Positive, as asserted by each plaintiff. Plaintiffs, on the other hand, claim that under the CAS Wyeth should only be able to challenge whether a qualified physician, in fact, diagnosed that plaintiff as FDA Positive during the respective time periods set out in the CAS. They further claim that it is Wyeth’s burden to establish by a preponderance of the evidence that the challenged physician is unqualified.

As of the date of this Opinion there are over 3,400 phen-fen cases consolidated for management before this Court. The question of how challenges to IOO and BEOO will be made is obviously of great importance to the management of these cases.

## II

### A.

As noted, mild aortic and moderate mitral regurgitation are the two (2) medical conditions that permit either an IOO or BEOO. These conditions involve

the backward or reverse flow of blood through defective valves during the heart's pumping cycle.

The heart consists of four chambers: the right atrium, the right ventricle, the left atrium and the left ventricle. The right atrium receives deoxygenated blood from the body and ejects that blood into the right ventricle through the tricuspid valve; the right ventricle then pumps that blood across the lungs through the pulmonic valve for oxygenation. The oxygenated blood, in turn, is received by the left atrium, which ejects blood into the left ventricle through the mitral valve. The left ventricle then pumps that oxygenated blood into the aorta through the aortic valve, and from there to the rest of the body. The heart chambers are connected by valves that open to allow blood to pass through and then close to prevent significant backflow. This process ensures the proper directional flow of blood through the heart.

The chambers of the heart fill and empty in a two-phase cardiac cycle that comprises diastole - - the filling cycle, and systole, - - the emptying cycle. For our purposes, we are concerned with the active contraction of the left ventricle and pumping of blood into the aorta through the open aortic valve during systole. Throughout this phase the mitral valve is closed to prevent backward flow or regurgitation from the left ventricle into the left atrium. We are also interested in the other phase of the cardiac cycle -- diastole -- which occurs when blood enters

the left ventricle through the open mitral valve. During this phase the aortic valve is closed to prevent leakage or regurgitation from the aorta back into the left ventricle.

Healthy heart valves rarely prevent all regurgitation. When these valves are closed there may be a minimal amount of leakage -- trace regurgitation. Moreover, during routine valve closure, blood caught between the valve leaflets is displaced backward resulting in some blood backflow. This backward displacement of blood is considered part of the closing process, and is not regurgitation. According to the Weyman Text "true" mitral regurgitation "should last throughout most or all of systole." A brief or non-sustained jet of mitral regurgitation is an indication that the regurgitation is usually less than mild. The same source teaches that "true" aortic regurgitation should continue "throughout diastole." Aortic regurgitation that is brief or non-sustained is usually less than mild.

Normally blood flows at a uniform velocity in a forward direction. This normal blood flow is laminar. Regurgitant flow, on the other hand, produces a jet of mixed velocities which is turbulent. It is this turbulent flow which is one of the focuses of echocardiography.

According to the Weyman and Feigenbaum Texts the degree of valvular regurgitation or valvular insufficiency is classified as trace, mild, moderate, or

severe. Trace aortic regurgitation and trace and mild mitral regurgitation are common in the general population and are considered normal findings.

## **B.**

Echocardiography is a principal technique used to evaluate the heart, including its function, structure and the flow of blood through it. The underlying principle involved in echocardiography is the use of high frequency sound waves. A transducer is placed on the patient's chest wall which emits sound waves that bounce off of the heart's structures, and that information is translated into moving images of those structures on a screen. There are several different techniques available in echocardiography. The technique relevant here is Doppler echocardiography. "Doppler echocardiography is based on the change in frequency of a sound wave that occurs when it strikes a moving target – in this case the red blood cells." Weyman Text at 143.

Color flow Doppler (or pulsed Doppler) is used to display the movement of blood flow through the heart by assigning different colors depending upon the direction and velocity of the blood flow. By convention, laminar blood flowing towards the transducer is depicted in shades of red, and laminar blood flowing away from the transducer is depicted in shades of blue; darker shades indicating slower velocity and lighter shades higher velocity. *See* Feigenbaum Text at 33. Turbulent blood flow is depicted in a "mosaic," multi-colored pattern, thus

displaying the different velocities and directions of the blood in the area under study. The absence of blood flow is depicted by black on color flow Doppler. Thus, in Doppler echocardiography blood flow is represented as discrete color areas (jets) in real time, superimposed on two-dimensional images of the heart's structure.

The quality of an echocardiogram depends on a number of factors including: the patient's body; the technical skill of the physician or sonographer performing the study; the equipment used and its settings; and, physician interpretation and measurements. The proper performance of an echocardiogram here must follow the guidelines set forth in the Weyman and Feigenbaum Texts.

Settings on the echocardiographic equipment can have a substantial impact on the quality of the images and the accuracy of the recordings. Two (2) key settings on the equipment are referred to as the Nyquist limit and gain setting. The Nyquist limit establishes the maximum velocity of laminar blood flow that can be detected in a monochromatic fashion (solid color).<sup>6</sup> When the velocity of the turbulent blood flow exceeds the pre-set Nyquist limit the blood flow appears as a "mosaic," multi-colored pattern. If the Nyquist limit is set too low, the velocity of normal blood flow may exceed a low Nyquist setting and will appear as turbulent

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<sup>6</sup> As the Feigenbaum Text at 29 notes: "The major disadvantages of pulsed Doppler is that the velocity one can measure is limited. The pulsed system inherently has a pulsed repetition frequency or PRF. The PRF determines how high a Doppler frequency the pulse system can detect. .... The inability of a pulsed Doppler system to detect high -frequency Doppler shifts is known as "aliasing." The upper limit of frequency that can be detected with a given pulsed system is known as the "Nyquist" limit or number. This limit is defined as one half the pulse repetition frequency or PRF.

regurgitation, even though it is actually normal non-regurgitant flow. Additionally, when the Nyquist limit is set too low it will exaggerate the degree of any regurgitation present by including normal blood flow velocity in the turbulent regurgitant jet area. According to Martin E. Goldman, M.D. (“Dr. Goldman”), one of Wyeth’s experts, the generally accepted practice regarding the Nyquist limit is “the higher the better.” He endorses the finding by Judge Bartle in PTO 2640 that “for measuring a mitral regurgitant jet, a Nyquist limit in the 60s or 70s cm/sec range is appropriate.” *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Products Liability Litigation (PTO 2640)*, 236 F. Supp. 445, 452 (E.D. Pa. 2002) (“PTO 2640”).

A color Doppler gain setting is another important variable in the echocardiographic system. If the gain on echocardiographic equipment is set too high, the image has “a background noise” or “speckling,” making it difficult to assess true regurgitation. As the Weyman Text teaches, the “detection of the Doppler frequency shift is critically dependent on the signal/noise ratio, and every effort must be made to maximize this relationship.” Weyman Text at 256.

Another important technical aspect of echocardiographic acquisition relates to the angle the transducer is placed relative to the heart when images are recorded. If those images are not acquired in the appropriate angle or plane, the amount of regurgitation and the sizes of the chambers of the heart may appear larger or

smaller than they really are. Again, the Weyman Text teaches that “doppler frequency shifts are maximal when the sound beam is parallel to the flow vector (i.e., aligned parallel to the path of blood flow in the vessel of interest) ... The Doppler beam, therefore, is ideally aligned parallel, rather than perpendicular, to flow because larger frequency shifts are easier to detect and the output is less subject to random fluctuation.” Weyman Text at 256.

FDA Positive heart valve regurgitation involving the aortic valve requires that two (2) measurements be made: (1) the height of the jet of aortic regurgitation (JH); and (2) the height of the left ventricular outflow tract (LVOTH or LVOT).<sup>7</sup> The JH measurement is the linear width of the jet of aortic regurgitation as it leaks backward into the left ventricle. The Feigenbaum Text tells us that this measurement must be made as close as possible to the point of origin of that jet on the ventricular side of the aortic valve. *Id.* at 283. Otherwise, the measurement will be exaggerated by the spray or “nozzle effect” that occurs when high velocity liquid (regurgitant blood) is ejected through a narrow orifice into a lower pressure chamber (the left ventricle in diastole). *Id.* at 283. The LVOT is the region of the left ventricle just below the aortic valve. These two measurements are then expressed as a ratio JH/LVOT. Wyeth’s experts advise that current technology utilizes digitally calibrated calipers or cursors, which can measure the linear width

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<sup>7</sup> A diagram illustrating how this measurement is actually made is displayed in the Feigenbaum Text at 285, Fig. 6-101.

of the JH and LVOT on a frozen frame or image off line using a digitally calibrated caliper or cursors, from commercially available software packages.

The definition of FDA Positive mitral regurgitation also requires two (2) measurements to be made: (1) the regurgitant jet area, or “RJA”; and (2) the size of the left atrium, or left atrial area, “LAA.” Unlike the linear width measurements made of the JH and LVOT, the RJA and LAA are area measurements. Again these measurements are expressed as a ratio, RJA/LAA, in assessing the degree of mitral regurgitation. These measurements of the RJA and LAA can be done while the sonographer is acquiring the study, or off-line, and are referred to as tracings or planimetry when using the technology just described.

According to the Weyman and Feigenbaum Texts, only mosaic colored turbulent blood flow should be included within the tracing of RJA. Blood already in the left atrium awaiting the next diastolic cycle to open the mitral valve, can be displaced by the high velocity turbulent regurgitant jet, and appears as a lower velocity laminar blue. According to Wyeth’s experts, this flow velocity blood is not regurgitation, and should not be included in the sonographer’s tracing of RJA.<sup>8</sup>

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<sup>8</sup> Stated another way by one of Wyeth’s experts, Dr. Charles Gibbs Vasey, M.D.,  
In the case of mitral regurgitation, a substantial pressure gradient exists between the high pressure that exists in the left ventricle and the normally low pressure in the left atrium. Consequently, the velocity of mitral regurgitation is normally very high and creates a turbulent color-flow map. The term “aliasing” refers to the more turbulent color-flow display seen with high velocity blood flow such as regurgitation. This pattern is also referred to as “mosaic.” When the high velocity (or “aliased” or “mosaic”) jet of mitral regurgitation enters the left atrium, it naturally displaces blood already within the left atrium. This displaced blood, typically represented as a solid laminar blue color, is not part of the mitral

Additionally, according to Wyeth's experts, a black area represents static, or still blood, and this area should not be within the tracing of RJA either.

### **III**

#### **A.**

The parties here have entirely different views as to what procedure should be followed by this and other courts in the phen-fen litigation where Wyeth challenges an IOO or BEOO. Wyeth sees its challenges being resolved through an adversarial process where the court, as a threshold matter, must determine as a fact finder whether each opt-out can establish that the time frames were met, the physician was qualified and the opt-out is, in fact, FDA Positive. The burden of proof on all these issues, according to Wyeth, should be placed on each plaintiff.

The plaintiffs, on the other hand, see any court's role in vetting the IOOs and BEOOs as practically non-existent. According to them, if a qualified physician determines that the plaintiff is FDA Positive within the applicable time frames, then that is the end of the matter. Challenges as to whether the time frames were met or the technician or physician performing or interpreting the echocardiogram were qualified can be made by Wyeth, but Wyeth bears the burden of proof of establishing non-eligibility. Whether the individual IOO or BEOO is FDA

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regurgitant jet and typically has a low velocity that can be detected by color flow Doppler. This displaced blood should not be included when calculating the mitral regurgitant jet area.

Positive by echocardiography, however, cannot be challenged as a threshold matter. According to plaintiffs, that question can only be raised before a jury in the context of what damages that plaintiff might have suffered.

As already noted in this Opinion, the Court disagrees with both the plaintiffs and Wyeth. But before explaining the Court's reasoning in reaching its conclusion, some legal background is in order.

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 of fraud 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(I). 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(1). 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 and BEOOs 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 or BEOO “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 ; § IV.D.4.c as to BEOOs (emphasis added).

It is inconceivable that Wyeth would have insisted on the right to challenge the IOOs and BEOOs, and at the same time would be satisfied with the mechanical gatekeeping suggested by the plaintiffs. After all, such a mechanical test would effectively prevent Wyeth from successfully challenging even outright fraudulent claims until well into the discovery process. There are now tens of thousands of cases which have been brought by the IOOs and BEOOs in the courts of this and other states, as well as those IOOs and BEOOs which remain in the federal courts. The interpretation of the CAS suggested by the plaintiffs places a huge financial burden on Wyeth for apparently no gain. In essence, the bargained for challenge process, as the plaintiffs would have it, would be virtually worthless as a winnowing tool. In view of the significant amount of money committed to the class action settlement by Wyeth, unequivocal language in the CAS would be necessary to support such a reading of the challenge provisions set out in CAS § IV.D.3.c and § IV.D.4.c. Plainly, no such language exists.

Other technical and definitional portions of the CAS support Wyeth’s view that it may challenge a physician’s conclusion that a plaintiff was FDA Positive

and the manner in which the echocardiogram was performed. The CAS provides two (2) definitions for the term FDA Positive, one applicable up to and including September 30, 1999 and the other applicable after that date. Prior to September 30, 1999 the physician interpreting the echocardiogram is the final arbiter of whether a claimant is FDA Positive, at least with respect to eligibility for some fund distributions.<sup>9</sup> This definition of FDA Positive does not specify the methodologic criteria to be used by the physician in this assessment either.

But, the FDA Positive definition relevant here -- CAS § I.22.b. -- is reserved for IOOs and BEOOs or those seeking matrix benefits. FDA Positive status in such cases only may be found when the echocardiography is “performed and evaluated by qualified medical personnel following the protocol as outlined in Feigenbaum (1994) or Weyman (1994).” CAS § I.22.b. Similarly, while in clinical practice there are a number of different accepted methodologies for identifying and quantifying the amount of regurgitation, the CAS specifies that the methodology

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<sup>9</sup> CAS § I.22.a defines FDA Positive as follows:

With respect to a diagnosis based on an Echocardiogram conducted between the commencement of Diet Drug use and September 30, 1999, 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; provided however, that this definition shall be applicable only to qualification of a Diet Drug Recipient for Fund A benefits. *In order to qualify for Matrix compensation Benefits, a Diet Drug Recipient must present evidence that he or she had an Echocardiogram prior to the end of the Screening Period that meets the requirements of Section 1.22.b below.* (the Section I.22.b definition of FDA Positive is relevant to this case, see page 7 of this opinion) (emphasis added).

described by Singh must be used to determine whether a class member is FDA Positive. The CAS also specifies which of the many possible echocardiographic views must be used to assess this regurgitation and the amount of regurgitation that must be found. Eligibility for a BEOO requires the satisfaction of even more conditions. In addition to meeting the specified echocardiographic criteria, a BEOO must have one of the medical conditions defined as “Matrix-Level,” and be “eligible for Matrix Compensation Benefits” using the medical criteria reported in the CAS. In short, a fair reading of the CAS supports Wyeth’s claim that the CAS permits it to mount an early and meaningful challenge to an IOO or BEOO.

Importantly, the plaintiffs’ interpretation of the challenge provisions in the CAS also appear at odds with the expressed views of the Federal Judge supervising MDL 1203. Judge Harvey Bartle has been supervising MDL 1203 since the retirement of Judge Bechtel. In that capacity Judge Bartle has been asked on several occasions to interpret the challenge provisions in issue here. To date he has declined to do, observing that under the CAS, challenges must be made in the court where each IOO or BEOO is proceeding. Judge Bartle, however, has made it clear, at least in the view of this Court, that the permitted challenge to the opt-outs under the CAS is designed to be more searching than suggested by the plaintiffs.

In *PTO 2640*, 236 F. Supp. 2d 445 (E.D. Pa. 2002), the Settlement Trust and Wyeth challenged the medical reasonableness of a number of echocardiograms

submitted to the Trust for the payment of matrix benefits. Judge Bartle found that 78 echocardiograms submitted on behalf of claimants seeking matrix benefits were medically unreasonable under CAS § VI.E.6-7 and denied payment to those claimants. Those cardiograms were interpreted by two (2) cardiologists that Wyeth sought to exclude from further participation in the CAS and the opt-out process. Specifically, and among other things, Wyeth sought to bar claimants from using echocardiograms performed and/or interpreted by either physician in support of IOOs or BEOOs. While denying this broad request for relief, Judge Bartle made it clear that in lawsuits brought by IOOs or BEOOs Wyeth would have the opportunity” to dispute any questionable conclusions or findings...” by these physicians “through the adversary process.” *See PTO 2640*, 236 F. Supp. 2d at 463.

Judge Bartle also has stated on several occasions that he views the right Wyeth has to challenge IOOs and BEOOs as a “preliminary or threshold” matter, though he has, to this date, declined to specifically interpret the provisions in the respective opt-out provisions. *See Memorandum and Pretrial Order No. 2654, In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Products Liability Litigation MDL No. 1203*. (E.D. Pa. November 25, 2002) at 4 (“PTO 2654”).

Class counsel who were responsible for negotiating the CAS also share the view that the challenge process must involve a more demanding inquiry than

simply “rubber stamping” an allegedly qualified physician’s view that an IOO or BEOO is FDA Positive. Their interpretation of the document they helped negotiate provides additional support as to the intent of the parties. Class counsel submitted a brief addressed to the challenge process and noted that:

An interpretation of the ... [CAS] that would prevent Wyeth from challenging whether a given opt-out plaintiff actually had FDA Positive valve disease as defined in the ... [CAS] would gut the animating purpose of the ... [CAS], render its implementing terms wholly ineffective and lead to an unreasonable result. The absence of any opportunity to challenge whether an opt-out plaintiff actually has FDA Positive regurgitation means that Class Members can effectively overwhelm Wyeth and the legal system with claims without any regard for whether they even arguably meet the detailed medical criteria for FDA positive regurgitation. Indeed, the absence of such an opportunity would mean that Wyeth and the legal system must suffer full blown adjudication of opt-out claims even where they are based on fraudulent or medically bogus physician “certifications” of a type that have become all too common in the Matrix claims process.

Such an interpretation would, therefore, render nugatory the intent of the “[CAS] to confine benefit claims to those who truly have valve disease. It would eviscerate the architecture of the [CAS] which is designed to assure that neither the claims process nor the opt-out process becomes bloated with inappropriate claims that will sap the financial resources of Wyeth to pay good claims. It would unreasonably encourage the filing of non-meritorious, and hence unlawful, claims while at the same time divesting the Court of an important tool to triage those claims out of the tort system before they demand application of the vast financial and legal resources engendered by full blown merits discovery. It

would effectively read the detailed definition of FDA Positive valve disease out of the [CAS]. And it would do so differentially for those electing to exercise downstream opt-out rights as compared with those subject to enforcement of the definition through the [CAS] audit mechanism, thereby destroying the carefully calibrated symmetry of the ... [CAS]

Class Counsel's Reply Memorandum in Support of Wyeth's Motion For Entry of an Order Establishing a Procedure for Challenging the Eligibility of Plaintiffs in MDL 1203 to Exercise Intermediate or Back-End Opt-Out Rights, at 10-11, May 15, 2002. ("Class Counsel Brief")

The plaintiffs argue that: despite the language of the CAS, the intent which it expresses, the views of Judge Bartle - the MDL Judge charged with its administration and the position of class counsel that had negotiated the CAS, the CAS is ambiguous as to the legal form the eligibility challenge must take. Thus, in their eyes, the terms of the CAS, like any contract where ambiguities exist must be determined by a jury when each case is ultimately tried. *See, e.g., Michaels v. Brookchester, Inc.*, 26 N.J. 379, 387 (1958); *Winslow v. Corporate*, 335 N.J. Super. 495, 502 (App. Div. 2000). This Court disagrees. Such an interpretation would, in the Court's view, "gut the animating purpose of the [CAS], render its implementing terms wholly ineffective and lead to an unreasonable result." The Court finds, that under the CAS, Wyeth may as a preliminary and threshold matter, challenge whether each IOO or BEOO "was timely and proper" and this challenge

will encompass the question of whether the interpretation of the echocardiogram supporting the IOO or BEOO was medically reasonable.

**B.**

If Wyeth, as a threshold matter, may challenge IOOs and BEOOs, the question next arises as to the procedure to be followed in exercising that challenge. There has been debate in the courts of several states as to which party has the burden of proof to establish that the IOO or BEOO in question was timely and proper. *See In re Phen-fen Litigation*, Case Management Order No. 15, slip op at 4 (Pa. C.P. December 29, 2003). Wyeth has indicated that in the face of a challenge, each IOO or BEOO should bear the burden of establishing his or her entitlement to opt-out. In the Court's view, the CAS appears to indicate otherwise.

The CAS, as noted, provides that “[Wyeth] shall have the right to challenge . . . whether the opt-out was timely and proper, including whether the Class Member was eligible to exercise an opt-out right.” CAS § IV.D.3.c; § IV.D.4.c. The relevant definition of FDA Positive, as already discussed, simply requires that the medical conditions permitting either an IOO or BEOO be diagnosed “based on an Echocardiogram” measured under specified medical criteria using specified techniques and “performed and evaluated by qualified medical personnel.” CAS § I.22.b. In the absence of a challenge, the opt-out is accomplished by plaintiff simply signing and timely filing a form appended to the CAS as Exhibit 7.

The Court finds that under the CAS, Wyeth must establish by a preponderance of the evidence that the opt-out either was not timely or not proper. Obviously, where the opt-out is untimely or the echocardiogram is performed or evaluated by unqualified medical personnel, the challenge is straightforward, much like a challenge to personal jurisdiction or, perhaps standing. *See, e.g., Carteret Sav. Bank F.A. v. Shusan*, 954 F.2d 141, 142 n.1 (3d Cir. 1992) (evidentiary hearing appropriate where personal jurisdiction is in dispute); *Munoz Mendoza v. Pierce*, 711 F.2d 421, 425 (1<sup>st</sup> Cir. 1983) (evidentiary hearing appropriate where standing issues raised). If Wyeth establishes a plaintiff has failed to satisfy these conditions, he or she will be returned to the class. The question then arises as to what is the scope of the challenge where it goes to the satisfaction by a plaintiff of the medical criteria or techniques specified in the CAS?

### C.

The rationale for IOOs and BEEOs in the first place is a change in that class member's medical condition. At the outset, “[a]ll Class Members . . . [were] eligible to exercise an Initial Opt-Out right.” CAS § IV.D.2.a. In order to opt-out, any class member need only have “submit[ted] timely written notice to the Claims Administrator(s), with a copy to AHP, clearly manifesting the Class Member’s intent to opt-out of the Settlement.” CAS § IV.D.2.b. But the plaintiffs presently before the Court did not do so. Instead, each plaintiff now has sought to opt-out

because of an alleged progression in his or her disease state and the CAS plainly anticipates he or she may do so. The Court already has determined that all aspects of this opt-out may be challenged. It is the scope of the challenge as to whether the specified techniques were employed by otherwise qualified medical personnel and yielded the necessary medical conclusions to which the Court must now turn.

The CAS itself provides for challenges by the Settlement Trust where claims are based on evidence of mild aortic or moderate mitral valve regurgitation which do not have “a reasonable medical basis.” CAS § VI. E.6-8. The Settlement Trust and Wyeth were successful in efforts to prevent some 78 claimants from obtaining matrix benefits in the MDL because the evidence supporting those claims were found to be medically unreasonable. *PTO 2640*, 236 F. Supp. 2d at 460. The hearing was triggered under the provisions of the CAS and focused on the way the 78 echocardiograms were performed and interpreted. Ultimately, Judge Bartle found that the same echocardiogram criteria at issue here had not been satisfied to a medically reasonable extent in the 78 cases under challenge. *PTO 2640*, 236 F. Supp. 2d at 451-460. In doing so, Judge Bartle made credibility determinations. As a result of the determinations, Judge Bartle denied those claims and granted other relief to the Settlement Trust and to Wyeth. *Id.* at 454-455 and 464-465. Of course, under the CAS, Judge Bartle was the ultimate finder of fact. CAS § VI.8.

That is not the case in the over 3400 actions presently before this Court. The disputed facts in these cases generally must be determined by juries.

Wyeth, however, urges that this Court decide the question of whether each opt-out is FDA Positive, claiming such a determination is a preliminary matter. Citing cases dealing with personal jurisdiction, standing and equitable suspension of statutes of limitations under the discovery rule, Wyeth claims that our state courts routinely make such preliminary determinations. *Al Walker Inc. v. Borough of Stanhope*, 23 N.J. 657, 666 (1957) (New Jersey courts regularly hear evidence in making threshold standing decisions); *Citibank v. Estate of Simpson*, 290 N.J. Super. 519, 531-532 (App. Div. 1996) (court may engage in fact-finding as to existence of requisite minimum contacts, and must do so when facts or their import are disputed by parties); *Lopez v. Swyer*, 62 N.J. 267 (1973) (factual determinations may be necessary to decide if party's claim is barred under statute of limitations); *Laborers' Local Union Nos. 472 and 172 v. Interstate Curb & Sidewalk*, 90 N.J. 456, 463 (1982) ("In the absence of an express contract provision conferring authority on the arbitrator, it is uniquely within the province of the courts, and not arbitrators, to make the initial and threshold determination regarding the arbitrability of a particular issue").

The Court rejects this facile argument because the CAS does not clearly provide that a judge may determine the issue of whether an opt-out plaintiff is

FDA Positive and in the absence of such clarity, the Court will not interpret the CAS so as to authorize such a broad challenge to a plaintiff's right to trial by jury. In this Court's view, where there is a legitimate factual dispute as to whether a plaintiff satisfies the definition of FDA Positive, Wyeth's proposed interpretation of the CAS collides with a plaintiff's right to have disputed issues of fact essential to success of his or her case (valvular regurgitation) decided by a jury.

Judge Bartle, the MDL Judge, recognized that the question of whether class members may exercise opt-out rights claiming they are FDA Positive raised issues going "to the merits"... of ... whether these class members may recover damages from Wyeth in their lawsuit[s]." Pretrial Memorandum and Order 3376, *In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Products Liability Litigation*, MDL 1203 slip op. at 5 (E.D. Pa. March 26, 2004) ("PTO 3376"). Specifically, Judge Bartle found that:

[The question of whether [plaintiffs] ... 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.

PTO 3376, slip op. at 5.

Judge Bartle again found that the procedure to be followed in resolving this issue should be decided in the state or federal transferor court where the lawsuit is pending. *Id.* at 6. Given Judge Bartle’s repeated and clear determination that the question of an IOO’s or BEOO’s eligibility to opt-out is a matter for the state or the federal transferor court, it is unlikely the MDL court will shed additional light or provide guidance on the interpretation of CAS § IV.D.3.c. or § IV.D.4.c. in this regard.

Given the volume of cases before this Court, it is essential for the purposes of case management that the parties have this issue resolved. This Court believes that the CAS, read in the light of federal and state court evidence rules already in place to assess the reliability of scientific evidence, permits Wyeth to disqualify an IOO or BEOO if it establishes that the performance and/or evaluation of the echocardiogram was medically unreasonable as a matter of law. Stated another way, Wyeth can disqualify in IOO or BEOO if it can show that the expert’s conclusions respecting the echocardiogram supporting the opt-out could not “reliably flow from the facts known to the expert and the methodology used.”

*Heller v. Shaw Industries, Inc.*, 167 F.3d 146, 153 (3d Cir. 1999); *see also Oddi v.*

*Ford Motor Co.*, 234 F.3d 136, 146 (3d Cir. 2000).<sup>10</sup>

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<sup>10</sup> Traditionally, New Jersey followed *Frye v. United States*, 293 Fed. 1013 (D.C. Cir. 1923). *Frye* held that before scientific evidence could be admitted it had to gain general acceptance in the particular field to which it belonged. *State v. Kelly*, 97 N.J. 178 (1984). In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) the United States Supreme Court rejected the *Frye* text as the template for **Fed. R. Evid** 702. In *Kemp ex rel Wright v.*

Under **Fed R. Evid.** 702 two (2) major requirements must be met before an expert may testify: one (1) the expert must be qualified; and (2) his or her opinion must be reliable. *In re Paoli Railroad Yard PCB Litigation*, 35 F. 3d 717 (3d Cir. 1994). The same requirements exist under **N.J. R. Evid.** 702. *Kemp ex rel Wright v. State*, 174 N.J. 412, 427 (2002).<sup>11</sup> The obvious battleground with respect to the IOOs and BEOOs challenged by Wyeth will be whether, as a matter of law, there is insufficient evidence in the echocardiogram to support the opt-out. Stated another way, in order to disqualify an opt-out, Wyeth must convince the Court that the echocardiogram evidence supporting that opt-out is not reliable. *Kemp ex rel Wright v. State*, 174 N.J. at 427; *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. at 595.

Generally speaking the question of reliability focuses on the methodology employed rather than ‘whether the court finds the expert’s reliance on the underlying data was reasonable ...’ *Rubanick v. Witco Chemical Corp.*, 125 N.J. 421, 452 (1991) (citing *Ryan v. KDI Sylvan Pools*, 121 N.J. 276, 289 (1990)). In such cases the courts should consider a number of factors. These factors were

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State, 174 N.J. 412 (2002), the New Jersey Supreme Court seems to have gone a long way to replacing Frye with the more flexible test formulated in Daubert. The foundation of this text is reliability.

<sup>11</sup> In *General Elec. Co. v. Joiner*, 522 U.S. 136 (1997) the United States Supreme Court affirmed the importance of the trial judge as a “gatekeeper” where the admissibility of expert testimony is involved. In stressing that the trial court’s ruling as to whether to permit or exclude expert testimony should be reviewed under the deferential abuse of discretion standard, the Supreme Court recognized that an expert’s “conclusions and methodology are not entirely distinct from one another.” *Id.* at 146. Our Supreme Court appears to agree. *Kemp ex rel Wright v. State*, 174 N.J. at 434 (“We must allow the trial courts to act as gatekeepers in ... cases (involving the presentation of scientific evidence”) (Poritz C.J. dissenting).

recently reiterated by the United States Court of Appeals for the Third Circuit in *Calhoun v. Yamaha Motor Corp. USA*, 350 F.3d 316 (3d Cir. 2003) and include:

- (1) whether a method consists of a testable hypothesis;
- (2) whether the method has been subject to peer review;
- (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted;
- (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

*Id.* at 321 (citing *In re Paoli Railroad Yard PCB Litig.*, 35 F.3d 717, 742, n.8 (3d Cir. 1994)).

Here the methodology to be employed is not in dispute. It is described in detail in CAS and, the methodology is taken from two (2) of the reference texts in the field of echocardiography. The methodological soundness of the medical criteria for the diagnosis of valvular disease obviously is not in dispute either. It is stipulated in the CAS. So what role do the reliability criteria discussed in *Kemp* and in the federal cases play in the hearings anticipated in the cases before this Court?

Simply stated reliability means more than the soundness of the methodology employed. It also means “that the expert’s testimony must ‘fit’ in that it must assist the trier of fact.” *Oddi v. Ford Motor Co.*, 234 F.3d at 145 (citing *In re Paoli Railroad Yard PCB Litig.*, 35 F. 3d at 743).

Admissibility thus depends in part upon “the proffered connection between the scientific research or test result to be presented and particular disputed factual issues in the case. This standard is not intended to be a high one, nor is it to be applied in a manner that requires the plaintiffs to prove their case twice – they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of evidence that their opinions are reliable. This is a very important distinction. The test of admissibility is not whether a particular scientific opinion has the best foundation or whether it is demonstrably correct. Rather, the test is whether the particular opinion is based on valid reasoning and reliable methodology. The analysis of the conclusions themselves is for the trier of fact when the expert is subjected to cross-examination.

*Nonetheless, conclusions and methodology are not entirely distinct from one another. A court must examine the expert’s conclusions in order to determine whether they could reliably flow from the facts known to the expert and the methodology used.*

*Oddi v. Ford Motor Co.*, 234 F.3d at 145-146 (emphasis added) (citations omitted).

Wyeth would prefer to require the Court to determine as a preliminary matter whether an IOO or BEOO is FDA Positive in each of the cases it challenges. However, Wyeth also has asserted that in some cases the performance and/or interpretation of the echocardiogram supporting an opt-out so deviated from the specified methodology and/or failed to satisfy the medical criteria established in the CAS that the FDA Positive finding made is medically unreasonable as a

matter of law. The Court will give Wyeth the opportunity to establish just that -- that the performance of or interpretation of the echocardiogram supporting an opt-out is so infirm that it fails the reliability prong under *Kemp ex rel Wright v. State*, 174 N.J. at 425-426, and *General Elec. Corp. v. Joiner*, 522 U.S. at 146. If Wyeth is able to do so that opt-out will be returned to the class.

In granting Wyeth this limited right to challenge an opt-out, this Court is fulfilling the obligations placed upon it by **N.J.R. Evid.** 702 and *Kemp ex rel Wright v. State*, 174 N.J. at 425-426. Moreover, this preliminary and threshold determination, to which this Court has found Wyeth is entitled, is not inconsistent with the practice of testing the scientific validity of an expert's opinions after discovery is complete.<sup>12</sup> See *Printing Mart-Morristown v. Sharp Electronics Corp*, 116 N.J. 739 (1989) (action should rarely be terminated in the absence of discovery). In the phen-fen cases under review here, discovery as to the issues of IOO or BEOO is complete. The echocardiogram supporting the opt-out already exists and has been identified in the Short Form Complaint. See Short Form Complaint, Order dated February 11, 2004. The cardiologist and any supporting technicians also have been identified at the outset. See CMO No. 2 dated October 20, 2003. As will be seen later in this Opinion, any experts appearing at the **N.J.R.**

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<sup>12</sup> The procedure discussed in this Opinion also is consistent with this State's standards for the grant of summary judgment. See *Brill v. Guardian Life Ins. Co. of America*, 142 N.J. 520, 522 (1995) (test for summary judgment is whether there exists a genuine issue with respect to material fact; that is, whether competent evidential materials exist which when reviewed in the light most favorable to the non-moving party are sufficient to permit a rationale fact finder to resolve the dispute issue in the non-movant's favor).

**Evid.** 104(a) hearing in which these challenges will be heard will be required to submit direct testimony in the form of an affidavit or certification. See **R.** 1:6-6, thus obviating the need for a discovery deposition. And, finally, the respective parties will have the right to cross-examine at the **N.J.R. Evid.** 104(a) hearing. Thus the preliminary hearing authorized by the CAS, where Wyeth may challenge whether each IOO or BEOO is “timely and proper,” is the functional equivalent of a *Kemp* hearing now mandated in these type of cases by the New Jersey Supreme Court. See *Kemp ex el Wright v. State*, 174 N.J. at 425-426.

#### IV

Echocardiography obviously is a technical and complex subspecialty of cardiology. As this Court already has found the hearings anticipated in this Opinion call for examinations of specific medical criteria, protocols and methodologies. In some cases the Court may have to determine whether an opinion that an IOO or BEOO is so wide of the mark that no reasonable juror could find the opt-out to be FDA Positive as the term is defined in the CAS. Wyeth has requested that the Court appoint an expert or experts in the field of echocardiography to assist it in evaluating the challenged echocardiograms. While

not essential to the determinations here, the Court believes that Wyeth's request has merit.<sup>13</sup>

In New Jersey, the power of a court to appoint an expert is established by case law.<sup>14</sup> See *Wayne Tp. v. Kosoff*, 73 N.J. 8, 13-15 (1977); *Handelman v. Marwen Stores Corp.*, 53 N.J. 404, 408-414 (1969). “[T]he court’s power to appoint an independent expert witness cannot reasonably be challenged,” and in New Jersey, as in other states, a court possesses the inherent power to call witnesses on its own initiative. See *Alk Assocs., Inc. v. Multimodal Applied Sys., Inc.*, 276 N.J. Super. 310, 318 (App. Div. 1994) (citations omitted).

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<sup>13</sup> Other state courts considering similar challenges have found the appointment of independent experts a useful device. See, e.g. In all Phen-Fen Cases Pending or to be Pending in the Counties of the First Administrative Judicial Region, State of Texas, Am. Master Pre-Trial Mgmt. Order at 24-27 (First Admin. Jud. Dist., April 25, 2003) (providing for a board-certified cardiologist to assist Texas courts in making eligibility determinations in diet drug cases). The Texas court has plainly indicated its belief such independent experts will serve a useful function in these eligibility challenges.

<sup>14</sup>The inherent power of a federal judge to appoint an expert both prior to and subsequent to the enactment of **Fed. R. Evid.** 706, is unquestioned. See *In re joint Eastern and Southern Districts Asbestos Litig.*, 830 F. Supp. 686 (E.D.N.Y. 1993); *Scott v. Spanjer Bros., Inc.*, 298 F.2d 928 (2d Cir. 1962); *Danville Tobacco Assn. v. Bryant-Buckner Assoc., Inc.*, 333 F.2d 202 (4<sup>th</sup> Cir. 1964).

As a result of New Jersey case law, the drafters of the New Jersey Rules of Evidence saw no need to adopt a counterpart to **Fed. R. Evid.** 706, which permitted appointment of so-called “Court Appointed Experts.” See **N.J.R. Evid.** 706 (not adopted), comments “[c]ontrary to the recommendation of The 1963 Report at 115-121 (proposed **N.J. R. Evid.** 59, 60 and 61), the 1967 New Jersey rules did not include provisions for the court appointment of experts. The power of a court to appoint expert witnesses and to deal with related procedural matters may be viewed primarily as a matter of practice and procedure rather than as a part of the law of evidence”).

**Fed. R. Evid.** 706, in part, provides:

The court may on its own motion or on the motion of any party enter an order to show cause why expert witnesses should not be appointed, and may request the parties to submit nominations. The court may appoint any expert witnesses agreed upon by the parties, and may appoint expert witnesses of its own selection.

New Jersey Practice and **Fed. R. Evid.** 706 are quite similar. Thus this Court will look to interpretation of **Fed. R. Evid.** 706 with respect to the procedures followed in the actual appointment of experts by the Court and disclosure to the parties of their conclusions. See *Brown v. Brown*, 86 N.J. 565, 581 (1981).

The New Jersey Supreme Court has suggested that such experts may be appointed where sought by one (1) of the parties or even *sua sponte*:

Whether or not the power to appoint an impartial expert ... should be exercised either by the court *sua sponte* or on application of one or more of the parties, would depend on the circumstances presented. However, where it appears that the trier of the facts will be confronted with extraordinarily disparate opinions as to valuation, and a timely motion for the appointment of an independent expert is made, the trial court should seriously weigh the possible advantage of an impartial expert.

*Wayne Tp. v. Kosoff*, 73 N.J. at 14. Intended as a general principle only, the details and application were to be left to the sound discretion of the trial court. *Id.* at 15.

*Alk Assocs., Inc. v. Multimodal Applied Sys., Inc.*, 276 N.J. Super. at 318, suggested a three-step process be followed where an expert is court appointed. Once appointed, an expert's tentative report should be initially disseminated to counsel and their experts who, in turn, can prepare questions and comments for him or her. After analyzing these responses, the expert should finalize his or her report to court and counsel. The *Alk* Court envisioned that, "further proceedings [a hearing] . . . may be necessary after the return of the independent expert's report." *Id.* The court appointed expert would then be subject to cross-examination at a hearing.

**Fed. R. Evid.** 706 provides a more rigid structure. There, an expert must provide the court and parties with advance notice of "his or her findings" and give

the adversary parties an opportunity to challenge the conclusions by deposition.

Specifically, **Fed. R. Evid.** 706 provides:

A witness so appointed shall advise the parties of the witness' findings, if any; the witness' deposition may be taken by any party; and the witness may be called to testify by the court or any party. The witness shall be subject to cross-examination by each party, including a party calling the witness.

**Fed. R. Evid.** 706, like New Jersey's case law, places procedural checks on the court's inherent power to appoint experts. These checks include: (1) the expert must agree to testify; (2) the expert witness must inform the parties of his or her findings; (3) the parties must be provided an opportunity to both depose and cross-examine the expert witness; (4) the court must establish the duties of the expert in written form, filing a copy of the document with the court's clerk for access by all parties; and (5) the court's appointment decision may be reviewed on appeal under an abuse of discretion standard.

The recent appointment of expert panels in the federal courts also provide useful models for the procedures to be followed here. In May 1996, United States District Chief Judge Sam C. Pointer, Jr. of the Northern District of Alabama, appointed a national expert panel, under **Fed. R. Evid.** 706 to investigate the question of causation in the combined federal cases dealing with the claimed harm to the plaintiffs' immune receptors from silicone gel breast implants. *See In re*

*Silicone Gel Breast Implants Prods. Liab. Litig., Order 31* (N.D. Ala. 1996), 4 MEALEY'S LITIG. REP.: BREAST IMPLANTS, June 13, 1996, at F-1; *see also Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1392 (D. Orr. 1996) (same). This panel initially was requested by the National Plaintiff's Steering Committee. Judge Pointer provided for an expert panel to review scientific data relevant to several issues in the breast implant litigation, in particular those issues impacting general causation. The panel members then were to serve as experts in any trial under the multidistrict litigation umbrella. This was to be accomplished by providing an initial "discovery-type," deposition. Thereafter, an individual expert's testimony was produced through a video-taped deposition presided over by Judge Pointer.

This Court, like the federal and state cases already discussed here, is faced with highly technical issues and potentially conflicting expert views. Obviously, the echocardiography used in the diagnosis of valvular regurgitation presents a complex picture. The complexity alone points to the desirability of neutral expert assistance to the Court. *See, e.g., In re High Fructose Corn Syrup Antitrust Litg.*, 295 F.3d 651, 665 (7<sup>th</sup> Cir. 2002) (Posner, C. J.)("[W]e recommend that the district judge use the power that Rule 706 of the Federal Rules of Evidence expressly confers upon him [or her] to appoint his own expert witness, rather than leave himself [or herself] and the jury completely at the mercy of the parties' warring

experts”). For these reasons then, the Court will grant Wyeth’s motion to appoint such an independent expert(s).

While potentially valuable, however, the appointment of these experts is not essential for the fair resolution of the motions presently before the Court and those expected in the future. During the March 22, 2004 case management conference (“CMC”), the Court suggested that the plaintiffs and Wyeth provide the Court with joint recommendations for five (5) experts. The Court would then contact these nominees to determine whether any or all of them would be willing to serve. The content of a solicitation letter was provided by Wyeth, was discussed at the April 8, 2004 CMC, and will be sent to these nominees on April 13, 2004, the date of this Opinion.

Given the limited scope of the anticipated **N.J.R. Evid.** 104(a) hearing, the Court believes that the procedures suggested in *Alk Associates* and **Fed. R. Evid.** 706 are not all necessary. The Court is inclined to select from the jointly agreed nominees who are willing to serve. The plaintiffs and Wyeth each will bear one half of the expenses of the expert(s). The scope of that or those experts’ responsibilities will be provided to them in writing with copies to the plaintiffs and Wyeth as provided in **Fed. R. Evid.** 706. The expert will also be provided with the expert affidavits or certifications submitted by the representative parties and the relevant echocardiograms. The expert(s) then will provide his, her or their reports

at least five (5) days before the hearing. That report will be adopted under oath by the expert(s) at the **N.J.R. Evid.** 104(a) hearing. Thereafter, all parties will be permitted to cross-examine the expert(s). These procedures are suggested by the Court, but as can be seen by examining the accompanying Order, have not as yet been directed by it. Those procedures will be set during a CMC after all parties have had an opportunity to comment or otherwise be heard.

## V

As noted, this Opinion also suggests the procedures to be followed where Wyeth challenges the right to opt-out of an IOO or BEOO. The 3400 IOO and BEOO cases have been or are being assigned to Groups of approximately 300 cases for discovery and other scheduling purposes. For each Group, there will be a date established in order for Wyeth to challenge whether an IOO or BEOO is “timely and proper.” Each challenge motion will be accompanied with no more than two (2) expert affidavits or certifications which will provide in detail the bases for the challenge, as already discussed in this Opinion, and will constitute the direct testimony of that expert during the **N.J.R. Evid.** 104(a) hearing. The IOO or BEOO will respond on the date assigned to the Group in which he or she is a member with no more than two (2) expert affidavits or certifications addressed to the issues raised. Like Wyeth’s witnesses, these affidavits or certifications will represent the direct testimony. During the **N.J.R. Evid.** 104(a) hearing, cross-

examination will be conducted. To the extent credibility determinations are made, they will be based on the testimony provided in the affidavit or certification and the cross-examination, and continuing testimony. Those hearing dates will be set by the Court on notice to the parties.

## VI

For the reasons set forth in this Opinion, Wyeth may challenge whether an opt-out by any IOO or BEOO is “timely and proper.” The challenge will be made in accordance with the procedures established in Part V of this Opinion and will encompass the subject matter discussed in Part III of this Opinion. Finally, the Court will appoint expert(s) as discussed in Part IV of this Opinion and those experts will testify following procedures to be established at a subsequently scheduled CMC.

An Order is enclosed with this Opinion.

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CHARLES J. WALSH, J.S.C.

CJW/jdk