

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

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

**MEMORANDUM AND PRETRIAL ORDER NO.**

Bartle, J.

March , 2005

The issue before the court is whether the Seventh Amendment to the Nationwide Class Action Settlement Agreement ("Settlement Agreement") involving Wyeth's<sup>1</sup> diet drugs Pondimin and Redux is fair, adequate, and reasonable.

We gave preliminary approval to the Seventh Amendment on August 26, 2004, in Pretrial Order ("PTO") No. 3880. Because it could be deemed to be an adverse change for some class members under the current Settlement Agreement approved by the court in August, 2000, notice was sent to some 620,000 class members and attorneys of class members who could be affected. The court held

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1. Wyeth was known as American Home Products Corporation ("AHP") when the Settlement Agreement was initially approved by the court on August 28, 2000. See In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liability Litig. ("In re Diet Drugs"), Memorandum and Pretrial Order No. 1415, No. CIV.A. 99-20593, 2000 WL 1222042 (E.D. Pa. Aug. 28, 2000).

a fairness hearing on the Seventh Amendment on January 18 and 19, 2005.

**I.**  
**Background**

Some six million people ingested either Pondimin and/or Redux before these drugs were withdrawn from the market on September 15, 1997. Their withdrawal from the market was accomplished in conjunction with an immense publicity campaign effectively warning diet drug users that they may have developed valvular heart disease ("VHD").<sup>2</sup> In essence, VHD involves a number of conditions "which cause a disruption in the normal structure and/or function of the heart valves" and which allow blood to leak backward or "regurgitate." In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liability Litig. ("In re Diet Drugs"), Memorandum and PTO No. 1415, No. CIV.A. 99-20593, 2000 WL 1222042, at \*9 (E.D. Pa. Aug. 28, 2000). There are varying degrees of regurgitation, which can be measured by an echocardiogram and are characterized as trace, mild, moderate, and severe. Id. at \*9. Indeed, the Food and Drug Administration ("FDA") has observed that "minimal degrees of regurgitation (i.e., trace mild mitral regurgitation or trace aortic regurgitation) are relatively common in the general population and are not generally considered abnormal." Id. at \*10 (citations omitted). Thus, only mild or greater aortic

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2. VHD also can be caused by several conditions other than diet drug use, each of which can also be diagnosed with an echocardiogram. In re Diet Drugs, 2000 WL 1222042, at \*9.

regurgitation and moderate or greater mitral regurgitation are referred to as "FDA Positive regurgitation." Id. at \*10. All of the experts who testified at the Settlement Agreement Fairness Hearing agreed that the FDA case definition, or "FDA Positive," is the appropriate way to define medically relevant valvular regurgitation and that the lesser degrees of regurgitation have no medical significance. Id. at \*10.

Pondimin and Redux have also been linked to primary pulmonary hypertension ("PPH"), which is a relentlessly progressive disease that affects pulmonary circulation and nearly always leads to heart failure and death. Id. at \*16. The Settlement Agreement specifically excluded PPH from the definition of Settled Claims. Settlement Agreement §§ I.46, I.53; In re Diet Drugs, 2000 WL 1222042, at \*16. Persons who meet the definition of PPH as set forth in the Settlement Agreement may pursue their claims in the court system without limitation imposed by the Settlement Agreement. See PTO No. 3065. Fortunately, PPH is uncommon.

## II.

### **The Current Settlement Agreement**

On October 12, 1999, a class action complaint was filed in this court for the purpose of settlement of thousands of claims against Wyeth. In re Diet Drugs, 2000 WL 1222042, at \*19. This court approved the Settlement Agreement on August 28, 2000 in PTO No. 1415. The Settlement Agreement was reached with respect to the class of all persons in the United States who had ingested Pondimin or Redux and their consortium claimants. In re

Diet Drugs, 2000 WL 1222042, at \*19. The class was divided into five discrete subclasses:

Subclass 1(a): those class members who took Pondimin or Redux for 60 days or less and who have not been diagnosed as having FDA Positive levels of valvular regurgitation by September 30, 1999;

Subclass 1(b): those class members who ingested Pondimin or Redux for 61 days or more and who, likewise, have not been diagnosed as having FDA Positive levels of valvular regurgitation as of September 30, 1999;

Subclass 2(a): those class members who ingested Pondimin or Redux for 60 days or less and who have been diagnosed as having FDA Positive levels of valvular regurgitation as of September 30, 1999;

Subclass 2(b): those class members who ingested Pondimin or Redux for 61 days or more and who have been diagnosed as having FDA Positive levels of valvular regurgitation by September 30, 1999; and

Subclass 3: those class members who ingested Pondimin or Redux and who are not FDA Positive but who have been diagnosed as having Mild Mitral Regurgitation.

Settlement Agreement § II.c.

The Settlement Agreement provides for various benefits for class members, including Matrix Compensation Benefits.<sup>3</sup>

Settlement Agreement § IV.B.2.a. Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices

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3. As discussed below, the Settlement Agreement provided screening benefits, medical monitoring, and purchase price refunds.

applicable. Settlement Agreement § IV.B.2.d(1). Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period,<sup>4</sup> or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs. Settlement Agreement § IV.B.2.d(2). Matrix A-2 and Matrix B-2 set forth the compensation available to derivative claimants of Diet Drug Recipients who are entitled to payments under Matrix A-1 or Matrix B-1, respectively. Settlement Agreement § IV.B.2.e.

Each matrix contains five levels. Settlement Agreement § IV.B.2.c. Generally, Level I encompasses persons with severe

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4. The Settlement Agreement defines the "Screening Period" as: the 12-month period beginning on the Final Judicial Approval Date during which benefits shall be available in the Screening Program. Class Members who have timely registered for benefits by Date 1 [210 days after Final Judicial Approval of the Settlement Agreement] and who are otherwise eligible for Screening Program benefits may receive the Echocardiogram and associated interpretative physician benefits after the end of this Screening Period, provided that: (i) all such Echocardiograms must be conducted no later than July 3, 2003, unless the Court, upon a showing of good cause and due diligence by or on behalf of a Class Member or group of Class Members, allows the Class Member or group of Class Members to receive an Echocardiogram and associated interpretative physician visit after such date; and (ii) any Class Member who receives an Echocardiogram provided by the Trust after the end of the Screening Period shall be considered to have been diagnosed during the Screening Period for all purposes under this Settlement Agreement, and shall have a period of 120 days after the date of the Echocardiogram to exercise, if otherwise eligible, a right of Intermediate Opt-Out. Settlement Agreement § I.49.

valvular regurgitation and nothing else. Settlement Agreement § IV.B.2.c(1). Level II references persons with FDA Positive regurgitation of the mitral or aortic valve, coupled with changes in the structure or functioning of the heart. Settlement Agreement § IV.B.2.c(2). Level III covers individuals who required valvular repair or replacement surgery. Settlement Agreement § IV.B.2.c(3).<sup>5</sup> Level IV describes those who either had complications of surgery which were significant or who did not have surgery but had the complications of untreated VHD. Settlement Agreement § IV.B.2.c(4). Finally, Level V includes persons who had the most morbid complications of either untreated valve disease or near-death-type conditions. Settlement Agreement § IV.B.2.c(5); see also (Tr. 1/18/05 at 30). Matrix benefits range from \$7,389 for a Matrix B-1 Level I claim by a person aged 70 to 79 to \$1.485 million for a Matrix A-1 Level V claim by a person 24 years old or younger. See Settlement Agreement § IV.B.2.a.

Under the Settlement Agreement there are five opt-out opportunities. All class members were eligible to exercise an "initial opt-out right" on or before March 30, 2000. Settlement Agreement § IV.D.2. Those who initially opted out are not part of the settlement class and have the right to pursue without limitation whatever remedies they may have had against Wyeth in

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5. Level III also included claimants who had an indication for surgery that could not be performed. Settlement Agreement § IV.B.2.c(3)(b).

the courts, subject to all defenses and other rights available to Wyeth.

The Settlement Agreement also provides "intermediate" and "back-end" opt-out rights. Settlement Agreement §§ IV.D.3, IV.D.4. Under certain circumstances, class members can exercise these rights and pursue all claims against Wyeth in the tort system except claims for punitive, multiple, or exemplary damages, consumer fraud damages, and medical monitoring. In return, Wyeth has waived its defenses based on statute of limitations or repose and the doctrine of laches, any other defense predicated on the failure timely to 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.

The Settlement Agreement includes in addition a "financial insecurity opt-out right." Settlement Agreement § III.E.9. If a condition of financial insecurity, as defined, arises with respect to Wyeth's obligations under the Settlement Agreement, all Diet Drug Recipients who were diagnosed as FDA Positive or mild mitral regurgitation by May 3, 2003 and who had registered for settlement benefits by the deadline have a right to opt out of the Settlement and pursue without limitation all of their Settled Claims against Wyeth and other Released Parties.<sup>6</sup>

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6. As set forth in the Settlement Agreement, Settled Claims are  
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Finally, the Settlement Agreement allows for a "Sixth Amendment Opt-Out." Settlement Agreement § IV.D.5. This right is available to class members who otherwise qualify for the back-end opt-out right under § IV.D.4 of the Settlement Agreement, who claimed matrix benefits within the meaning of § IV.D.4.b on or before May 3, 2003, and who qualify for Matrix Compensation Benefits but have not received them or payment of any settlement funds from Wyeth. Class members who exercised a Sixth Amendment opt-out are subject to the same limitations and protections as back-end and intermediate opt-out class members.

The Settlement Agreement established the AHP Settlement Trust ("Trust") to administer settlement benefits for those who do not exercise a right to opt out and do not sue Wyeth in the tort system. Settlement Agreement § III.A. An aggregate global settlement fund of \$3.75 billion was created to be used for

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6. (...continued)

those claims by class members arising out of or relating to the purchase, use, manufacture, sale, dispensing, distribution, promotion, marketing, clinical investigation, administration, regulatory approval, prescription, ingestion and labeling of Pondimin and/or Redux, except claims based upon PPH and claims that are subject to validly exercised rights of opt-out under the Settlement Agreement. Settlement Agreement § I.53.

The Released Parties under the Settlement Agreement are Wyeth, its subsidiaries, affiliates, and divisions, its predecessors, successors and shareholders, the suppliers of materials, components and services used in the manufacturer of Pondimin or Redux and distributors of Pondimin and Redux. In addition, physicians who prescribed and pharmacists who dispensed Pondimin and Redux are Released Parties except to the extent that claims against them are based on their independent negligence or culpable conduct. Manufacturers, sellers, wholesalers or distributors of phentermine are not Released Parties. Les Laboratoires Servier S.A. and all of its affiliates and Interneuron Pharmaceuticals, Inc. are not Released Parties. See Settlement Agreement § I.48.

several purposes. One billion dollars were allocated to Fund A for the payment of non-matrix benefits.<sup>7</sup> Settlement Agreement § III.B.1. Payment for a transthoracic echocardiogram and cash/medical services ("CMS") benefits is available to enable qualifying class members to diagnose and ensure ongoing medical monitoring of any condition so that if they worsened, they can obtain appropriate treatment.<sup>8</sup> Settlement Agreement § IV.A. Additionally, there is a purchase price refund available to persons who can prove they took diet drugs. Settlement Agreement § IV.A.

There is also a Fund A escrow account of \$200 million from which attorney fees to Class Counsel, Common Benefit Attorneys, and incentive awards to class representatives in state and federal court class actions are to be paid.<sup>9</sup> Settlement

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7. Initially, anything left over in Fund A would later be poured into Fund B. Settlement Agreement § III.B.4. These funds became merged and are now referred to as the Settlement Fund. See PTO No. 2677. The Trust may call on Wyeth to provide additional funding to furnish what were previously Fund A benefits. Wyeth's maximum obligation to provide funding for the Fund A benefits under the existing Settlement Agreement is \$1 billion, plus the additional amount, if any, necessary to pay cash/medical service ("CMS") benefits. PTO No. 2677 at 5.

8. The CMS benefit, a non-matrix benefit paid from Fund A, is \$6,000 in cash or \$10,000 in medical services for persons who used diet drugs for 61 days or longer or \$3,000 in cash or \$5,000 in medical services for persons who used diet drugs for 60 or fewer days.

9. On October 3, 2002, after a hearing, the court ordered a class action interim counsel fee award of \$80 million, \$40 million from Fund A and \$40 million from Fund B. In addition, \$80 million in counsel fees were awarded from the MDL Fee and Cost Account, an account established by PTO Nos. 467 and 517 and  
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Agreement § III.B.3; PTO No. 2622 at 12. Any amount in the Fund A escrow account not awarded by the court is to be returned to Wyeth. Settlement Agreement § III.B.3.

The remaining \$2.55 billion of the \$3.75 billion payable by Wyeth was allocated to Fund B. (Tr. 1/18/05 at 28). This money, which is used to pay Matrix Level benefits, is now known as the maximum available in Fund B amount ("MAFBA"). Settlement Agreement § I.1; PTO No. 4391 at 1-2; (Tr. 1/18/05 at 50-51). Besides benefits to class members, there are other draws on Fund B, such as certain of the Trust's administrative expenses. Settlement Agreement § III.B.4.d. Wyeth is currently entitled to "credits" against MAFBA based upon verdicts or settlements reached with respect to persons who have exercised certain opt-out rights. Settlement Agreement § VII.A; (Tr. 1/18/05 at 53-54). Additionally, there is what is referred to as a "progression reserve" of \$255 million which was set aside under the Sixth Amendment to fund claims of individuals who already have received matrix benefits but who may progress to more serious medical conditions. Settlement Agreement § IV.D.5.d;

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9. (...continued)

funded by required sequestration of nine percent in federal cases and six percent in state cases of all payments made by defendants to plaintiffs in settlements or in satisfaction of judgments in Multi-District Litigation No. 1203. See PTO No. 2622. The actual award from the MDL Fee and Cost Account represented a reduced amount of six percent for federal cases and four percent for state cases, rather than the entire sequestered percentages of nine and six. The court found that the reduced amounts were "more reasonable and fairer to the individual litigants involved, yet still fairly compensate[d] the PMC and others for their expenses and work in MDL 1203." PTO No. 2622 at 41.

(Tr. 1/18/05 at 52). Fund B also has an escrow account which is used to pay all attorneys' fees arising out of payments from Fund B. The fees are not to exceed \$229 million, which is nine percent of the \$2.55 billion Fund B amount. Settlement Agreement § VIII.E.1.b. Nine percent of every Matrix Compensation payment is deducted from payments made to class members and their attorneys, if any, and set aside in the Fund B escrow account. Settlement Agreement § VIII.E.1.b. If the court awards less than the nine percent assessments, what remains will be returned to the class members or their individual attorneys. Settlement Agreement § VIII.E.1.

The Settlement Agreement contains a mechanism by which a class member was to demonstrate entitlement to matrix benefits. Settlement Agreement § VI.C.4. A key feature is the requirement that a qualified physician attest to the medical conditions of a class member. Settlement Agreement § VI.C.4.a. To obtain benefits, a claimant is required to submit an echocardiogram read by a board-certified cardiologist who has attested that the claimant's condition meets the definitions set forth in the Settlement Agreement. Settlement Agreement § VI.C. The cardiologist must supply on a court-approved form known as a Green Form various medical information about the claimant including the echocardiogram readings and must attest to the accuracy of the information presented under penalty of perjury. Settlement Agreement, § VI.C.4; Green Form, Part II. The Green Form includes a section to be completed and signed by the

claimant and one to be completed and signed by the claimant's attorney. Green Form, Parts I and III.

The Settlement Agreement called for audits of up to 15 percent of the claims submitted to the Trust. Settlement Agreement §§ VI.E.1, VI.F. The Trust could designate for audit up to five percent of claims filed each quarter, and Wyeth could designate up to ten percent. Id. The audit process requires a qualified cardiologist engaged by the Trust to examine the materials submitted by the claimant and the attesting physician and to determine whether there is a reasonable medical basis for the attestation of that physician. Settlement Agreement § VI.E.7. If there is a reasonable medical basis, the claim would pass audit, and if there is not, the claim would go to a show cause proceeding in which the claimant would be required to show cause as to why the claim should be paid.<sup>10</sup> Settlement

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10. As stated in PTO No. 3164:  
Under the show cause process, if a claimant contests the Trust's final post-audit determination, the Trust must file an application for issuance of an order to show cause seeking relief requested by the Trust. After the court has issued an order directing the claimant to show cause why the relief requested by the Trust should not be granted and referring the application to the Special Master for further proceedings, the claimant has the burden of proving to the court that there was a reasonable medical basis for the attesting physician's answer to each Green Form question at issue and/or the truth of all of claimant's representations of material fact in connection with the claim. If the court determines that there was no reasonable medical basis to support the attesting physician's answer to each Green Form question at issue and/or the claimant intentionally made a misrepresentation of fact in connection with the claim,  
(continued...)

Agreement § VI.E.7; (Tr. 1/18/05 at 31-32). There is also a provision, which has never been used, allowing Wyeth to designate claims in audit for an independent medical examination.

Settlement Agreement § VI.F.5; (Tr. 1/18/05 at 32). Those results would be able to be considered by an auditing cardiologist in determining whether there is a reasonable medical basis for the attestation. Settlement Agreement § VI.F.6.

At the 2000 Fairness Hearing which led to the approval of the Settlement Agreement in PTO No. 1415, evidence was presented showing the anticipated level of demand for Fund B benefits given that six million people nationwide had taken one or both of the diet drugs. Expert witnesses analyzed, among other things, the number of potential class members, the expected participation rate in the settlement, the proportion of participants who would be diagnosed with FDA Positive levels of regurgitation, and the proportion of claimants who would be entitled to Fund B payments who would be recovering from Matrix B rather than Matrix A. In re Diet Drugs, 2000 WL 1222042, at \*28.

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10. (...continued)

the court shall confirm the Trust's post-audit determination and may grant such other relief as it finds appropriate. If the court determines that there was a reasonable medical basis and/or that the claimant did not make an intentional misrepresentation of a material fact, the court shall enter an order directing the Trust to pay the claim in accordance with the Settlement Agreement. See PTO No. 2807.

PTO No. 3164 at 4-5 n.1. Although PTO No. 3164 described the show cause process under the Audit Rules approved in PTO No. 2807, this process is virtually identical to the one established in the Audit Procedures, which were approved in PTO No. 2457.

Based in part on "conservative assumptions likely to overstate the demands on [both] Fund A and Fund B," the expert testimony demonstrated that a maximum of 8,345 individuals would qualify for the larger Matrix A payments from Fund B and that no more than 27,227 people would qualify for reduced payments on Matrix B. Id. at \*28 (emphasis added); see Report of Samuel J. Kursh, D.B.A., Settlement Agreement Fairness Hearing Ex. P-94 at 4-5. Matrix B claims therefore should have numbered three times the number of Matrix A claims. Further, the projected ratio of diet drug-induced aortic regurgitation to diet drug-induced mitral regurgitation was five to one. See Supp. Decl. of Steven N. Goodman, M.D., M.H.S., Ph.D., Settlement Agreement Fairness Hearing Ex. P-90 at 3. A strong body of epidemiological studies supported all these projections. No evidence was offered to the contrary. In re Diet Drugs, 2000 WL 1222042, at \*29. Only after considering the expert testimony and other supporting evidence did our predecessor Judge Louis C. Bechtle determine that the \$2.55 billion in Fund B would be "sufficient to provide all likely benefits under the Settlement Agreement." Id. at \*29

Prior to court approval of the Settlement Agreement, the parties agreed to four amendments to the Settlement Agreement. These amendments were approved in PTO No. 1415 as part of the Settlement Agreement. The court approved a Fifth Amendment on December 10, 2002, making five technical changes to the Settlement Agreement, after finding that the changes were fair, adequate, and reasonable and that no additional notice to

the class was required. See PTO No. 2677. On March 12, 2003, the court also approved a Sixth Amendment, creating an additional opt-out right, in PTO No. 2778. Our Court of Appeals affirmed PTO No. 2778 on October 5, 2004. In re Diet Drugs, 385 F.3d 386 (3d Cir. 2004).

### **III. Subsequent Events**

During the summer of 2002, the Trust received a massive influx of Green Forms claiming matrix benefits. (Tr. 1/18/05 at 34). As of August 12, 2002, the Trust had received approximately 42,000 Green Forms for matrix level claims from Fund B. (Tr. 1/18/05 at 34). At the rate claims were being filed, one could predict at that time that the Trust would receive approximately 75,000 claims by the cutoff date for claims registration. (Tr. 1/18/05 at 34). Both Wyeth and Class Counsel maintained that the principal reason for the disparity in the number of claims predicted and the number being filed was that claimants were not following the medical model upon which the Settlement Agreement was based. It had been assumed, as they put it, "that Class Members would go to their own physicians or Screening Program doctors and would receive a diagnosis in the course of their medical care and treatment." Class Counsel and Wyeth's Joint Proposed Findings of Fact in Connection with the Seventh Amendment Fairness Hearing ¶ 16.; (Tr. 1/18/05 at 38-39). Instead, many plaintiffs' attorneys set up "echocardiogram mills," or facilities in hotels and other non-medical sites to conduct large numbers of echocardiograms, which Wyeth and Class

Counsel contend often lacked any reasonable medical basis to support a matrix claim. (Tr. 1/18/05 at 39). Whether the individuals performing these echocardiograms were properly supervised by cardiologists and whether these echocardiograms therefore should be disregarded in determining benefits is now a major controversy before the court.

In July, 2002, the Trust filed a motion for a temporary restraining order and preliminary injunction in connection with 78 claims submitted by two firms and attested to by two cardiologists. After an extensive evidentiary hearing in September, 2002, we issued PTO No. 2640 in which we found that the two physicians had interpreted echocardiogram reports in a medically unreasonable manner. The court ordered the Trust not to pay these claims and allowed the claimants to submit new echocardiograms and Green Forms signed by different physicians. PTO No. 2640 ¶ 1. The court also compelled all claims that were submitted by those law firms or attested to by those physicians to be audited by the Trust. PTO No. 2640 ¶¶ 2-3; (Tr. 1/18/05 at 39).

Soon after the entry of PTO No. 2640 and upon a joint motion by Wyeth and Class Counsel and presentation of the other evidence gathered during the summer of 2002, the court found good cause in PTO No. 2662 to impose a 100 percent audit of matrix claims, as permitted in § VI.E.8 of the Settlement Agreement. Beyond the matter of the number of unexpected alleged injuries, the Green Forms filed also demonstrated a pattern of filings that

departed dramatically from what was expected when the Settlement Agreement was approved. By August 12, 2002, the Trust had received far more claims seeking benefits for alleged mitral regurgitation than it had for aortic regurgitation. PTO No. 2662 at 8. Although the estimates had projected five aortic regurgitation claims to every one mitral regurgitation claim, the actual number of claims filed was just the opposite: nearly eight mitral regurgitation claims were filed for every three aortic regurgitation claims as of August 12, 2002. There were also a number of claims for damage to both the mitral and aortic valves as of that date. PTO No. 2662 at 9.

Prior to entry of PTO No. 2662, 85 percent of claims were being paid without any real check on their legitimacy. This court found that:

the undisputed statistics offered by the moving parties ... reflect an obvious increase in the number and value of claims totally at odds with impressive and undisputed epidemiological evidence presented at the Fairness Hearing. The claims simply do not mesh with legitimate expectations of the court and the parties. Common sense compels the conclusion that something may be seriously amiss. While it is always possible that the epidemiologists were wrong, it is also quite possible that they were right and that the huge influx of claims is not legitimate. The only way we can ever find out which answer is correct is through 100% audits. Good cause clearly exists to implement this remedy.

PTO No. 2662 at 12.

In consultation with statistical experts and four highly qualified cardiologists beginning in the summer of 2002,

Class Counsel reviewed a stratified random sample of 500 claims and determined that only about 25 percent of these claims were payable under the settlement criteria. (Tr. 1/18/05 at 40-42). Trust audit results revealed a similar pattern of claims showing that only 38 percent of the claims being audited at Level I and II were payable. (Tr. 1/18/05 at 42-44). Further review of these claims indicates that the audit pass rates would really be 12.5 percent.<sup>11</sup>

While the 100 percent audit addressed the problem of potential payment by the Trust of claims unsupported by any reasonable medical basis, it created a heavy burden on the Trust in processing so many thousands of claims through audit. At a hearing held in November, 2002 to address the parties' motion to implement the 100 percent audit, the Trust announced a goal of processing 2,000 claims through audit per month. (Tr. 1/18/05 at 44-45). Nonetheless, it took almost a year for the Trust to recruit and train new auditors and begin increasing audit output. (Tr. 1/18/05 at 44-45). In August, 2003, the Trust revised downward its projected audit output to 1,000 audits per month. (Tr. 1/18/05 at 45); Motion of the AHP Settlement Trust for Authorization to Proceed in Accordance with its Operations Plan, for Imposition of Certain Reporting Requirements, for Suspension of Certain Deadlines and Time Periods and for Approval of Certain

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11. The 12.5 percent pass rate was extrapolated by the Trust based on Dr. Kisslo's review of about 1000 claims that had passed audit. (Tr. 1/18/05 at 42-43); see also Audit Results Summary Table, Ex. W-2 at the Seventh Amendment Fairness Hearing.

Procedures and attached "AHP Settlement Trust Operations Plan," filed 8/4/03. However, according to its monthly reports, the Trust has remained at least 50 percent behind this projection. (Tr. 1/18/05 at 46; P-13). If the Trust were to continue to conduct audits at its current rate of 200 to 700 per month, it would take somewhere between 5 and 17 years to complete the task. (Tr. 1/18/05 at 48).

In an effort to prevent the dissipation of the settlement's funds through fraud and abuse of the claims system, the Trust instituted a "Claims Integrity Program" ("CIP") in August, 2003. (Tr. 1/18/05 at 54-55). In November, 2003, the Trust filed a motion seeking to disqualify all 60,000 echocardiograms conducted by a company known as EchoMotion from supporting claims for matrix benefits on the grounds that these echocardiograms were not "conducted under the supervision" of a Board-Certified Cardiologist as required by § VI.C.1.b(4) of the Settlement Agreement. The CIP, along with the controversy over whether echocardiograms were properly supervised as well as other aspects of the Trust's processing of Matrix claims, has generated many hotly contested issues and substantial motion practice. Unfortunately, all of these actions have unduly delayed the payment of valid claims.

By April, 2004, there were approximately 85,000 Green Forms on file with the Trust, only a little less than half of which were sufficiently complete to state on their face a claim for matrix benefits. (Tr. 1/18/05 at 34-35). Moreover, the data

presented by Wyeth at the Seventh Amendment Fairness Hearing demonstrated that as of January 5, 2005, more than 120,900 Green Forms were filed with the Trust, representing more than 87,700 potential claims after duplicates were tagged. See Wyeth's Seventh Amendment Fairness Hearing Ex. W-1. In sum, these numbers manifest an enormous increase over what was anticipated at the Fairness Hearing in 2000.

As of January 5, 2005, there were 42,444 Green Form claims remaining to be audited. (Tr. 1/19/05 at 15, 25; W-1). Of those claims, 40,756 were claims for Level II benefits. (Tr. 1/19/05 at 30-31; W-1). Based on the pattern of audit passage rates for Level II claims, it could be predicted that 33 percent, or 13,449 of those claims would be found payable after audit. (Tr. 1/19/05 at 30-31; Ex. W-2). See also PTO No. 2662 at 4. Additionally, there are another 15,474 Green Forms on file with the Trust that are incomplete but potentially could be completed in the future. (Tr. 1/19/05 at 21-22; W-1). There are also between 450,000 and 500,000 class members who are arguably "registered" for benefits, depending on how the term is defined. (Tr. 1/19/05 at 26-27). Claimants who were deemed FDA Positive or having mild mitral regurgitation by the end of the Screening Period may qualify for matrix benefits in the future if they meet other requirements in the Settlement Agreement. Settlement Agreement § IV.B.1.a.

Given the large number of matrix claims on file, it now appears that Wyeth's funding obligations under the Settlement

Agreement will be exhausted before all claimants that passed audit are paid benefits. (Tr. 1/18/05 at 34-35, 50). Wyeth's total financial obligation under the existing Settlement Agreement is capped at \$2.55 billion for payment of matrix benefits. This maximum obligation in the existing Settlement Agreement was negotiated and approved based on uncontradicted expert advice and testimony presented by Class Counsel and Wyeth at that May, 2000 Fairness Hearing that these funds would be sufficient to fund all likely claims for benefits. See PTO No. 1415 at 63-66; (Tr. 1/18/05 at 49).

Presently, \$1.6 billion of the \$2.55 billion fund remains to pay matrix benefits.<sup>12</sup> The average payment value for a Level II claim found payable after audit has been \$400,000. (Tr. 1/18/05 at 50). In addition, there are a number of matrix claims that have passed audit but have not been paid, including claims which are the subject of Preliminary Audit Determinations ("PAD's") and Post-Audit Determination Letters ("PADL's"). They collectively have a value, based on the face of the claims, of \$500 million. (Tr. 1/18/05 at 51-52). As previously mentioned,

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12. However, MAFBA does not include funds for certain non-matrix benefits, such as CMS benefits and prescription reimbursements which initially came out of Fund A. Wyeth is required to provide additional funds for these benefits should the initial \$1 billion set aside for Fund A be exhausted. As of June 30, 2004, the Trust had paid over \$94.5 million in prescription reimbursements, referred 398,908 class members for diagnostic medical screening, paid physicians \$166,675,689 for performing 203,878 diagnostic echocardiograms and for related consultations, and paid \$191,718,210 in CMS benefits to 32,339 class members. See Monthly Report of AHP Settlement Trust for month ending June 30, 2004 pursuant to PTO No. 3185. These payments amount to over \$452.9 million.

the Trust must also use these funds to pay certain administrative expenses, which have amounted to \$50 million a year. Settlement Agreement § III.B.4.d; (Tr. 1/18/05 at 52-53). The Trust must also pay Matrix Level III, IV, and V claims from this money. As noted above, if more than a small fraction of the claims currently on file for matrix benefits are found payable, the Trust will not have enough money to pay the all claimants under the existing Settlement Agreement.

It has become clear to virtually all concerned that business as usual is no longer a viable option. The Trust has been inundated with many more claims than had ever been anticipated and has not been able to undertake the 100 percent audit program in a timely fashion. Appeals to this court under the show cause process involve time-consuming individual judicial determinations, a far cry from what was anticipated to be an essentially administrative process. The pending question of whether thousands of echocardiograms were properly supervised and other Trust-related litigation, if not otherwise resolved, will mire this court in literally years of continuous hearings.

Finally, should Trust funds for the payment of matrix benefits turn out to be inadequate, as now appears to be the case, one does not need a crystal ball to foresee a legal tsunami on the horizon. If history in the matter is any indication, years of contentious, complex litigation will undoubtedly ensue. While the final outcome is impossible to predict, it is not unlikely, absent some curative amendment, that thousands of

deserving class members may never receive any compensation for their medical conditions from ingesting Pondimin and Redux.

**IV.**  
**The Seventh Amendment**

In this unenviable setting, Class Counsel, the Seventh Amendment Liaison Committee ("SALC"),<sup>13</sup> and Wyeth negotiated the Seventh Amendment. In October, 2002, Class Counsel and counsel for Wyeth began discussing the idea of creating a comprehensive solution to the problems at hand. Shortly thereafter, Class Counsel joined forces with attorneys Wayne Spivey and Jerry Alexander, who subsequently became part of the SALC.

Negotiations involving various structures for a resolution proceeded for many months, including a series of meetings in late August and September, 2003. By the end of October, the parties arrived at the basic structure that is ultimately reflected in the Seventh Amendment. They presented it to the court in the form of a Term Sheet in May, 2004.

On May 10, 2004, we granted the motion of Class Counsel, Wyeth, and counsel for certain individual class members to stay pending litigation related to the processing, auditing,

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13. Wayne Spivey, Esquire, of Shrager, Spivey and Sachs and Jerry Alexander, Esquire, of Alexander and Associates, P.C., L.L.O. began negotiations with Class Counsel and Wyeth. When the Term Sheet that preceded the Seventh Amendment was constructed, Ellen Presby, Esquire, of Baron & Budd, P.C.; James Doyle, Esquire, of Fleming and Associates; and Tony Martinez, Esquire, of Martinez, Barrera & Martinez, L.L.P. were added to the working group that was part of the joint effort to finalize the Seventh Amendment and secure its implementation. The group was formally recognized as the Seventh Amendment Liaison Committee with Mr. Spivey as the chair when this court preliminarily approved the Seventh Amendment on August 26, 2004. See PTO No. 3880 at ¶ 11.

or payment of claims potentially payable on Matrix Level I or II as well as other litigation surrounding the Trust's processing of claims. See PTO No. 3511.<sup>14</sup> After we entered the stay, intense arm's length negotiations took place from May through July, 2004 in an effort to transform the eight-page Term Sheet into what would become a 100-page Seventh Amendment with 13 different exhibits. Those at the negotiation table included not only Wyeth's counsel, Class Counsel, and members of the SALC, but also certain Wyeth executives who could authorize funding. The parties engaged in robust conversation over such issues as how to treat those claimants who had pre-stay payable PADL's, problems with the audit process, and the process by which the funds would be managed and distributed. The discussions also included the issue of Enforcement Actions by the Trust and Wyeth against claimants, attorneys, and physicians for alleged misconduct related to the Settlement Agreement. Seventh Amendment § I.B.24.

The negotiations culminated in a proposed Seventh Amendment on July 21, 2004. The Seventh Amendment was then placed in escrow with the Special Master because the parties were unable to finish the exhibits by that time. The court extended the stay in PTO No. 3747, and the negotiations over the exhibits, particularly the official class notice to the Seventh Amendment ("notice"), continued until August 10, 2004, at which time the parties presented the entire Seventh Amendment to the court for

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14. We subsequently extended the stay several times. See PTO Nos. 3725, 3747, 3786, 3880.

preliminary approval. Thereafter, the Trust filed an objection. The parties met with the Trust and subsequently made minor modifications.<sup>15</sup> A revised Seventh Amendment was filed with the court on August 24, 2004, and we preliminarily approved it on August 26, 2004 in PTO No. 3880.

As with the initial Settlement Agreement, those negotiating the Seventh Amendment on behalf of the plaintiffs had no understandings with Wyeth with respect to any of their individual cases. The terms and conditions of the Seventh Amendment were the product of a tough bargaining process. Throughout the negotiations, members of the SALC and Class Counsel were always willing to walk away. (Tr. 1/18/05 at 121). Michael Fishbein, Esquire was the lead negotiator on behalf of the class. He provided zealous and unconflicted representation of the class during the negotiations of the Seventh Amendment. The members of the SALC did not represent the class during the Seventh Amendment negotiations but acted as a liaison for lawyers who represented large numbers of claimants to make sure that there would be strong support for the Seventh Amendment among claimants' attorneys. (Tr. 1/18/05 at 121-22).

The prospect of a deal to settle opt-out cases was never discussed as part of the Seventh Amendment negotiations. (Tr. 1/18/05 at 123). The parties recognized that resolving problems with the Settlement Agreement through the Seventh

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15. The only adjustments the parties made after meeting with the Trust were the elimination of whereas clauses and changes to the Term Sheet references. (Tr. 1/18/05 at 119).

Amendment might make it easier for Wyeth to settle inventories of claims. However, Wyeth made no promises that it would settle anything other than the claims covered by the Seventh Amendment in exchange for members of the SALC's support of the Seventh Amendment. (Tr. 1/18/05 at 221).

Under the Seventh Amendment, if approved, Wyeth will contribute an additional \$1.275 billion (the "Supplemental Fund") for the payment of benefits in excess of its obligations under the current Settlement Agreement. These funds will be held and distributed by a Fund Administrator rather than the existing Trust.<sup>16</sup> Seventh Amendment § IV.A.1. The money will be divided ratably among all qualified class members based on a medical review of their claims.

Generally, the Seventh Amendment provides for the payment of: (1) reduced Matrix Compensation Benefits to eligible class members who have submitted Matrix Level I and II claims; and (2) \$2,000 payments to class members who are found ineligible for Matrix Compensation Benefits, who withdraw their claims, or who are diagnosed as having only FDA Positive or mild mitral regurgitation. Class members who are eligible for Matrix Compensation Benefits will be paid based on a Relative Payment Grid, which assigns values based on medical condition, age at

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16. In the order preliminarily approving the Seventh Amendment, we appointed Heffler, Radetich and Saitta, LLP ("Heffler Radetich"), a certified public accounting company, to serve as the Fund Administrator. PTO No. 3880 at ¶ 9. Heffler Radetich has had extensive experience in the administration of class action litigation. (Tr. 1/19/05 at 236).

first diagnosis, duration of diet drug use, and the presence of alternative causation factors. Seventh Amendment § VII.A. In addition, these class members and those who have FDA Positive or mild mitral regurgitation are guaranteed additional payments if they develop higher level diseases. Seventh Amendment § IX. Wyeth will also offer those who participate in the Seventh Amendment a "surgery guarantee." Seventh Amendment § IX.B. This will extend to claimants the prospect of future compensation should their VHD progress to the point where surgery is required.<sup>17</sup> Seventh Amendment § IX.B. Wyeth will provide this money regardless of whether the MAFBA, that is, the maximum available Fund B amount limitation, has been exhausted. (Tr. 1/18/05 at 84).<sup>18</sup>

The Seventh Amendment takes the medical criteria of Matrix Level I and II in the existing Settlement Agreement and divides them into "High Threshold" and "Low Threshold" conditions in recognition of the fact that certain medical conditions on current Matrix Level I and II are more severe than others. Seventh Amendment §§ I.B.31, I.B.39. Class members who are found during the medical review process to have High Threshold medical

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17. The Seventh Amendment provides that Wyeth will offer payment of benefits for people who actually have surgery or reach Matrix Level IV or V by the earlier of 15 years from the claimant's last date of ingestion or December 31, 2011. Seventh Amendment § I.B.30.c.

18. The Settlement Agreement also provides benefits to derivative claimants, that is, eligible spouses, significant others and/or children of diet drug users.

conditions will receive more compensation from the Supplemental Fund than those fitting the Low Threshold description. (Tr. 1/18/05 at 171-72).

The Seventh Amendment does not change the amount payable to claimants with claims that fall under Matrix Level III, IV, and V. Seventh Amendment § IX.A. However, it does change some of the medical criteria for Matrix Level III, IV, and V for Seventh Amendment participants. Seventh Amendment § I.B.30. For example, surgery-related claims will qualify for benefits on Matrix Level III only if surgery is actually performed.<sup>19</sup> Seventh Amendment §§ I.B.30.a, I B.30.c.

The level of the Seventh Amendment benefits for any claimant depends on which of two categories applies. (Tr. 1/18/05 at 83). Category One includes claimants who have submitted Matrix Level I and II claims which have not been adjudicated. Seventh Amendment § III.A.1. These claimants must have echocardiogram tapes as well as proof of their diet drug use on file with the Trust. Category Two class members are any claimants who have timely registered with the Trust by May 3, 2003. Seventh Amendment § III.A.2. In addition, these claimants

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19. The qualification that the claimant have surgery is a prerequisite for Matrix Level III benefits in every case except where a claimant is ineligible for surgery due to medical reasons (other than acute conditions that merely require a postponement of surgery). Actual surgery is not required, however, for claimants whose conditions progress to Matrix Level IV and V and otherwise qualify under Matrix Level IV and V. Seventh Amendment, § I.B.30.

must have had within the Screening Period<sup>20</sup> an echocardiogram demonstrating mild or greater regurgitation of either the aortic valve or the mitral valve and who would qualify based on these conditions potentially for back-end opt-out rights or Matrix payment rights in the future. Seventh Amendment § III.A.; (Tr. 1/18/05 at 83-84; Ex. P-1).

Wyeth, Class Counsel, and the SALC assigned numbers, known as Diet Drug Recipient (DDR) numbers, to identify all the class members who appeared to qualify for Category One benefits. This list is Exhibit B to the Seventh Amendment, which was posted by the Trust on the official Trust website on August 26, 2004 and again in early September, 2004. It was also posted on the BrownGreer<sup>21</sup> website. (Tr. 1/19/05 at 63-64). Class members and their attorneys could look up their claim numbers to see if they were in Category One. The initial Category One list included 40,518 class members of whom 1,881 have opted out of the Seventh Amendment.

The Seventh Amendment provides a process by which class members not on the initial Category One list may request

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20. For most class members, the end of the Trust's Screening Period was January 3, 2003. For certain class members who received echocardiograms provided by the Trust in its Screening Program but who could not obtain an echocardiogram by that date, the diagnosis must have occurred by July 3, 2003, unless extended by the court. Settlement Agreement § I.49; Seventh Amendment, Ex. L (Part II of the notice § II.A).

21. BrownGreer is a firm that specializes in providing legal services and claims administration services. Orran Brown, Esquire, of BrownGreer serves as Wyeth's liaison counsel with the Trust and with Class Counsel to assist in implementing the Settlement Agreement.

inclusion on the Category One list by filing certain documents with Wyeth and the Fund Administrator. Seventh Amendment § XIV.C.<sup>22</sup> Wyeth, Class Counsel, and the SALC went through the requests for inclusion and determined the final Category One class member list. This list was filed with the court on March 9, 2005.<sup>23</sup>

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22. A class member who filed a request for inclusion to be on the Category One list must have submitted proof of diet drug use, a Green Form signed by the class member and his or her attesting physician in which the answers contain sufficient information on medical conditions to support a claim on Matrix Level I or II, and the echocardiogram on which the claim is based. Seventh Amendment § XIV.C.4. In addition, the class member must have already submitted to the Trust on or before May 3, 2003 the following materials: a Pink, Blue and/or Part I of a Green Form, and/or a substantially completed Green Form Part II signed by an attesting physician. The class member must have had an echocardiogram after he or she used the diet drugs but before the end of the Screening Period that demonstrates mild mitral or FDA Positive regurgitation, and an echocardiogram after diet drug use that demonstrates a Matrix Level I or II condition. Seventh Amendment § XIV.C.3. The request for inclusion process does not apply to class members who had filed an initial, intermediate, or back-end opt-out. Instead, the only way for a person who initially filed an initial, intermediate, or back-end opt-out to be included in Category One is if they filed a Green Form by May 6, 2004, in which the answers to Part II contain sufficient information on medical conditions to support a claim on Matrix Level I or II. Seventh Amendment §§ XIV.B.2, XIV.C.

23. The list included an additional 2,596 Category One class members and 363 provisional Category One class members. Provisional Category One class members are claimants who appear, from the materials furnished by the class members and those on file with the Trust, to have submitted a timely Green Form asserting a claim for Matrix Compensation Benefits on Matrix Level I or II and who were not otherwise excluded from membership in Category One under the Seventh Amendment, but who also have another Green Form on file with the Trust that the Trust has processed to some extent, but not to conclusion. Such class members shall be considered Category One Class Members if the processed Green Form is finally denied without payment of any Matrix Compensation Benefits or the class member withdraws that Green Form to pursue the claim as a Category One class member  
(continued...)

Under the Seventh Amendment, the amount of benefits available to a Category One class member will depend on the outcome of the Supplemental Fund's medical review process. The Fund Administrator will divide \$1.275 billion<sup>24</sup> among Category One class members who pass medical review.

Once claims of all Category One claimants have been processed through medical review, the Fund Administrator will assign a "Relative Payment Value" to each claim. "This determination shall be final, binding, and, in the absence of actual fraud, shall not be subject to appeal, challenge before, or review of any kind by, any court, agency, arbitrator, mediator, or otherwise." Seventh Amendment § XV.O. The Relative Payment Value will depend on how long the claimant used the diet drugs, whether the claimant's medical condition falls into either a High or Low Threshold Condition, how old the claimant was at the time of diagnosis, and whether the claimant has an alternative causation factor. Seventh Amendment §§ VII.A.3-4. Alternative causation factors are medical factors that cause some

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23. (...continued)  
instead.

24. Specifically, an eligible Category One class member will receive an "Individual Payment Amount", which is calculated by applying a formula to the "Net Supplemental Class Settlement Fund Amount." Seventh Amendment § VII.A.7. The "Net Supplemental Class Settlement Fund Amount" is \$1.275 billion, plus accrued interest, less: administration costs; Minimum Payment Amounts (\$2,000 payments to Category One class members who are found ineligible to receive benefits subject to medical review, or failed to submit or complete the claim in a timely manner); and Category Two Election Amounts (Category One class members who withdraw their Category One claims). Seventh Amendment §§ VII.A.7, VII.B, & VII.C.

of the same medical conditions as those claimed to have been caused by the diet drugs. As in the existing Settlement Agreement, an alternative causation factor found during medical review will reduce the value of the claim.<sup>25</sup> Seventh Amendment § VII.A. Similarly, if the claimant has taken the diet drugs for 60 days or less, his or her claim for benefits subject to medical review will be reduced. Seventh Amendment § VII.A.

To expedite the payments for Category One claimants, the Seventh Amendment allows for the Fund Administrator, upon court approval, to make a partial payment to eligible claimants once at least 50 percent of all Category One class members have completed medical review. Seventh Amendment § XV.P. A partial payment may not exceed 40 percent of the estimated final payment.<sup>26</sup>

The current Settlement Agreement provides for CMS, that is, cash/medical services,<sup>27</sup> benefits for class members diagnosed

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25. Under the Seventh Amendment, alternative causation factors will be determined based on the claimant's echocardiogram without evaluating other medical history. The existing Settlement Agreement provides that alternative causation factors can be determined based on nonechocardiographic factors apparent in a claimant's medical records. Settlement Agreement, § VI.C.4. Because most people are not disqualified based on nonechocardiographic factors, the Seventh Amendment eliminates the obligation on the part of the Trust to review a plethora of medical records for a relatively small return. Seventh Amendment § VII.A.; (Tr. 1/18/05 at 112).

26. Before making any partial payment, the Fund Administrator must ensure that the partial payments will not put the Supplemental Fund at risk of not being able to pay all eligible claimants. Seventh Amendment § XV.P.

27. See supra note 8 for a definition of CMS benefits.

as FDA Positive between the beginning of diet drug use and the end of the Screening Period. However, the Seventh Amendment eliminates the availability of CMS benefits to Category One class members who pass medical review and receive benefits from the Supplemental Fund. Seventh Amendment § X.A.1. Those Category One class members who, after the review process is completed, are found to be FDA Positive, but not to have High Threshold or Low Threshold Conditions, are eligible for payment of the same CMS benefits from the Trust as would otherwise be available under the existing Settlement Agreement. Seventh Amendment § X.A.2; see also Settlement Agreement §§ IV.A.1.c, IV.A.2.c.

With respect to Category One claimants who fail or elect not to undergo medical review, these class members will still receive \$2,000 from the Supplemental Fund provided that they can prove diet drug use. Seventh Amendment § VII.B.1. A Category One class member who fails medical review but has an echocardiogram that is determined in the medical review process to show FDA Positive regurgitation between the beginning of the diet drug use and the end of the Screening Period qualifies for the CMS benefits if he or she has not previously been paid or provided this benefit as long as he or she can prove diet drug use. Seventh Amendment § X.A.2.

Category Two class members will receive a payment of \$2,000 upon proof that they used the diet drugs and that they had an echocardiogram between the commencement of diet drug use and the end of the Screening Period showing that they are FDA

Positive or have mild mitral regurgitation. Seventh Amendment § VIII.A.1. This qualifying diagnosis must be documented on the class member's Green or Gray Form. Category Two claimants are not eligible to participate in the medical review process and the pro rata distribution of the available money in the Supplemental Fund. Instead, their claims will be administered and paid by the Trust. Seventh Amendment § VIII.B. Wyeth will deposit money into the Trust to make these \$2,000 payments to Category Two class members, and these deposits will not reduce the amount of money Wyeth is obligated to pay under the existing Settlement Agreement. Seventh Amendment § VIII.B.6.

Category Two class members will also be eligible for the CMS benefits if they have not previously been paid or been provided this benefit and they have been diagnosed as FDA Positive between the beginning of diet drug use and the end of the Screening Period. Seventh Amendment § VIII.A.2. The class member must have all proof required by the Settlement Agreement, including proof of diet drug use. Seventh Amendment § X.C. In addition, as with the existing Settlement Agreement, Wyeth may designate for audit up to ten percent of these claims for CMS benefits. See Seventh Amendment § X.C; Settlement Agreement § VI.F.2.

The medical review process under the Seventh Amendment is designed to be more efficient than the Trust's current audit process. It will involve cardiologists with Level 2 or greater training in echocardiography ("Participating Physicians"). They

will review de novo the echocardiograms and other specified information submitted with each claim to determine if the required medical conditions exist. Seventh Amendment § XV.I. In contrast to the terms of the Settlement Agreement, the Participating Physicians will not defer to the echocardiogram reading of the cardiologist who attested to the claimant's Green Form. Seventh Amendment § XV.M; (Tr. 1/18/05 at 185-86, 209-10). Moreover, all Category One class members, their counsel, and anyone acting on their behalf, are barred and permanently enjoined from having any communication or contact of any kind with any Participating Physicians with respect to any of their functions under the Seventh Amendment. Seventh Amendment § XV.L.; PTO No. 3880 at ¶ 18.

The Seventh Amendment establishes a Medical Review Coordinating Committee ("MRCC") to supervise the Participating Physicians. Seventh Amendment § IV.C.1. Upon preliminary approval of the Seventh Amendment, Dean Karalis, M.D., F.A.C.C. ("Dr. Karalis"), Gregg Reis, M.D., F.A.C.C. ("Dr. Reis"), and Frank Silvestry, M.D., F.A.C.C. ("Dr. Silvestry"), were nominated jointly by Class Counsel and the SALC and approved by the court to serve as members of the MRCC.<sup>28</sup> See PTO No. 3880 ¶ 12. These

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28. Dr. Karalis is affiliated with Hahnemann University Medical Center and Drexel University College of Medicine as Attending Cardiologist and Clinical Associate Professor of Medicine. He has acted as key medical consultant for Class Counsel throughout the course of this litigation. Dr. Silvestry is affiliated with the Hospital of the University of Pennsylvania as Director of Penn Cardiac Care at Radnor and as an instructor in medicine. Dr. Reis is affiliated with Pennsylvania Hospital at the

(continued...)

prominent Philadelphia cardiologists with Level III training in echocardiography are to train the Participating Physicians and to help ensure that they review the echocardiograms in a consistent and appropriate manner.<sup>29</sup> Seventh Amendment § XV.J.

The MRCC had been working since August, 2004 to recruit qualified physicians. At the time of the Seventh Amendment Fairness Hearing, the MRCC had solicited 122 Level II board certified cardiologists who had each been checked for conflicts and are expected to accept a position as a Participating Physician. (Tr. 1/18/05 at 175-76). Each physician must commit to reading 30 echocardiograms each month. This will mean all echocardiographic tapes will be reviewed within a year. (Tr. 1/18/05 at 177).

All Participating Physicians will now use the EchoAnalysis software. (Tr. 1/18/05 at 182-83). Dr. Silvestry and Dr. Craig Scott, a cardiologist at the University of Pennsylvania, created this software to support the accurate and

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28. (...continued)

University of Pennsylvania Medical School as Attending Physician and Clinical Assistant Professor of Medicine. (Tr. 1/18/05 at 132).

29. Under the Seventh Amendment, the MRCC's responsibilities are threefold: (1) assisting in recruiting qualified cardiology centers; (2) developing and implementing a protocol to train Participating Physicians as to how to employ accepted principles and practices of cardiology to review the relevant echocardiograms submitted to the Fund Administrator for payment under the Seventh Amendment; and (3) assisting the Fund Administrator in the development and implementation of quality control procedures to secure uniform application of the medical criteria specified by the Seventh Amendment. Seventh Amendment § XV.J.

reliable reading of echocardiograms and to overcome some of the serious problems with the interpretations made by attesting physicians under the procedure set forth in the Settlement Agreement.

Dr. Karalis identified a number of these problems during his testimony at the Seventh Amendment Fairness Hearing. For example, in some of the echocardiograms submitted in support of Matrix claims, the degree of regurgitation was overtraced and included flow that was not part of the regurgitant jet. In other studies, the "gain" on the echocardiogram was set high, causing extraneous color that could be misinterpreted as regurgitant jet flow. (Tr. 1/18/05 at 180-82); see also PTO No. 2640 at 15-16, 25. In addition, some echocardiograms submitted to the Trust have been found to contain "inserted frames or loops," representing portions of an echocardiogram study that were acquired out of the time sequence of the remainder of the echocardiogram. (Tr. 1/18/05 at 57-58; 182-83). Without passing judgment on these allegations, some have argued that what has occurred is nothing less than blatant fraud.

We find that the MRCC's procedure for the use of the EchoAnalysis software is "well poised to be able to accurately, reliably and fairly assess these echocardiograms as to whether they meet the high or low threshold claims" as specified by the Seventh Amendment. (Tr. 1/18/05 at 190-99, 204).

In an effort to remedy what has become an unwieldy process under the Settlement Agreement's current show cause

process,<sup>30</sup> the Seventh Amendment eliminates the show cause hearings. Instead, the claimants who do not pass medical review have 30 days to elect a second review. Seventh Amendment § XV.M; (Tr. 1/18/05 at 104). The Fund Administrator will establish a fee not to exceed \$2,500 to cover the cost of the second review in which the claim will be decided de novo by a different reviewer. The second review will be determinative. Seventh Amendment § XV.M.; (Tr. 1/18/05 at 103-04).

The Seventh Amendment deals with the issue of "covering opt-outs." (Tr. 1/18/05 at 106). Some claimants have completed a Green Form and submitted it to the Trust seeking matrix benefits. However, these claimants have also filed with the Trust their intention to exercise their intermediate opt-out right in the event that the Trust auditors found them FDA Positive only but not entitled to matrix benefits. Because the covering opt-outs' primary purpose was to be paid matrix benefits, the Seventh Amendment treats them as Category One claimants who are required to opt out of the Seventh Amendment if they want to preserve their downstream or other opt-out rights. Thus, the Seventh Amendment effectively eliminates the covering opt-outs' ability to take a second bite at the apple. In an effort to end the type of litigation that ensued from the close to 60,000 downstream opt-outs in the existing Settlement Agreement, those who participate in the Seventh Amendment will no

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30. See supra note 10 for an explanation of the show cause process.

longer have any right to exercise an intermediate, back-end, Sixth Amendment, or financial insecurity opt-out and thus will forgo the right to sue Wyeth in the tort system. Seventh Amendment § XI.A.

Effective upon Final Judicial Approval, all Category One or Two class members who did not timely and properly opt-out of the Seventh Amendment<sup>31</sup> relinquish their rights to exercise any opt-out from the Settlement or to seek Matrix Level I or II benefits under the current Settlement Agreement. Seventh Amendment §§ XI.A. and XI.B. Moreover, these class members may only claim Matrix Level III, IV or V benefits in accordance with the criteria specified in the Seventh Amendment. Seventh Amendment § XI.B. The Seventh Amendment also releases and discharges all "Settled Claims" against any "Released Party," including Wyeth, arising from the activities of the Trust or Wyeth's role in negotiating and implementing the Settlement Agreement, and reaffirms all releases previously provided by these class members. Seventh Amendment XI.C.1. Finally, these class members are foreclosed from bringing claims against the Trust arising from the performance of its duties under the Settlement Agreement. Seventh Amendment XI.C.2.

In line with its goal of reducing the burden of collateral litigation on the parties and court and preserving the

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31. Each Category One or Two class members who did not timely and properly opt-out of the Seventh Amendment is known as a "Releasing Party" under the Seventh Amendment. Seventh Amendment § I.B.58.

assets of the Trust for the benefit of eligible class members, the Seventh Amendment also precludes the Trust and Wyeth from bringing Enforcement Actions based on or arising out of any claim submitted to the Trust. Seventh Amendment § XVIII.B.1. It does so without prejudice to the right of any person to cooperate in providing evidence to appropriate law enforcement agencies and other appropriate government agencies and officers. Seventh Amendment § XVIII.B. In addition, the Trust's CIP<sup>32</sup> will not proceed with respect to Category One and Category Two class members who have not opted out of the Seventh Amendment. Seventh Amendment § XVIII.A. Upon Final Judicial Approval of the Seventh Amendment, the parties shall also take steps to dismiss or otherwise discontinue with prejudice certain appeals, motions, and other matters currently subject to stay. Seventh Amendment § XVIII.A.; Seventh Amendment, Exs. H, I.

The Seventh Amendment, of course, provided an opportunity for any Category One class member or Category Two class member (or representative claimant) to opt out. Seventh Amendment § XII.A. They were eligible to exercise their opt-out rights by submitting a notice of their intention to do so by November 9, 2004 - a date that was 60 days from the date on which the class notice process commenced. Seventh Amendment § XII.B.

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32. As noted above, the Trust instituted the Claims Integrity Program in August, 2003, in an effort to prevent the dissipation of the settlement's funds through fraud and abuse. A major component of the CIP involved the Trust issuing to physicians who had certified matrix claims medical practice questionnaires about their practices in completing the Green Forms.

PTO No. 3880 ¶ 5. Class members who have timely and properly exercised a Seventh Amendment opt-out remain subject to the terms of the Settlement Agreement as they existed before the Seventh Amendment and also retain any opt-out right to which they are entitled under the current Settlement Agreement. Seventh Amendment § XII.C.<sup>33</sup>

As with the current Settlement Agreement, the Seventh Amendment places limitation on awards of counsel fees from class funds. With respect to each class member represented by an attorney, the Seventh Amendment allows for payment to that attorney in accordance with the terms of any applicable contingent fee agreement and applicable law, provided that the attorney may not charge or collect a contingent fee that is, in the aggregate, larger than 40 percent of the total individual payment amount. Seventh Amendment § XV.T.1.a. With respect to Category Two class members or Category One class members who elected the minimum payment by choosing not to go through with the medical review process, an amount not to exceed \$650 shall be deducted for attorneys' fees from the \$2,000 payments made by either the Trust or the Fund Administrator. Seventh Amendment §§ XV.U.1, XV.V.1.

The Seventh Amendment affords the court maximum flexibility in determining what is an appropriate common benefit

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33. Class members who exercised a Seventh Amendment opt-out also had the opportunity to revoke that opt-out at any time prior to the end of the walkaway period, which was January 9, 2005, or 60 days after the opt-out deadline of November 9, 2004. Seventh Amendment § XII.

fee, if any, and in equitably allocating that fee across the various pools of money that are available in the settlement. Seventh Amendment §§ I.B.21, XV.T.1.b; (Tr. 1/18/05 at 126). If the court awards a common benefit fee payable from the Supplemental Fund, that award will be prorated among all of the class members who receive a pro rata share of the Supplemental Fund. Seventh Amendment §§ I.B.21, XV.R.1. The common benefit percentage amount, if any, will be deducted from the amount of fees to which such attorneys are entitled and will not be deducted from the client's share of the recovery. Seventh Amendment § XV.T.1.b. No such common benefit fee will be deducted from any minimum \$2,000 payment from the Supplemental Fund.

Finally, the Settlement Agreement states that the payment of Matrix Compensation by the Trust will be subject to a nine percent deduction for common benefit fees, subject to court approval. That provision will continue to apply to Matrix Level III, IV, and V compensation payable to class members participating in the Seventh Amendment.

#### **V.**

#### **The Fairness Hearing**

In our order preliminarily approving the Seventh Amendment, we scheduled a formal Seventh Amendment Fairness Hearing to determine whether to grant final approval in accordance with the standards set forth under Rule 23(e) of the Federal Rules of Civil Procedure. PTO No. 3880 ¶ 6. The Fairness Hearing took place on January 18 and 19, 2005. During

the two-day hearing, proponents of the Seventh Amendment and persons who objected pursuant to the terms of PTO No. 3880<sup>34</sup> ("the Objectors") had a full and fair opportunity to offer evidence, cross-examine witnesses, and make argument.

Class Counsel and the SALC offered the following witnesses in support of the Seventh Amendment:

1. **Michael D. Fishbein, Esquire.** Mr. Fishbein's testimony concerned the background for the Seventh Amendment, the negotiations leading up to the execution of the Seventh Amendment, and the terms of the Seventh Amendment.
2. **Dean G. Karalis, M.D., F.A.C.C.** Dr. Karalis testified about the medical review process under the Seventh Amendment and his involvement with this process as the head of the MRCC.

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34. PTO No. 3880 provided that "Any Class Member wishing to object to any aspect of the Seventh Amendment must submit specific and detailed written objections in support of those objections," which must be filed with the Clerk of the Court and served upon Wyeth and Class Counsel by the close of the Seventh Amendment Opt-Out/Objection Period. PTO No. 3880 ¶ 7. Any class member who failed to object within this time period was deemed to have waived his or her objection. PTO No. 3880 ¶ 7. A class member who filed objections and wished to appear at the Fairness Hearing in person or through his or her attorney was required within the objection period to submit a written request for an opportunity to be heard. PTO No. 3880 ¶ 8. We also required those persons who filed timely objections and requested in writing time to speak at the Seventh Amendment Fairness Hearing along with Class Counsel, Wyeth, and the Seventh Amendment Liaison Committee, to file with the court a statement identifying fact witnesses, exhibits, and expert witnesses who would be offered at the Seventh Amendment Fairness Hearing. These disclosures were to be filed by December 30, 2004. See PTO No. 4241.

3. **Wayne Spivey, Esquire.** Mr. Spivey testified about his involvement in the Seventh Amendment negotiations.

Wyeth offered the following witness on matters relevant to the Seventh Amendment:

**Orran Lee Brown, Esquire.** Mr. Brown testified about his role in the dissemination of the official notice for the Seventh Amendment.<sup>35</sup>

Twelve law firms filed objections to the Seventh Amendment on behalf of their clients and 81 unrepresented class members did as well. In total, 641 class members, either on their own behalf or through counsel, purported to object or filed submissions related to the Seventh Amendment. See PTO No. 4307. However, only two lawyers representing a total of six objectors appeared at the Fairness Hearing and cross-examined witnesses.

#### **VI.** **Notice to the Class**

In approving the original Settlement Agreement, Judge Bechtel set forth in PTO No. 1415 the personal jurisdiction and notice requirements under Rules 23(c)(2) and 23(e) of the Federal Rules of Civil Procedure as follows:

In the class action context, "the district court obtains personal jurisdiction over the

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35. Wyeth also offered through affidavit the testimony of Joseph R. Zielinski, Jr., a Senior Sales Representative and Account Manager for R.R. Donnelley, who served as the mailing agent for Wyeth, Class Counsel, and the Seventh Amendment Liaison Committee to facilitate the printing and mailing of notifications of the Seventh Amendment. See Ex. W-3 at 93-98. No one at the Seventh Amendment Fairness Hearing objected to the affidavit or requested that Mr. Zielinski appear in person for cross-examination. (Tr. 1/18/05 at 14-15).

absentee class members by providing proper notice of the impending class action and providing the absentees with the opportunity to be heard or the opportunity to exclude themselves from the class." In re Prudential Ins. Co. of Am. Sales Practices Litig., 148 F.3d 283, 306 (3d Cir. 1998), cert. denied sub nom., Krell v. Prudential Ins. Co. of Am. Litig., 525 U.S. 1114 (1999) (citing Phillips Petroleum Co. v. Shutts, 472 U.S. 797, 811-12 (1985)). Reasonable notice combined with an opportunity to be heard and withdraw from the class satisfy the due process requirements of the Fifth Amendment. Id. Thus, "silence on the part of those receiving notice is construed as tacit consent to the court's jurisdiction." Id. (citing Shutts and Carlough v. Amchem Prods., Inc., 10 F.3d 189, 199 (3d Cir. 1993)).

In addition, in a settlement class maintained under Rule 23(b)(3), class notice must meet the requirements of both Federal Rules of Civil Procedure 23©(2) and 23(e). See Carlough v. Amchem Prods., Inc., 158 F.R.D. 314, 324-25 (E.D. Pa. 1993). Under Rule 23©(2), notice to the class must be "the best practicable notice under the circumstances, including individual notice to all members who can be identified through reasonable effort." Zimmer Paper Prods., Inc. v. Berger & Montague, P.C., 758 F.2d 86, 80 (3d Cir. 1985); see Fed. R. Civ. P. 23©(2). The Rule also requires that the notice indicate an opportunity to opt out, that the judgment will bind all class members who do not opt out and that any member who does not opt out may appear through counsel. Fed. R. Civ. P. 23©(2).

Rule 23(e) requires that notice of a proposed settlement must inform class members: (1) of the nature of the pending litigation; (2) of the settlement's general terms; (3) that complete information is available from the court files; and (4) that any class member may appear and be heard at the Fairness Hearing. See 2 H. Newberg, Newberg on Class Actions, § 8.32, at 8-103. The court should consider the mode of dissemination and its content to assess whether notice was sufficient. The notice need not be unduly

specific. See In re "Agent Orange" Prod. Liab. Litig., 818 F.2d 145, 170 (2d Cir. 1987) (other citations omitted). Instead, notice need only be reasonably calculated to inform interested parties of the pendency of the proposed settlement and afford them an opportunity to present their objections. See Mullane v. Central Hanover Bank & Trust Co., 339 U.S. 306, 314 (1950).

Our Court of Appeals has recently explained that the notice document must describe, in detail, the nature of the proposed settlement, the circumstances justifying it, and the consequences of accepting and opting out of it. See In re Diet Drugs, 369 F.3d 293, 308-10 (3d Cir. 2004).<sup>36</sup>

The Seventh Amendment seeks to afford valuable benefits to class members, but it also makes material changes to the Settlement Agreement in that it reduces payment amounts to certain eligible class members and extinguishes certain opt-out rights. As a result, notice of the Seventh Amendment was disseminated to class members who were then given the opportunity to opt out or object and to appear at a scheduled Fairness Hearing. In addition, the Seventh Amendment extended a "walkaway right" to Wyeth if the opt-outs or objections proved unpalatable. See Seventh Amendment §§ XII, XIII.

As we noted previously, on August 26, 2004, we approved a 93-page, two-part notice in the form appended to the Seventh

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36. In PTO No. 1415, Judge Bechtle also specifically found that this court has subject matter jurisdiction over MDL 1203 pursuant to 28 U.S.C. § 1332. See In re Diet Drugs, 2000 WL 1222042, at \*33; Settlement Agreement § VIII.B.1. Counsel for certain class members have recently challenged the subject matter jurisdiction of this court. We will address this motion separately. See PTO No. 4311.

Amendment as Exhibit L. PTO No. 3880 ¶ 3. Our order preliminarily approving the Seventh Amendment and the notice to class members directed Wyeth, Class Counsel, and the SALC to commence service of the notice as follows:

The parties shall commence service of such notice by first-class mail, postage prepaid, as soon as reasonably practicable, and no later than 15 days after the entry of this Pretrial Order, to all Class Members who have ever registered or purported to register with the Trust or who have submitted any type of form to the Trust (including Class Members who have exercised or attempted to exercise any right of opt-out) and to all known attorneys representing such Class Members, at the addresses reflected in the most recent version of the Trust's database made available to the Parties at the time notice is disseminated.

PTO No. 3880 ¶ 4.

Pursuant to PTO No. 3880, every person who registered with the Trust or who was known to be interested in making a claim under the Settlement Agreement was sent a personal, two-part notice. Notifications were mailed to each class member in the Trust's database notwithstanding the fact that the addresses of some class members were either facially incomplete or missing altogether.<sup>37</sup> In addition, the parties undertook considerable efforts to supplement the information in the Trust's database.<sup>38</sup>

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37. There were 8,352 facially incomplete addresses and 1,429 missing addresses in the Trust's database. See Ex. W-4 at Ex. B.

38. Claims Specialists at BrownGreer, along with a private investigation firm, were successful in updating or confirming all but 1,015 facially incomplete or missing addresses. See Ex. W-4 at Ex. B, "Wyeth's Supplemental Report on Distribution of Notice (continued...)"

In order to monitor which class members and law firms received the notice, a unique identifying number for each class member and law firm was printed on the envelope of each notice packet.

Between September 8, 2004 and September 14, 2004, RR Donnelley ("Donnelley"),<sup>39</sup> the mailing agent, transmitted notice packages by first-class mail, postage prepaid, to 620,148 individual class members and their counsel potentially affected by the Seventh Amendment. In addition, standard notice packets were mailed to 6,684 law firms that the Trust listed as primary or secondary counsel to class members. Donnelley also sent special notices to law firms on behalf of their current or former clients for whom it had incomplete addresses.<sup>40</sup>

Of the 620,148 notice packets that were sent out, 58,351 were returned undelivered. Although not required by PTO No. 3880, 13,028 class members and 463 law firms were mailed another notice packet through November 4, 2004. The postal service, counsel for current or former clients, and the private

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38. (...continued)  
Relating to Seventh Amendment."

39. Donnelley also served as the mailing agent for the notice of Final Judicial Approval of original Settlement Agreement, as well as the notice of the May 3, 2003 registration deadline. (Tr. 1/19/05 at 41).

40. On September 10, 2004, in PTO No. 3926, we approved the mailing of Special Inserts to class members and law firms to provide particular information regarding the status of their claims in addition to the original Seventh Amendment notice. See PTO No. 3926; see also Joint and Supplemental Reports of Wyeth, Class Counsel and SALC on Distribution of Notice Relating to Seventh Amendment, admitted as Exs. W-3 & W-4 at the Seventh Amendment Fairness Hearing.

investigation firm hired by Wyeth provided forwarding addresses for these individuals. (Tr. 1/19/05 at 44). In total, over 95 percent of class members received at least one copy of the Seventh Amendment notice at their home address or through their counsel. See Ex. W-6.

Class Counsel also supplemented the mailed notices. It served the Seventh Amendment, the motion for preliminary approval of the Seventh Amendment, supporting memorandum of law, all of the exhibits to the supporting memorandum of law, and all the exhibits to the Seventh Amendment on all of the over 3,000 lawyers shown in the Trust database as representing matrix claimants. In addition, Class Counsel, along with the SALC, sponsored a seminar on the Seventh Amendment at the Convention Center in Philadelphia on September 23, 2004. Notice of the seminar was sent to the same list of attorneys in the Trust database, and over 300 attorneys attended this event where speakers made presentations and answered questions related to the Seventh Amendment. Class Counsel's office also devoted two high-level attorneys and three paralegals to answering over 1,300 calls related to it. (Tr. 1/18/05 at 129).

The official notice package approved by the court was optimally designed to be read and understood by class members. The notice was sent in a standard nine-inch by twelve-inch booklet mailing envelope. The text on the envelope alerted recipients that the envelope contained an "official court approved notice" of the "Seventh Amendment to the

Pondimin®/Redux™ Diet Drug Class Action Settlement Agreement." The cover sheet read "Attention: Class Members, Current Opt-Outs, and Attorneys Representing Class Members or Opt-Outs in the Pondimin/Redux Diet Drug Class Action." Ex. W-5(a). It further informed recipients that the information contained within "is very important to you and concerns your legal rights." Id. It instructed them that the court had preliminarily approved the Seventh Amendment and that "you must decide whether you would like to be subject to the terms of the Seventh Amendment or to remain bound by the terms of the existing Settlement Agreement (as previously amended)." Id. Part I of the notice contained a summary overview of the proposed Seventh Amendment, and Part II included a more detailed description of the proposed Seventh Amendment.<sup>41</sup> The first page of both Part I and Part II of the notice prominently displayed the November 9, 2004 deadline for opting out of the Seventh Amendment and filing written comments with the court, along with the January 18, 2005 date of the Fairness Hearing.

The two-part notice contained a comprehensive description of the circumstances leading to the Seventh Amendment, the benefits afforded by the Amendment, its limitations, and all other information that class members would

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41. Part I and Part II of the notice, as originally presented to the court, contained several incomplete sections that could not be finalized until the court preliminarily approved the Seventh Amendment. After we preliminarily approved the Seventh Amendment, Class Counsel, Wyeth, and the SALC formatted the notice and inserted all necessary deadlines before sending the notice to the printer for dissemination to class members.

need to make an intelligent decision as to whether to participate in the Amendment, object to it, or exclude themselves from its application. The notice also clearly explained that class members or attorneys could obtain a copy of the full Seventh Amendment electronically or from the Trust's website, by writing or calling the Trust, or through the office of the Clerk of Court. See Official Court Notice, Part I (Ex. W-5a) at 14; Official Court Notice, Part II (Ex. W-5b) at 33.

The notice advised class members who had submitted an initial, intermediate, or downstream opt-out form that if they were on the initial Category One class member list, the Seventh Amendment automatically revoked their initial, intermediate, or back-end opt-out. See Official Court Notice, Part I ¶ 6; Seventh Amendment, Ex. L. The notice further explained that class members who submitted an initial, intermediate, or back-end opt-out form and who did not qualify for Category One, but qualified for Category Two, could participate in the Seventh Amendment "if you ask Wyeth to revoke your opt-out and Wyeth consents to your request." Id.

Pursuant to PTO No. 3880, class members who chose not to remain in the Seventh Amendment were required to file an opt-out form by November 9, 2004. Of the over 95 percent of class members who received a notice packet, Wyeth received only 6,959 opt-outs by that date.<sup>42</sup> See Ex. W-7.

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42. This number breaks down into 1,906 class members who were on  
(continued...)

The evidence demonstrates that the plan of notice was highly effective in making class members aware of the circumstances leading up to the proposed Seventh Amendment, the nature of the Seventh Amendment, and the potential impact of the Seventh Amendment on their legal rights. In addition, the response to the notice clearly indicates that the notice program was sufficient to afford class members a full, informed, and effective opportunity to opt out of the Seventh Amendment. Finally, the response to the class notice shows that although there are a number of class members who chose to opt out of the Seventh Amendment, the class overwhelmingly supports the Seventh Amendment as fair and equitable. See In re Diet Drugs, 2000 WL 1222042, at \*38.

We find that the notice plan satisfies the requirements of personal jurisdiction, due process, and Rules 23©(2) and 23(e) of the Federal Rules of Civil Procedure. As with the notice for the original Settlement Agreement, the notice plan was implemented by experienced specialists and utilized a variety of media to disseminate notice, including mailings to individual class members where possible, mailings to class members' counsel, and publication on the Internet. This comprehensive notice

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42. (...continued)  
the initial Category One class member list and 5,053 opt-outs from class members who may be on Category Two class members. See Ex. W-7; (Tr. 1/19/05 at 59). As explained above, the Seventh Amendment permits class members who were not on the "initial Category One Class List" compiled by the parties, but believe that they are eligible to be Category One class members, to take certain steps to be included in Category One.

program fulfilled the "best notice practicable" requirement of Rule 23©)(2). See Phillips Petroleum Co. v. Shutts, 472 U.S. 797, 812 (1985). In addition, the Seventh Amendment clearly extended an opportunity for class members to exclude themselves from the class by exercising an opt-out right by November 9, 2004. Accordingly, the notice program, together with the opt-out opportunity, was sufficient to warrant this court's exercise of personal jurisdiction over the class. See In re Diet Drugs, 2000 WL 1222042, at \*39 (citing Prudential, 148 F.3d at 306).

The content of the notice was also sufficient to satisfy the requirements of Rule 23©)(2) and 23(e). The notice package included a "plain language" description of the Seventh Amendment and class members' rights thereunder. It detailed the nature of the litigation and the right of class members to opt out. It also set forth that class members would have an opportunity to appear and be heard at the Fairness Hearing. Thus, we find that the notice plan comported with the requirements of due process under the Fifth Amendment and Rules 23©)(2) and 23(e) of the Federal Rules of Civil Procedure. See In re Diet Drugs, 2000 WL 122042, at \*39.

#### VII.

#### **Fairness, Adequacy, and Reasonableness of the Seventh Amendment**

Our Court of Appeals has explained that a court may "approve a proposed class action settlement ... if it is 'fair, adequate, and reasonable' to Class Members." Harris v. Reeves, 761 F. Supp 382, 394 (E.D. Pa. 1991) (citing Walsh v. Great Atlantic & Pacific Tea Co., Inc., 726 F.2d 956, 965 (3d Cir.

1983)); see Girsh v. Jepson, 521 F.2d 153, 156-57 (3d Cir. 1975)). In order to make this determination, we must apply and analyze the following nine factors:

- (1) the complexity, expense and likely duration of the litigation ... ;
- (2) the reaction of the class to the settlement ... ;
- (3) the stage of the proceedings and the amount of discovery completed ... ;
- (4) the risks of establishing liability ... ;
- (5) the risks of establishing damages ... ;
- (6) the risks of maintaining the class action through the trial ... ;
- (7) the ability of the defendants to withstand a greater judgment;
- (8) the range of reasonableness of the settlement fund in light of the best possible recovery ... ;
- (9) the range of reasonableness of the settlement fund to a possible recovery in light of all the attendant risks of litigation ...

Girsh, 521 F.2d at 157 (citations omitted). These factors were of course enunciated in the context of a class action settlement, not in connection with an amendment to a class action settlement already approved as fair, adequate, and reasonable. Nonetheless, finding the Girsh factors to offer the most appropriate test in the present context, we consider these factors to the extent they are relevant.

At the outset, we note that there is "an initial presumption of fairness when reviewing a proposed settlement where: (1) the settlement negotiations occurred at arm's length; (2) there was sufficient discovery; (3) the proponents of the settlement are experienced in similar litigation; and (4) only a small fraction of the class objected. In re Warfarin Sodium Antitrust Litig., 391 F.3d 516, 535 (3d Cir. 2004) (citing In re Cendant Corp. Litig., 264 F.3d 201, 232 n.18 (3d Cir. 2001)

(internal quotations omitted)). Based on the record before us, the presumption of fairness properly attaches to the Seventh Amendment. It has resulted after intense arm's length negotiations between experienced counsel and came only after years of active and often contentious litigation and significant expense involving the interpretation and implementation of the Settlement Agreement. With hindsight and the benefit of experience, the parties saw a compelling need for changes to forestall the likely exhaustion of funds, continued contentious litigation, potential fraud or other wrongdoing, and interminable delays in the payment of deserving claimants, all of which have been detailed above. Moreover, only a tiny fraction of the purported class members have filed objections. See In re Warfarin, 391 F.3d at 535.

One would have expected that relative calm would have prevailed after the approval of the original Settlement Agreement. Instead, the landscape has been filled with innumerable disputes, motions, and hearings. The court and the parties have faced issues concerning purportedly illegitimate claims, the Trust's handling of the audit process, appeals from audits, excessive numbers of claims beyond what anyone anticipated at the 2000 Fairness Hearing, and now the likely insufficiency of the Settlement Fund to pay all legitimate claimants. The Seventh Amendment deals fairly and simply with the prospect of illegitimate claims by adopting a straightforward, independent medical review process, and by

replacing the disputed procedures of the CIP to deal with the prospect of fraud. Moreover, the Seventh Amendment eliminates claim-specific litigation over benefits and resurrects claims administration as the principal method to adjudicate and disburse benefits. It reduces to a manageable level the amount of judicial involvement necessary to govern the Settlement Agreement. By utilizing a streamlined benefit-eligibility criteria and removing the bulk of matrix processing from the Trust, the Seventh Amendment promises a mechanism to administer benefits promptly and fairly, with disposition of the claims of some 40,000 Category One class members within approximately one year. Accordingly, we find that the "complexity, expense and likely duration of the litigation" militates in favor of approving the Seventh Amendment. Girsh, 521 F.2d at 157.

Second, we have already recognized that the "the reaction of the class to the settlement," is favorable. Id. The response to the class notice detailed above shows that the class overwhelmingly supports the Seventh Amendment as fair and equitable. See In re Diet Drugs, 2000 WL 1222042, at \*38.

We must consider the "stage of the proceedings and the amount of discovery completed." While this factor is more pertinent to an initial settlement, the experience in this action over the last four years is more than sufficient to provide the parties with an adequate basis for the Seventh Amendment.

Next, we must take into account the risks of establishing liability and the risks of establishing damages.

Girsh, 521 F.2d at 157. Again, this factor is more relevant to an initial settlement than it is here. In any event, close to 60,000 claimants have exercised a downstream opt-out and sued Wyeth in the tort system. As evident from the varied results of the opt-out cases that have proceeded to a verdict, claimants who have had the burden of establishing liability and damages in the tort system face substantial risks. (Tr. 1/18/05 at 61-63). During the Fairness Hearing, Class Counsel testified about the results of several trials of downstream opt-out cases tried primarily in the Court of Common Pleas of Philadelphia County. A majority of the plaintiffs that proceeded to a verdict in these trials have received no compensation or minimal compensation. A significant number of plaintiffs have discontinued or dismissed their claims without any payment from Wyeth. A considerable percentage of these trials resulted in a defense verdict. Finally, a number of the plaintiffs received a verdict of less than \$50,000, which may not even be enough to cover litigation costs. (Tr. 1/18/05 at 62-63). These trial results, together with the Settlement Agreement's bar against punitive damages, counsel in favor of the Seventh Amendment. Girsh, 521 F.2d at 157.

The sixth Girsh factor requires us to consider "the risks of maintaining the class through the trial." Id. This factor is not germane with respect to the Seventh Amendment since a settlement has already been approved.

We next consider whether Wyeth could withstand a judgment for an amount greater than the funds it has already allocated to the Settlement Agreement and the additional \$1.275 billion designated to the Seventh Amendment's Supplemental Fund. Again, we question the relevance of this factor in the present posture of this action. The fact that Wyeth may be able to afford to pay more does not mean that it is obligated or could be required to pay any more than what class members are entitled to receive under the Settlement Agreement and the theories of liability that existed at the time the settlement was reached. See In re Warfarin, 391 F.3d at 538.

The last two Girsh factors require us to review the reasonableness of the Seventh Amendment in light of the best possible recovery and reasonableness in light of the risks of litigation. Girsh, 521 F.2d at 157; see also Prudential, 148 F.3d at 322. We have already documented the various risks to class members under the Settlement Agreement as it currently exists. These strongly militate toward approving the Seventh Amendment. With respect to the reasonableness in light of the best possible recovery for class members, the Seventh Amendment requires class members to release certain rights under the existing Settlement Agreement in exchange for Wyeth's obligation to pay benefits in excess of \$1 billion beyond what it is now legally obligated to pay. This infusion of funds assures that all deserving class members will receive fair compensation. It eliminates a system that permits persons with marginal or no

legitimate injuries to consume large resources that should be available to those significantly injured and guarantees payment to all class members who suffer injuries caused by diet drug-induced valvular heart damage. Accordingly, the benefits offered here are within the range of reasonableness considering the best possible recovery and all the attendant risks of litigation. These factors weigh in favor of the Seventh Amendment.

Objectors contend that the Seventh Amendment is unfair, unreasonable, and inadequate because it requires class members to give up additional rights for lesser compensation while Wyeth is required to do something it has already obligated itself to do. Without deciding whether these objectors have standing to assert their objections, we find the objections without merit. Wyeth has allocated an additional \$1.275 billion over and above what the initial Settlement Agreement required at a time when there is now probably not enough money available to pay all legitimate claimants their due. The infusion of new funds far outweighs the limited rights which class members are giving up.

In addition, certain class members have objected on the ground that class members who previously filed a Green Form and filed with the Trust their intention to exercise an opt-out will have this opt-out automatically revoked and will be Category One class members unless they opt out again under the Seventh Amendment. The Seventh Amendment honors the opt-out decisions previously made by class members unless they affirmatively revoke their prior opt-out with the consent of Wyeth. Seventh Amendment

§ XI. However, as explained above, the Seventh Amendment recognizes the primary intent of covering opt-outs by presuming that these class members who have completed a Matrix claim want to participate in the Seventh Amendment unless they affirmatively opt out.

Other objectors contend that class members who had pre-stay payable PADL claims or claims in the contest or show cause phases of the audit process that were ultimately denied would be included in Category Two of the Seventh Amendment.<sup>43</sup> These objectors argue that this is unfair because they would not be allowed to file additional Green Forms seeking Level I or II Matrix benefits.<sup>44</sup> We are not persuaded. Class members who have pre-stay payable PADL claims or claims in the contest or show cause process had the opportunity to file a request for inclusion in Category One of the Seventh Amendment if they believed that there was another Green Form and another echocardiogram that qualified them in a way that was better than the one that was in the show cause process. See supra note 22; (Tr. 1/19/05 at 131-32). Moreover, class members with claims in this situation

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43. The class members raising this objection have subsequently filed a notice to withdraw their objections. However, because counsel representing these objectors did not file a motion for approval of the withdrawal as required by Rule 23(e)(4)(B) of the Federal Rules of Civil Procedure, we will address this objection. See Fed. R. Civ. P. 23(e)(4)(B).

44. Notably, none of the class members who filed this objection is a Category Two class member. Two of them filed Seventh Amendment opt-outs; one filed a downstream opt-out; and one is a Category One class member.

retain matrix progression rights. (Tr. 1/19/05 at 127). In the event that their conditions worsen to surgery,<sup>45</sup> Matrix Level III or beyond, they have the right to seek payment from the existing Trust under the Seventh Amendment Matrix Compensation Benefits. (Tr. 1/19/05 at 127). Seventh Amendment § IX.A. Similar to the Seventh Amendment's treatment of "covering opt-outs," we find nothing unfair, inadequate, or unreasonable in denying these class members the ability to take a second bite at the apple by requiring them to chose which echocardiogram should serve as the basis of their claims.

Some objectors argue that the Seventh Amendment is unfair, unreasonable, and inadequate because there are no subclasses or subclass representatives to protect the interests of class members who have lost benefits and/or rights under the Seventh Amendment. This objection is likewise without substance. Subclasses were created by the Settlement Agreement and subclass representatives are in place to protect their interests. See In re Diet Drugs, 2000 WL 1222042, at \*44-45, 51-52. The adequacy of representation prerequisite of Rule 23(a)(d) that these objectors challenge requires that class representatives have interests aligned with those of the class. Here, there is no conflict of interest between class members affected by the Seventh Amendment. Each one who has not had a matrix claim

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45. As previously noted, such diagnosis must occur by the earlier of 15 years after the date of the Diet Drug Recipient's last ingestion of diet drugs or December 31, 2011. See supra note 17.

processed or adjudicated faces the same prospect that the existing Settlement Fund, absent approval of the Seventh Amendment, will be insufficient to fund payment of benefits.

Certain objectors contend that the court should delay approval and implementation of the Seventh Amendment to appoint an independent panel of experts to assist the court in an objective review of the Seventh Amendment. Under Rule 23(e) of the Federal Rules of Civil Procedure, this court has the discretion and authority to determine whether a class action settlement and any amendments thereto are fair, adequate, and reasonable. See Girsh, 521 F.2d at 157. We will exercise that discretion and authority.

In addition, certain class members have objected to provisions in the Seventh Amendment pertaining to the scope of Wyeth's release. They also maintain that the fees associated with obtaining a second medical review for class members who fail the medical review process and/or processing fees for resubmitting echocardiograms or other qualifying documents to the Trust are unfair. Further, these objectors find unfair the cap on attorneys' fees and the common benefit fee for Class Counsel. Others objectors argue that official court notice is too complex to apprise class members of their rights and obligations under the Seventh Amendment. We have considered the merits of these and all other objections and are not persuaded. As we have previously noted, each of the terms and conditions of the Seventh Amendment was the product of a tough bargaining process. The

notice plan fulfills the "best notice practicable" requirement of Rule 23©) (2). Moreover, any class member who opposed the terms of the Seventh Amendment was free to opt out and continue under the terms of the current Settlement Agreement, which was found to be fair, adequate, and reasonable. See In re Diet Drugs, 2000 WL 1222042, at \*68.

The Trust objects to the Seventh Amendment on the ground that the Enforcement Action bar does not provide adequate protection to the Trust. We do not agree. As we previously explained, the Seventh Amendment prohibits the Trust and Wyeth from bringing an action based on or arising out of any claim submitted to the Trust by a class member subject to the Seventh Amendment. Seventh Amendment §§ I.B.24, XVIII.A and B. However, the Trust is not precluded from utilizing customary defenses, including the assertion of compulsory counterclaims, in the event that it is sued by a class member or third party. We do not interpret the Seventh Amendment to preclude the Trust from protecting itself against its legal adversaries.

#### **VIII.** **Conclusion**

Accordingly, the Seventh Amendment to the Nationwide Class Action Settlement Agreement is approved as fair, adequate and reasonable. See Fed. R. Civ. P. 23(e).

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

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

**PRETRIAL ORDER NO.**

**(Approving the Seventh Amendment to the  
Nationwide Class Action Settlement Agreement)**

AND NOW, this            day of March, 2005, for the reasons  
set forth in the accompanying Memorandum, it is hereby ORDERED  
that:

(1) the Joint Motion for Approval of the Seventh  
Amendment to the Nationwide Class Action Settlement Agreement is  
GRANTED;

(2) the capitalized terms used in this Order shall be  
defined as set forth in the Settlement Agreement and the Seventh  
Amendment;

(3) the Seventh Amendment is approved in its entirety  
as non-collusive and as fair, adequate, and reasonable in all  
respects;

(4) all Releasing Parties, the AHP Settlement Trust, Wyeth, Class Counsel, and other Released Parties, the Seventh Amendment Liaison Committee, the Fund Administrator, the Escrow Agent, the Medical Review Coordinating Committee, and all other persons or entities affected by the Seventh Amendment, and the agents, contractors, counsel, and any person or entity acting or purporting to act on behalf of any of the foregoing, are hereby directed to comply with all the terms and provisions of the Seventh Amendment;

(5) all Releasing Parties are hereby permanently barred and enjoined from initiating and/or continuing to maintain, prosecute, or pursue in any manner any claim, action, motion, proceeding, or any litigation of any kind based on the exercise or purported exercise of any Initial Opt-Out, Intermediate Opt-Out, Back-End Opt-Out, Sixth Amendment Opt-Out, and/or Financial Insecurity Opt-Out;

(6) subject to Final Judicial Approval, all Releasing Parties are hereby permanently barred and enjoined from initiating and/or continuing to maintain, prosecute, or pursue in any manner any claim, action, motion, proceeding, or any litigation of any kind that is released, discharged, waived, relinquished, prohibited, or otherwise precluded by Section XI.C of the Seventh Amendment;

(7) upon Final Judicial Approval, all Releasing Parties, are hereby permanently barred and enjoined from initiating and/or continuing to maintain, prosecute, or pursue in

any respect any claim for Matrix Compensation Benefits that is terminated, relinquished, barred, discharged, or otherwise precluded by § XI.B of the Seventh Amendment;

(8) subject to Final Judicial Approval, the Trust and Wyeth (and their successors and/or assigns), are hereby permanently barred and enjoined from initiating and/or continuing to maintain, prosecute, or pursue in any manner any Enforcement Action precluded by § XVIII.B.1 and § I.B.24 of the Seventh Amendment, based on or arising out of any claim submitted to the Trust; *provided, however,* that the terms of the Seventh Amendment and of this Order are without prejudice to the rights of any person to cooperate in providing evidence to appropriate law enforcement agencies and other appropriate government agencies and officers;

(9) nothing in this Order or in the Seventh Amendment shall be construed as limiting the Trust or Wyeth (or their successors and/or assigns) from initiating or maintaining any Enforcement Action based on or arising from claims submitted by class members who have exercised a Seventh Amendment Opt-Out, as provided in § I.B.24 of the Seventh Amendment;

(10) nothing in this Order or in the Seventh Amendment shall prohibit the Trust or Wyeth (or their successors or assigns) from initiating or maintaining in any action or proceeding against the Trust and/or Wyeth (and/or their successors or assigns) any claim that constitutes or could be deemed in effect a compulsory counterclaim under Rule 13(a) of

the Federal Rules of Civil Procedure or comparable state rules, common law, or statute, against any person or entity that would be an appropriate counterclaim defendant on such a compulsory counterclaim. For purposes of the tolling of any and all statutes of limitation otherwise applicable to any claim that becomes a compulsory counterclaim pursuant to the foregoing, the injunction directed by this Paragraph 8 of this Order shall be deemed to constitute the continuation of the stay against the initiation or continuation of such Enforcement Actions first entered by the court as to such matters in Pretrial Order No. 3511 on May 10, 2004, and continued in Paragraph 16 of Pretrial Order No. 3880 entered on August 26, 2004, with such stay continuing up to the time of filing by the Trust or Wyeth (and/or their successors and/or assigns) of such compulsory counterclaim;

(11) all Category One class members, their counsel, and anyone acting on their behalf from having any communication or contact of any kind with any Participating Physician and the MRCC with respect to any of their functions under the Seventh Amendment, except to the extent that Class Counsel and the SALC, acting jointly, in their official capacities, and without reference to any specific claims that will be subject to Medical Review under the Seventh Amendment, assist the MRCC in performing those activities specified in § XV.J of the Seventh Amendment;

(12) without affecting the finality of this Order in any way, the court retains original and exclusive jurisdiction over the interpretation, implementation, and enforcement of the

Seventh Amendment incident to its exclusive, retained jurisdiction under § VIII.B.1 of the Settlement Agreement and Paragraph 11 of Pretrial Order No. 1415 entered by the court on August 28, 2000; and

(13) as there is no just reason for delay of the entry of this Order, the court directs that judgment be entered.

BY THE COURT:

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J.