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April 1, 2004

The Honorable Charles J. Walsh
Superior Court of New Jersey – Bergen County
Justice Center
10 Main Street
Hackensack, NJ 07601

Re: IN RE DIET DRUG LITIGATION VENUED IN BERGEN COUNTY
BER-L-7718-03-MT

Dear Judge Walsh:

In accordance with the Court's instructions and comments at the March 22, 2004 motion argument, Plaintiffs represented by Napoli Kaiser Bern & Associates, LLP, ("NKB Plaintiffs") hereby supplement the record with additional Orders and transcripts that support Plaintiffs' previously asserted and argued position, eschewing the appointment of an expert and extensive hearings with expert testimony urged by Wyeth to determine "eligibility". To the contrary, as set forth by Class Counsel and the District Court at the Fairness Hearing and by subsequent decisions, the attesting physician's opinion determining eligibility is not to be second-guessed nor subjected to a credibility challenge should eligibility be challenged prior to trial.

A. THE SETTLEMENT AGREEMENT HISTORY AND BENEFITS

1. Brief History of the Settlement Agreement

Wyeth and representatives of various state and federal plaintiffs met in the spring of 1999 to initiate negotiations toward a possible "global settlement" of all diet drug claims. In October 1999, the parties filed suit in *Brown v. American Home Prods. Corp.,* No 99-20593 to create a settlement class. After lengthy negotiations, on November 18, 1999, a 140 page document entitled the "Nationwide Class Action Settlement Agreement With American Home Products Corporation," including three amendments (hereinafter "the Settlement Agreement") was executed. The intended class benefits of the Agreement were simple: each class member would be quickly paid based upon the attestation of a qualified physician, without the need for multiple levels of investigation and protracted litigation.

Five days later, the District Court granted preliminary approval to the Settlement Agreement and its first three amendments and conditionally certified the *Brown* settlement class. A hearing on the fairness, adequacy and reasonableness of the Settlement was held before Judge Bechtle from May 2 through 11, 2000. After a further hearing on August 10, 2000, the District Court approved the Settlement Agreement and its (by then) four amendments, certifying the Class on August 28, 2000 in PTO 1415.

2. Settlement Benefits

As the Court is well aware from its' own study of the Agreement and the numerous briefs filed by the Plaintiffs over the past several months, the Settlement Class consists of all persons injured by Wyeth's diet drugs, regardless of the scope or type of their injuries. As a threshold to qualification, each claimant, Matrix or opt-out, was to undergo an echocardiogram by a qualified physician of their choosing. The "Official Notice of Final Judicial Approval," sent to all class members, summarized the minimal threshold required to receive compensation from Wyeth, either as Matrix or opt-out claimants:

> If you took Pondimin® and/or Redux™ for any period of time and you are diagnosed by a Board-Certified cardiologist or cardio thoracic surgeon as having either FDA Positive regurgitation or mild mitral regurgitation after you began using the diet drugs and on or before January 3, 2003, you have the right to recover monetary compensation if you presently have serious valvular heart disease ("VHD") or later develop serious VHD at any time before December 31, 2015.

Claimants electing not to opt out would have their diagnosing cardiologist complete a 32-page "Green Form," the document that, when filed, triggered the benefit request process. The Green Form was submitted along with a videotape or digital disk of the claimant's echocardiogram, prescription proof, and medical records. The claimant's physician, required to be a Level 2 board-certified cardiologist or cardio-thoracic surgeon, would attest to the claimant's qualifying VHD level under Settlement Agreement criteria. By signing the Green Form, the claimant's cardiologist verified under oath that the echocardiogram that is the basis of his diagnosis was performed according to the Settlement Agreement's requirements under the penalties of perjury. Both the claims procedure and the audit process made the attestation by the claimants' chosen physician an integral part of the Settlement Agreement.

A key benefit to class members seeking Matrix benefits was that the claims process was not subject to the exercise of discretion by the administrators of the Settlement nor by any court but, rather, on the sworn certification of claimant's board certified physician. Under the original Settlement Agreement, if the class members' Green Form was properly completed, the required medical documentation (including a videotape or disk of an echocardiogram) submitted, and the claimant's qualification for matrix level benefits verified by her Level 2 cardiologist, the claimant was to be compensated. PTO 1415, which approved the Settlement, explains the objectivity built into the claims process:

> Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an **objective system of compensation whereby claimants need only prove that they meet objective criteria** . . .

. . .

> Under the Settlement Agreement, the determination of a Matrix benefit is not subject to the exercise of discretion by the administrators of the Settlement or by any court . . . [but] . . . are based on the sworn certification of a board certified physician . . .

During the fairness hearing preceding PTO 1415, this benefit was emphasized to class members by Class Counsel and others. Claimants emphasized that the Settlement Agreement was expressly and intentionally structured to prohibit the exercise of the Trust's subjective judgment in matrix benefit determinations, as a result of the parties' concerns about subjectivity in previous class settlements. Michael Fishbein, one of the Class Counsel who was selectively quoted out of context by Wyeth at the motion argument before this Court on March 22, testified to the removal of the administrators (of the Trust) from the process:

> [O]ur settlement . . . defines all the criteria necessary to enter the Matrix and where you are on the Matrix in terms of objective medical facts . . . and the settlement essentially requires the administrator to accept the word of the board certified cardiologist given under oath that the claimant has what the doctor says the claimant has, and then the processing of benefits is simply a mechanical process of putting in all the doctor's answers into a computer program and coming up with a Matrix Compensation for that person.

Fairness Hearing, May 2, 2000 (Day 3), p.79. Accordingly, the District Court concluded that:

> These procedures are fair and reasonable for two reasons. First, they precisely define the criteria necessary for a member to qualify for benefits. . . . ***With respect to Matrix benefits, claims administrators are essentially bound to accept the certification of a qualified board certified physician regarding a claimant's medical condition when that certification is accompanied by appropriate information on the claim form.*** These provisions serve to protect against the insertion of subjective judgment on the part of the claims administrators in making benefits determinations. Second, the audit and appeals procedures protect against fraud and misuse of settlement funds.

See Memorandum and PTO 1415, at p. 143 (emphasis added). The District Court also specifically found that the right of class members to opt out weighed in favor of Settlement approval. *Id.*, at 147. For example:

> All class members who are not members of Subclasses 2(a), 2(b) or 3 **and who have been diagnosed as having FDA Positive levels of regurgitation** by the end of the Screening period may exercise an "intermediate opt-out right." A class member who timely and properly exercises an intermediate opt-out right **may pursue all claims against AHP based on injury to the valve or valves which were diagnosed as having FDA Positive regurgitation**.....With respect to each class member who timely and properly exercises an intermediate opt-out right and initiates a lawsuit.....the AHP Released Parties shall not assert any defense based on.....the existence of the Settlement Agreement.

See Memorandum and PTO 1415, at p. 61-62 (emphasis added). Similar provisions exist for "back end opt-outs." Id, at 61-62.

No mention is made of any right to challenge the eligibility diagnosis of FDA Positive injury. To the contrary, eligibility to opt out is merely based upon a claimant having received an FDA Positive diagnosis by the end of the screening period and timely exercising that right. There is no provision in the Agreement, express or implied, which permits the dismissal of an opt out claim based upon the mere difference of opinion as to the diagnosis of FDA Positive injury by competing cardiologists. The overall thrust of the Agreement is to prevent such "second-guessing" when it comes to diagnosed claim eligibility. In the context of Matrix audits, Class Counsel Fishbein testified at the fairness hearing that the intent behind the Agreement was to give deference to the opinions of the attesting cardiologist:

> That auditing highly qualified cardiologist doesn't try to second-guess the submitting cardiologist, but he says or she says, is there a reasonable medical basis for the determination that was made by this doctor here? Yes or no. And the trustees or claims administrators along with the auditing cardiologist will say, is there any reason to believe that there's been fraud here...

Fairness Hearing, May 2, 2000 (Day 3), p.80-81.

The issue on an opt out eligibility challenge, then, cannot be whether the attesting or diagnosing cardiologist was wrong or right in his or her diagnosis, for whatever reason. The issue is simply whether the diagnosis of the respective level of valvuler injury was made at the appropriate time and whether the opt out was timely made. In other words, eligibility is an objective procedural requirement under the Settlement Agreement, nothing more, nothing less. Wyeth, however, claims that you can look behind the diagnosing report and question the conclusions and findings, but the language Wyeth cites has been pulled from PTOs dealing with the new, recently altered, Trust claims procedures affecting current Matrix claimants, not the opt-out plaintiffs currently before this Court. Wyeth's argument seeks to obtain a benefit not conferred to it under the unmodified Agreement, which still governs the opt out claimants now before this Court. This must not be permitted. As set forth in the Agreement, the deference due the diagnosis establishing the eligibility of an attesting physician must be maintained.

3. Interpreting Decisions

Judge Bartle, the MDL judge, has recently held that the type of challenge now urged by Wyeth before this Court was improper, in the context of Wyeth's challenge to a PPH claimant's eligibility.[1] In the Merle Hall case, Judge Bartle was asked to determine whether the claimant was "eligible" to pursue her PPH claim. During the hearing, Judge Bartle made the following comments:

> JUDGE BARTLE: Isn't that enough to meet the threshold? I am not here to determine issues of credibility and if Dr. Appleyard makes the statement that she has, that was the one issue that was of concern and why isn't that enough to allow the case to go forward and let the court in Texas and the jury decide whether she has primary pulmonary hypertension or she does not.

[1] It should be noted that although Wyeth avoided answering the issue of appellate review posed by the Court prior to the March 22, 2004 motion argument, in practice, Wyeth has sought review of trial court eligibility determinations by Judge Bartle in the MDL, as it did here in Merle Hall.

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JUDGE BARTLE: If some expert says they are ruled out, I don't make a determination that that expert is credible or not. If one expert says they are ruled out, and one expert says they are not ruled out, I have to let the case go forward, don't I? I don't bring the experts in and say which one I believe and which one I don't believe.

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JUDGE BARTLE: Because if I did, then I'd be deciding the case. If I decide she hasn't made it out, then I believe Wyeth's expert and I don't believe the plaintiffs' expert. That's not what the settlement agreement contemplates.

See October 1, 2003 Hearing Tr. at 148, 151-152.

In PTO 3066 that followed the aforesaid hearing, Judge Bartle made it clear that the determination of whether a particular plaintiff is eligible to file a lawsuit is a threshold issue where extensive hearings with testimony was not contemplated in the Agreement.

> In paragraph D of PTO 2383, we stated '[a] determination of whether a putative PPH plaintiff has been diagnosed with PPH, as defined by Section I.46 of the Settlement Agreement, is a threshold question that determines the eligibility of that Class Member to assert such a claim' Under paragraph 12 of PTO 2383, a resolution of this issue 'in most if not all instances' will result from an **examination of medical records** and a comparison with the criteria for PPH set forth in the Settlement Agreement. **Extensive hearings with testimony were not contemplated.**
>
> ****
>
> **It is not the function of this court to pass upon [the diagnosing physician's] credibility. Whether or not Ms. Hall actually suffers from PPH and is entitled to damages from Wyeth is a matter for the fact finder at her trial in the state court.**
>
> Accordingly, we will....allow Ms. Hall to proceed with her underlying lawsuit in the District Court of Jefferson County, Texas. Wyeth, of course, is not precluded from challenging her PPH claim in the state court. See PTO 2383, at ¶ 13.

See PTO 3066, p. 2-3 (emphasis added). Clearly, Judge Bartle does not consider the threshold determination of eligibility to amount to weighing the word of one qualified physician against another, or for that matter, a "special master." Indeed, Judge Bartle acknowledges that the statement of a qualified physician is enough to let a case go forward and to have the jury determine whether a claimant suffers from his or her alleged injury. Anything more would be adding terms to the Settlement Agreement that were not contemplated by the parties.

Even more recently, within the past few days, Judge Bartle entered PTO 3376, reaffirming that eligibility challenges to the diagnosis upon which an opt out is based are not properly the subject of pretrial inquiry and should be resolved at trial.

Underlying PTO 3376 was a motion filed by Wyeth challenging the eligibility of two class members, Kerr and Raines, to exercise intermediate opt-outs. The Kerr and Raines actions had been transferred to the MDL Court from another federal district court for pretrial proceedings, in accord with the MDL litigation process by which all pretrial discovery is completed in the MDL with the case then remanded to the originating court for trial. Both plaintiffs had been diagnosed as FDA Positive by a board-certified cardiologist, Dr. Joshua Penn, from echocardiogram readings. Wyeth challenged Dr. Penn's findings and conclusions, alleging that Dr. Penn and his mobile echocardiography company were engaged in "an assembly-line echocardiogram reading process" which deprived them of reliability as the diagnoses were not rendered in the course of medical treatment. Wyeth further challenged the diagnoses as being incorrect and contrary to the opinions of their proffered expert cardiologist, Dr. Miguel Quinones. *See*, PTO 3376, p. 2-5.

The district court denied Wyeth's eligibility challenges without considering the medical correctness of the diagnoses nor the merits of the challenge to the diagnosing doctor's credibility. Whether the diagnosing physician properly found plaintiffs to be FDA Positive or, as Wyeth contended, the doctor's readings were wrong, were rejected as the standard by which an eligibility challenge is to be weighed. PTO 3376, p.5. As the court stated,

> [T]he 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.
>
> *****
>
> Wyeth cites to PTO No. 2984 in which.....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.**

Id., at 5-6. While the court denied Wyeth's eligibility challenge without prejudice to refile it with the transferor trial court, for all practical purposes, given the federal standards for summary judgment and Judge Bartle's ruling in PTO 3066, the "contested factual issues of a medical nature with respect to...eligibility" will be decided by the jury, the proper trier of such contested facts in all federal cases. Similarly, following the

holding and reasoning of Justice Albin in *Knorr v. Smeal*, __N.J.__(2003) concerning the medical affidavit of merit statute, any such eligibility challenge filed after the close of discovery in these diet drug matters should be denied as untimely.

The thirteen eligibility challenges Wyeth is currently mounting against NKB Plaintiffs[2] consist of the same type of "contested factual issues of a medical nature" that Judge Bartle refused to consider in PTO 3066 and PTO 3376. Whether or not these and other similarly situated plaintiffs are actually FDA Positive is a matter for the fact finder at their respective trials. PTO 3066, p.3. The Settlement Agreement does not require this Court to engage in the extensive factual inquiry nor attempt to resolve the merits of the respective expert controversies, with or without the assistance of a court appointed expert or "special master," which Wyeth improperly seeks in the guise of an eligibility challenge. As Judge Bartle and every other court to consider these issues have held, these determinations must be properly made by a jury at trial.[3] The parties to the Settlement Agreement negotiated and agreed that opt out plaintiffs have the right to prove their claims in a lawsuit before a jury of their peers. The plaintiffs never agreed, nor does the Settlement Agreement provide, that claims be precluded in a procedural hurdle erected to resolve contested complex medical facts and opinions. The plaintiffs should be permitted to receive the benefit of their bargain by having a jury resolve the contested medical issues. That is especially true here in New Jersey, where long established procedure and notions of fairness have traditionally reserved such contested matters for the trier of fact, not the court.

B. MEDICAL REASONABLENESS

The court began argument on March 22 by inquiring as to the definition of "medical reasonableness." As used in the Settlement Agreement and subsequent modifying federal PTOs, eligibility diagnoses for class members seeking Matrix benefits must be found to be "medically reasonable" upon audit. However, as previously argued by Plaintiffs in their prior submissions, the term "medically reasonable" is not used in connection with opt out plaintiffs' eligibility diagnoses. In PTO 3077, Judge Bartle expressly ruled against Wyeth's attempt to impose a similar new condition to an opt out plaintiff's eligibility diagnosis, finding that a diagnosing physician need not have rendered his or her opinion as part of a course of treatment, nor personally met or examined the plaintiffs. *See*, PTO 3077, 2-5. The Agreement was strictly construed so that where, as here, a term was expressly used in the Agreement in another context but omitted in connection with an opt out plaintiff, it was held not to apply to that plaintiff. Accordingly, the diagnosing echocardiogram in these eligibility challenges should not be held to the "medically reasonable" standard applicable only to Matrix claims.

This is not to suggest, however, that plaintiffs' diagnosing echocardiograms are or should be medically unreasonable. As indicated in the medical and legal definitions discussed, below, medical reasonableness is a relative concept which does not lend itself to easy determination nor without weighing complicated factors and credibility properly left for resolution by a jury.

1. Legal Definition

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[2] Several challenges are apparently based upon nothing more then the alleged lack of clarity of the disks submitted pursuant to CMO 2, despite Wyeth's ability to obtain additional and presumably clearer copies with the medical authorizations provided by plaintiffs.

[3] Wyeth incredulously argued that other jurisdictions have adopted the standards it now seeks from this Court, including the Court of Common Pleas of Philadelphia County. As represented at argument, however, the Order entered by the Philadelphia trial court states: "1. The Wyeth Defendants suggested Case Management Order No. 15 is rejected." Instead, the Philadelphia Court set forth a procedure that requires that any challenge be proved by prima facie evidence, precluding the contested medical factual inquiry and resolution sought here.

The NKB Plaintiffs believe the term "reasonable medical basis" does not mean that the a claim should be dismissed based on a disagreement between experts as to whether the plaintiffs suffered a given condition. The term "reasonable medical basis" generally applies to prevailing medical knowledge and standards. *See City of Akron v. Akron Center,* 462 US 416, 430 (1983), *quoting Roe v. Wade*, 410 US 113, 163 (1973). Here, the fact that a physician hired by Wyeth disagrees with a medical finding made by duly qualified physicians does not establish a lack of reasonable medical basis.

In *Cicio v. Does*, 321 F.3d 83 (2d Cir. 2003), the Second Circuit held that a failure to provide a certain regimen of treatment under an ERISA plan deemed to be experimental by the provider could set forth a state law cause of action for medical malpractice, based on the opinion of experts that such treatment was medically necessary. The court quoted heavily from *Pegram v. Herdrich*, 530 US 211 (2000), which described the role of disparate medical opinion even in "mixed eligibility and treatment decisions" involving ERISA claims, holding essentially that the opinion of a competent medical expert was sufficient to establish the applicability of a given standard.

The phrase "reasonable medical basis" has been held, in circumstances such as those at bar, to apply to disputed medical opinions of claimants' experts. In *Lesley v. Chie*, 250 F.3d 47 (1st Cir. 2001), defendant was sued because he denied the claimant treatment "solely because she was HIV-positive;" the district court granted summary judgment to defendant. On appeal, the First Circuit found that it must "determine how far courts should defer to a doctor's judgment as to the best course of treatment for a disabled patient in the context of discriminatory denial of treatment claims." Holding that the "doctor's judgment is to be given deference absent a showing by the plaintiff that the judgment lacked any reasonable basis," the First Circuit affirmed. While noting that "Courts cannot simply defer unquestioningly to a physician's subjective judgment," the First Circuit added that "Courts should not probe so far into a doctor's referral decision as to inquire whether it was the correct or best decision under the circumstances, or even whether it met the standard of care for the profession" *Lesley*, 250 F.3d at 54-55.

In *Lesley,* the defendant obstetrician referred the claimant to a community hospital based practice, not feeling he was able to provide appropriate care for plaintiff during her high- risk pregnancy. Plaintiff claimed that the decision was motivated by inappropriate discriminatory intent, and set forth expert medical testimony that the care provided was within the general knowledge of most physicians in the community; thus there was no reasonable medical basis for transferring her. The First Circuit held that her evidence was insufficient, stating that it merely goes toward proving that in 1995, as a general matter, a licensed obstetrician would have been competent to administer AZT to an HIV-positive patient. However...statements of prevailing medical opinion should not be read so broadly as to sweep case-specific factors under the rug...Rather, reasonableness depends on the circumstances, and here a number of circumstances supported [defendant's] judgment to transfer [plaintiff] elsewhere. *Lesley,* 250 F.3d at 57. Accordingly, the court held that a medical decision could constitute "a reasoned medical judgment" even where the patient disagreed and submitted contrary expert testimony. *Id.*, 250 F.3d at 58.

In *Locket v. Bd. of Comm.*, 909 F.2d 820, 832 (5th Cir. 1990), the issue was whether the plaintiff was properly dismissed from his job at the Terre bone General Medical Center, or was unfairly targeted due to his failure to submit the results of his HIV antibody test. The hospital came into information that one of its employees, the plaintiff, was an associate of a current AIDS patient who had been treated at the hospital. The hospital ascertained that the patient was plaintiff's roommate and was homosexual. Wishing to prevent the spread of HIV based on Centers for Disease Control studies, members of the hospital staff asked that plaintiff take an

The hospital's Infection Control Practitioner asked plaintiff if he would provide the results to the hospital; plaintiff first agreed but then refused to do so, and was suspended from practicing nursing at the hospital until the test results were provided to it. Ultimately, plaintiff was terminated. The Fifth Circuit found that there was "a reasonable medical basis for suspecting that [plaintiff] had been exposed to HIV and for requiring that he submit the results of his HIV antibody test;" the hospital, it found, had a "substantial and compelling interest in enforcing such infection control policies."

In *Gallagher v. Latrobe Brewing Co.*, 31 F.R.D. 36, 38 (W.D. Pa. 1962), disparate medical testimony created an impasse, and it was proposed that the court must appoint an impartial expert. The court found that this would not be necessary because testimony lacks a medically reasonable basis when it is "of such a nature or so slanted that in the present state of medical science a reasonable medical scientist could not accept it either as to diagnosis, causal connection or prognosis, or some other good and sufficient reason;" the fact that experts have disparate opinions does not necessarily mean that either opinion lacks a reasonable medical basis. Thus, testimony lacks a reasonable medical basis where there is "no sufficient factual basis to support" the claim. *Harry v. U.S.*, 705 F.2d 500, 503 (D.C. Cir. 1983).

An opinion lacks a "reasonable medical basis" when it ignores a specific standard or applicable fact. *See Glister v. Missionary*, 189 F. Supp. 2d 930, 937-938 (ED Wis. 189) (Administrative Law Judge's finding that "The claimant's subjective statements lack a reasonable medical basis" because "her primary medically determinable impairment involves the perception of persistent non-organic disturbances for which there are no demonstrable organic findings or known physiological mechanisms" was improper because it "ignores the objective evidence of fibromyalgia" and was "adversely affected" by the ALJ's improper opinion of that condition).

In *Yumukoglu v. Provident Life*, 131 F. Supp. 2d 1215, 1227 (D.C. N.Mex. 2001), the issue was whether defendant insurer improperly denied payments on a disability policy without a "reasonable medical basis;" citing *Oulds v. Principal Mut. Life Ins.*, 6 F.3d 1431, 1436-7 (10th Cir. 1993), the *Yumukoglu* Court found that there was a proper medical basis for the disclaimer, given the "substantial conflicting evidence regarding the severity" of plaintiff's condition; surveillance tapes established a possibility of malingering, and defendant's expert noted that plaintiff's "test findings were inconsistent with the result of his MRI" and he appeared to be "exerting less than full effort during his examination."

Thus, where there is a conflict in medical testimony, a "reasonable medical basis" for the claim or defense is presented for the fact finder, at least on a summary judgment motion. *Sparks v. Morrison & Forester*, 129 F. Supp. 2d 182 (NDNY 2001).

Simply put, a mere divergence of expert opinion does not establish a lack of reasonable medical basis. Plaintiffs completely complied with their obligations under the Settlement Agreement by timely obtaining echocardiograms from appropriately credentialed physicians. The construction of the term "reasonable medical basis" in the context of these cases clearly means that unless an opinion is completely contrary to accepted principles of medicine and science or based upon a demonstrably false premise, the determination of the diagnosing cardiologist, *who followed the procedures outlined in the Settlement Agreement*, must be credited.

2. Medical Definition

In connection with Matrix claims submitted on behalf of NKB Plaintiffs, Arthur L. Caplan, Ph.D., a leading expert and educator in the field of medical ethics and bioethics,

prepared an affidavit discussing what constitutes a "reasonable medical basis" for reaching a diagnosis of a disease, disorder or disability in the medical community. Explaining that medicine is both an art as well as a science, Dr. Caplan states that judgment is an unavoidable part of any medical determination, and that diagnosis must – of necessity – involve value judgments. He further states, notably, that this is true even in those areas of medicine where measurements predominate, such as echocardiology, radiology, and neurology and laboratory medicine. *See*, Affidavit of Dr. Arthur Caplan, attached to the Certification of Counsel as Exhibit " ".

Medicine, according to Dr. Caplan, must always involve decisions about value and the range of value judgments rendered by qualified physicians is known as a "medical reasonable basis." The range of that reasonable medical basis can be very broad or very narrow, depending on the type of medicine and the diagnosis being rendered, and two competent physicians can have very differing views as to a diagnosis or treatment and may both be right, within a medically reasonable basis. Dr. Caplan further explains that:

> Every physician, when faced with evidence from human patients, must make decisions about how to weigh and interpret that evidence. This is partly due to the fact that human beings are variable – there is no fixed or set pattern that can be said to be present in each and every case where a particular disease or disorder is present. Measurement of symptoms and of information requires that the physician evaluate and make value judgments involving the interpretation of these measurements. The measurements themselves involve "variability" among qualified physicians.
>
> Measurement itself involves judgment. The measurement associated with the determination of any physical state will produce a certain rate of error and a certain amount of indeterminacy no matter how precise the instruments used or how controlled the conditions under which measurement is undertaken. This is true in echocardiography as well as other modalities in medicine. ...

See Arthur Caplan Affidavit, at ¶¶8-9.

Finally, Dr. Caplan opines that a mere divergence of opinion between two similarly-credentialed physicians does not establish a reasonable medical basis. He opines that Wyeth's contention in their proposed eligibility challenge standards and procedures, *i.e.*, that the diagnosing physician's opinions may be deemed medically unreasonable, based solely on the unsupported opinion of another, similarly credentialed cardiologist, is "facially insupportable." *See*, Caplan Aff., at ¶19. In this regard, Dr. Caplan says, the contrary expert "opinion, as such, is entitled to no more weight or credibility than the opinions of the attesting physician and the claimant's expert cardiologist in the claims contest and show cause proceedings. Moreover, claims should not be denied solely on the opinion of one physician over another." *See*, Caplan Aff., at ¶20.

Dr. Caplan's opinions, rendered in the context of a Matrix claim, are equally applicable to the proposed opt out eligibility challenges here. Medical reasonableness is simply not an issue that can be determined objectively. Being subjective in nature and relative to a number of factors, the issue must be determined by a jury at trial.

We thank the Court for its' kind consideration of these materials and arguments. We would be happy to supply any additional materials and respond to any issues or questions, in person or by tele-conference, at the Court's discretion.

Respectfully submitted,

NAPOLI KAISER BERN & ASSOCIATES, LLP

By: _____
W. Steven Berman, Esquire

CC: all counsel via Verilaw
Enclosures

Napoli Kaiser Bern & Associates, LLP New Jersey Diet Drug Plaintiffs, Plaintiffs, vs. WYETH, and JOHN, JANE and JOE DOES 1-20, Defendants.	: : : : : : : : : :	SUPERIOR COURT OF NEW JERSEY LAW DIVISION BERGEN COUNTY DOCKET NO. 7718-03 MT *Case Code: 240* CIVIL ACTION DIET DRUG LITIGATION JURY TRIAL DEMANDED

CERTIFICATION OF COUNSEL

W. Steven Berman hereby certifies as follows:

1. I am an attorney at law of the State of New Jersey associated with Napoli Kaiser Bern & Associates, LLP (a New York Limited Partnership), attorneys for the Plaintiffs, herein. I submit this Certification to present Exhibits referenced in the attached supplemental brief regarding eligibility challenges and the need for a court appointed expert raised by Defendant Wyeth and argued on March 22, 2004.

2. Attached as Exhibit 1 is a true and correct copy of Pretrial Order No. 3066 entered in In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig., MDL Docket No. 1203 (E.D.Pa. October 10, 2003).

3. Attached as Exhibit 2 is a true and correct copy of Pretrial Order No. 3077 entered in In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig., MDL Docket No. 1203 (E.D.Pa. March __, 2004).

4. Attached as Exhibit 3 is a true and correct copy of Pretrial Order No. 1415 entered in In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig., MDL Docket No. 1203 (E.D.Pa. August 28, 2000).

5. Attached as Exhibit 4 is a true and correct copy of pages 1-16 and 79-82 of the Fairness Hearing before the Honorable Louis C. Bechtle in In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig., MDL Docket No. 1203 (E.D.Pa. May 2, 2000).

6. Attached as Exhibit 5 is a true and correct copy of Case Management Order No. 15 entered by the Honorable Norman Ackerman of the Philadelphia Court of Common Pleas on December 29, 2003.

7. Attached as Exhibit 6 is a true and correct copy of the Affidavit and Curriculum Vitea of Arthur L. Caplan, Ph.D.

I certify that the foregoing statements are true. I understand that if any of the foregoing statements are willfully false, that I may be subject to punishment.

W. Steven Berman, Esquire

Dated March 29, 2004

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

IN RE: DIET DRUGS (PHENTERMINE, FENFLURAMINE, DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 1203
THIS DOCUMENT RELATES TO:	:	
SHEILA BROWN	:	
v.	:	
AMERICAN HOME PRODUCTS CORPORATION	:	CIVIL ACTION NO. 99-20593

PRETRIAL ORDER NO. 3066

AND NOW, this 10th day of October, 2003, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that:

(1) the motion of class member Merle Hall for relief from Pretrial Order No. 2912 is GRANTED; and

(2) the injunction entered in Pretrial Order No. 2912 is VACATED.

BY THE COURT:

Harvey Bartle III
J.

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

IN RE: DIET DRUGS (PHENTERMINE, FENFLURAMINE, DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 1203
THIS DOCUMENT RELATES TO:	:	
SHEILA BROWN	:	
v.	:	
AMERICAN HOME PRODUCTS CORPORATION	:	CIVIL ACTION NO. 99-20593

MEMORANDUM AND PRETRIAL ORDER NO. 3066

Bartle, J. October 10, 2003

Class member Merle Hall has pending a lawsuit against Wyeth in the District Court of Jefferson County, Texas in which she has asserted a claim based on primary pulmonary hypertension ("PPH"). In Pretrial Order ("PTO") 2912, we enforced PTO 1415 (which approved the Nationwide Fen-Phen Class Action Settlement Agreement and enjoined class members from bringing certain actions) and enjoined Ms. Hall from proceeding with her underlying state court action because she had not shown that she had met the criteria for PPH as set forth in the Settlement Agreement. See also PTO 2383. Linda Boderek v. American Home Products, Cause No. A-160872, Jefferson County, Texas. We did so on the record then before us. Specifically, it was found that the Board Certified Pulmonologist who diagnosed Ms. Hall with PPH had not ruled out connective tissue disease or gastroesophogeal

reflux disease (GERD) as a cause of her condition. See PTO 2912. Ms. Hall now seeks to have PTO 2912 vacated based on a July 10, 2003 letter from Dr. Joan Appleyard, a rheumatologist, which was written after we entered PTO 2912.

In that letter Dr. Appleyard states, among other things, "I do not find any evidence on the medical record or on my review of Ms. Hall to diagnose her with gastroesophageal reflux disease [GERD]." She continues, "I have, in fact, ruled out connective tissue disease in this patient and any statement to the contrary would be a misrepresentation of my medical opinion." Class Member Merle Hall's Motion for Relief from Pretrial Order 2912, Exhibit F.

In paragraph D of PTO 2383, we stated "[a] determination of whether a putative PPH plaintiff has been diagnosed with PPH, as defined by Section I.46 of the Settlement Agreement, is a threshold question that determines the eligibility of that Class Member to assert such a claim." Under paragraph 12 of PTO 2383, a resolution of this issue "[i]n most if not all instances" will result from an examination of medical records and a comparison with the criteria for PPH set forth in the Settlement Agreement. Extensive hearings with testimony were not contemplated.

With this latest submission from Dr. Appleyard, the key omission in the record has been rectified. Ms. Hall now satisfies the threshold requirements for a diagnosis of PPH as defined under Section I.46 of the Settlement Agreement. It is

not the function of this court to pass upon Dr. Appleyard's credibility. Whether or not Ms. Hall actually suffers from PPH and is entitled to damages from Wyeth is a matter for the fact finder at her trial in the state court.

Accordingly, we will vacate PTO 2912 and allow Ms. Hall to proceed with her underlying lawsuit in the District Court of Jefferson County, Texas. Wyeth, of course, is not precluded from challenging her PPH claim in the state court. See PTO 2383 at ¶ 13.

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

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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.

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

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

MEMORANDUM AND PRETRIAL ORDER NO. 1415

BECHTLE, J. AUGUST 28, 2000

Presently before the court is the Joint Motion of the Class Representatives and American Home Products Corporation ("AHP") for an order certifying and approving the nationwide settlement class embodied in the Settlement Agreement entered into between the parties on November 19, 1999. For the reasons set forth below, the court will grant the motion and will certify the class and approve the settlement pursuant to Federal Rule of Civil Procedure 23. The court's findings of fact and conclusions of law are as follows.

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I. BACKGROUND

A. The Diet Drug Litigation

they would otherwise have of suffering from bacterial endocarditis. Moreover, early diagnosis of asymptomatic VHD together with the medical surveillance benefits offered by the settlement will allow patients to be carefully monitored over time to determine if the level of regurgitation attributable to their valve disease is progressing. This will permit these individuals to obtain medical and surgical treatment of their valve disease before they suffer irreversible injuries to their heart such as dilatation, hypertrophy, reduced ejection fraction and secondary pulmonary hypertension. In addition, the medical research and medical registry provisions of the Settlement Agreement provide a means to conduct extensive research with respect to the diagnosis and treatment of VHD in general and diet drug induced valvulopathy in particular. Collectively, implementation of these provisions will undoubtedly reduce the morbidity and mortality that would otherwise be attributable to diet drug induced valvular heart disease. (Tr. 5/3/00 at 110-12 & 115-16; Ex. P-95 ¶ 41.)

g. Exit Rights

The Settlement Agreement provides multiple opportunities for class members to gain information concerning the injuries they have suffered as a result of taking Pondimin and Redux and to opt-out of the settlement in light of the information gained through those opportunities. The Settlement Agreement actually provides for four separate opt-out opportunities. All class members were eligible to exercise an "initial opt-out right" by submitting a notice of their

intention to opt-out by March 30, 2000--a date that was 120 days from the date on which the class notice process commenced. (Ex. P-3 at 57 of 148; Pretrial Order Nos. 997 & 998.) Each class member who has timely and properly exercised an initial opt-out right may initiate, continue with, or otherwise prosecute any legal claim against AHP without any limitation, impediment or defense arising from the terms of the Settlement Agreement and subject to all defenses and rights which AHP would otherwise have in the absence of the Settlement Agreement.[7] (Ex. P-3 at 57 of 148.)

All class members who are not members of Subclasses 2(a), 2(b) or 3 and who have been diagnosed as having FDA Positive levels of regurgitation by the end of the Screening Period may exercise an "intermediate opt-out right." (Ex. P-3 at 57-60 of 148.) A class member who timely and properly exercises an intermediate opt-out right may pursue all claims against AHP based on injury to the valve or valves which were diagnosed as having FDA Positive regurgitation except claims for punitive, multiple or exemplary damages, consumer fraud damages and medical monitoring. (Ex. P-3 at 57-60 of 148.) Each class member who wishes to exercise a right of intermediate opt-out must do so by submitting a written notice of his or her intent to do so no later than Date 2. (Ex. P-3 at 57-60 of 148.) With respect to each class member who timely and properly exercises

[7] Class members may revoke an election to exercise a right of initial opt-out and thereby receive the benefits of the settlement provided that the revocation takes place with the written consent of AHP which shall not be unreasonably withheld. (Ex. P-3 at 57 of 148.)

the intermediate opt-out right and initiates a lawsuit against the AHP Released Parties within one year from the date on which the intermediate opt-out right is exercised, the AHP Released Parties shall not assert any defense based on any statute of limitations or repose, the doctrine of laches, any other defense predicated on the failure to timely pursue the claim, any defense based on "splitting" a cause of action, any defense based on any release signed pursuant to the Settlement Agreement and/or any other defense based on the existence of the Settlement Agreement. (Ex. P-3 at 57-60 of 148.)

All class members who are diagnosed as having mild or greater mitral regurgitation or mild or greater aortic regurgitation by the end of the Screening Period, who reach a matrix level condition after September 30, 1999, but before December 31, 2015 and who have registered for settlement benefits by Date 2 are entitled to exercise a "back-end opt-out." (Ex. P-3 at 61-63 of 148.) Each class member who wishes to exercise a right of back-end opt-out must submit a written notice of intent to do so within the latter of 120 days of the date on which the class member first knows (or should have known in the exercise of reasonable diligence) that the Diet Drug Recipient developed a matrix level condition or by Date 2. (Ex. P-3 at 61-63 of 148.) A class member who timely and properly exercises a back-end opt-out may pursue all of his or her settled claims against AHP and the AHP Released Parties except claims for punitive, multiple or exemplary damages, consumer fraud claims and medical monitoring claims. (Ex. P-3 at 61-63 of 148.) With respect

to each class member who timely and properly exercises the back-end opt-out right and who initiates a lawsuit against AHP or any of the AHP Released Parties within one year from the date on which the back-end opt-out right is exercised, the AHP Released Parties shall not assert any defense based on any statute of limitations or repose, the doctrine of laches, any other defense predicated on the failure to timely pursue the claim, any defense based on "splitting" a cause of action, any defense based on a release signed pursuant to the Settlement Agreement and/or any other defense based on the existence of the Settlement Agreement. (Ex. P-3 at 61-63 of 148.)

Finally, the Settlement Agreement provides for a "financial insecurity opt-out right." (Ex. P-3 at 32-33 of 148.) If a condition of financial insecurity with respect to payment of AHP's obligations under the Settlement Agreement occurs in accordance with the conditions defined in the Agreement, then all Diet Drug Recipients who were diagnosed as having FDA Positive or Mild Mitral Regurgitation by the end of the Screening Period and who have registered for settlement benefits by Date 2 have a right to opt-out of the settlement and pursue all of their settled claims against AHP and the other Released Parties, including claims for punitive, multiple and exemplary damages. (Ex. P-3 at 32-33 of 148.)

3. Creation of a Settlement Trust

The Settlement Agreement requires the creation of a Settlement Trust which has responsibility for receiving the amounts deposited by AHP to fund the settlement, investing such amounts (under

investigations involving over 12,000 patients. (Tr. 5/11/00 at 69.) In fact, fenfluramine and dexfenfluramine "have been the most extensively studied anorectic drugs of the past 30 years." (Dunn LT-84 at 123.) As stated above, the court finds that the scientific knowledge is sufficiently developed here and that this factor weighs in favor of settlement.

c. Comparison of Class Recovery to Individual Claimant Recovery.

For the reasons discussed with regard the eighth and ninth Girsh factors, the court finds this factor weighs in favor of settlement. See supra, at § II.E.7..

d. Whether Class Members Have Opt Out Rights.

Class members have multiple and unprecedented opt out opportunities, and thus, this factor weighs in favor of Settlement. See supra, at § I.F.2.g..

e. Reasonableness of Attorneys' Fees.

Attorneys' fees under the Settlement are to be fashioned by the court and determined in accordance with prevailing Third Circuit precedent. See supra, at § II.D.4.b.(ii)(F). The Settlement Agreement provides for a cap on these fees. As the ultimate determination of fees is for the court, this factor is neutral with regard to the Settlement.

f. Fairness of Procedure for Processing Individual Claims.

The court has already discussed the provisions of the Settlement Agreement relating to the review, processing and

administration of claims by class members. See supra, at § I.F.2.a.. These procedures are fair and reasonable for two reasons. First, they precisely define the criteria necessary for a class member to qualify for benefits. For medical monitoring benefits, an intricate network of cardiologists has been established to perform echocardiograms, interpretive visits and additional medical services. With respect to Matrix benefits, claims administrators are essentially bound to accept the certification of a qualified board-certified physician regarding a claimant's medical condition when that certification is accompanied by appropriate information on the claim form. These provisions serve to protect against the insertion of subjective judgment on the part of the claims administrators in making benefits determinations. Second, the audit and appeal procedures protect against fraud and the misuse of Settlement funds.

9. Provision for Joint Tortfeasor Liability.

The Settlement Agreement states that it is the intent of the settling parties that no class member "shall recover, directly or indirectly, any sums for Settled Claims from AHP or any Released Party" in addition to those received under the Settlement. (Ex. P-3 at 121 of 148.) The Settlement Agreement also reflects the settling parties' intent that AHP "shall make no payments" to any non-settling defendant "for any amounts arising out of a Settled Claim" brought by a class member against a non-settling defendant. Id.

May 2, 2000

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

IN RE: DIET DRUGS (PHENTERMINE/ : MDL NO. 1203
FENFLURAMINE/DEXFENFLURAMINE) :PRODUCTS LIABILITY LITIGATION :

SHEILA BROWN, ET AL.
V. CIVIL ACTION NO. 99-2059
AMERICAN HOME PRODUCTSCORPORATION

PHILADELPHIA, PENNSYLVANIA TUESDAY, MAY 2, 2000

BEFORE: HONORABLE LOUIS C. BECHTLE, CHIEF JUDGE EMERITUS

FAIRNESS HEARING
DAY ONE

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