

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 :
: :
THIS DOCUMENT RELATES TO: :
: :
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SHEILA BROWN, et al. :
: :
v. :
: :
: :
AMERICAN HOME PRODUCTS :
CORPORATION : CIVIL ACTION NO. 99-20593

MEMORANDUM AND PRETRIAL ORDER NO. 1415

BECHTLE, J.

AUGUST 28, 2000

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

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I. BACKGROUND

A. The Diet Drug Litigation

This litigation involves claims regarding the health effects of two related prescription drugs--fenfluramine and dexfenfluramine. Fenfluramine is an appetite suppressant that affects blood levels of the neurotransmitter, serotonin. Dexfenfluramine, the "d-isomer" of fenfluramine, is chemically related to fenfluramine and acts as an appetite suppressant by stimulating the release of serotonin from nerve cells in the brain and by reducing the reuptake of the released serotonin. In 1973, The United States Food and Drug Administration ("FDA") approved A.H. Robins, Inc.'s new drug application to market fenfluramine in the United States. (Ex. P-180.)

Before 1989, A.H. Robins, Inc. was responsible for the marketing, sale and labeling of fenfluramine in the United States. In 1989, AHP acquired A.H. Robins. Following the acquisition, fenfluramine was marketed by AHP under the trade name "Pondimin." Between December 1989 and September 15, 1997, AHP was the only company to market fenfluramine in the United States and had the exclusive responsibility for its regulatory compliance, adverse event reporting, safety surveillance and labeling.

Sales of Pondimin were relatively flat until 1992. In 1992, a series of articles by Michael Weintraub, M.D., were published in the Journal of Clinical Pharmacology and Therapy, in which Dr. Weintraub advocated the use of fenfluramine together with the drug phentermine for weight loss management without the adverse side effects associated with the use of fenfluramine alone. This regimen

popularly became known as "Fen-Phen." With the introduction of "Fen-Phen" therapy to the market place, sales of Pondimin skyrocketed. From January 1995 to mid-September 1997, approximately 4,000,000 persons in the United States took the drug Pondimin. (Tr. 5/2/00 at 26-27; Ex. P-183 at 29 of 33; Ex. P-182 at 5 of 13.)

Dexfenfluramine, the chemical cousin of Pondimin, was developed by Les Laboratoires Servier S.A. ("LLS") in France. The drug afforded the same anorexic effects as Pondimin without the need to add phentermine to ameliorate adverse side effects. Before 1994, the Lederle Division of American Cyanamid Company had the right, together with Interneuron Pharmaceuticals, Inc., to develop and promote dexfenfluramine in the United States under the trade name "Redux." In 1994, AHP acquired American Cyanamid. Following that acquisition, responsibility for the development and promotion of Redux in the United States in conjunction with Interneuron was assumed by AHP. Interneuron received approval to market Redux in the United States in mid-1996. As with Pondimin, sales of Redux were brisk. From June 1996 through September 15, 1997, two million people in this country took Redux. (Tr. 5/2/00 at 28; Ex. P-183 at 29 of 33; Ex. P-182 at 5 of 13.)

The distribution of Redux users by age and sex was virtually the same as that for Pondimin. (Ex. P-94 at 3 of 41; Ex. P-53 at 9 of 54.) Most of the individuals who took the diet drugs Pondimin and Redux were middle aged women. (Ex. P-94 at 3 of 41; Ex. P-53 at 9 of 44.)

From the viewpoint of plaintiffs' counsel, the evidence reveals that before Pondimin and Redux were withdrawn from the market in 1997, which is discussed infra, AHP received considerable information from a number of sources that both drugs could cause damage to the valves in the heart leading to valvular regurgitation. This information consisted of reports in the medical literature, reports from animal studies, reports concerning heart valve damage in patients taking drugs with similar effects on serotonin metabolism, adverse event reports and reports from a doctor commissioned to analyze certain facts for Interneuron. According to plaintiffs, notwithstanding this information, during the period of time AHP marketed dexfenfluramine and fenfluramine, it failed to investigate these reports, to look at whether or not the drugs were cardiotoxic or to label the drugs as being potentially harmful to the heart valves.

In response, AHP has vigorously contested the plaintiffs' interpretation of these events, noting that much of this information was submitted to the FDA for its own analysis; that none of the doctors or scientists who reported on Pondimin or Redux, either in the published literature or in the adverse event reports, concluded that either product caused any valvular disease; and that, given the substantial prevalence of such valvular disease in the general population, it was not possible to conclude, on the basis of these reports, that its products caused disease.

In March 1997, researchers at the Mayo Clinic in Rochester, Minnesota began observing an association between the use of fenfluramine and/or dexfenfluramine and a particular type of valvular heart disease. Eventually, the Mayo Clinic researchers observed this unusual form of valvular heart disease in 24 women who had used fenfluramine in combination with phentermine. (Ex. P-95 ¶ 39; Tr. 5/2/00 at 29; Ex. P-113; Ex. P-181; Ex. P-182.) The findings of the Mayo researchers were first brought to the attention of the public in a July 8, 1997 press release and were eventually published on August 28, 1997, in the New England Journal of Medicine. (Exs. P-181 & P-113.)

On July 8, 1997, the FDA issued a public health advisory, followed by letters to 700,000 physicians requesting information about similar patients. Based on information the FDA received in response, the FDA requested the withdrawal of fenfluramine and dexfenfluramine from the U.S. market. On September 15, 1997, AHP and the FDA announced that there would be no further sales of Pondimin and Redux in the United States. Subsequently, the causal relationship between valvular heart disease and the use of dexfenfluramine and fenfluramine was investigated and confirmed in three epidemiological studies published in the New England Journal of Medicine in September 1998. (Exs. P-127 (Jick), P-130 (Khan) & P-170 (Weissman).)

A wave of litigation followed. As of the time that class notice issued in this matter, approximately 18,000 individuals who

used Pondimin or Redux filed lawsuits against AHP. (Tr. 5/2/00 at 196-97.) Many of these lawsuits involved actions in which individuals sought to recover for personal injuries, primarily valvular heart disease, that they sustained as a result of using Pondimin or Redux. In addition, over one hundred plaintiffs instituted class actions in which they sought either: (1) to create an equitable fund to provide medical screening services to patients who had used Pondimin and/or Redux for varying periods of time to determine if they had asymptomatic valvular heart disease; and/or (2) to recover the amounts expended by consumers to purchase Pondimin and/or Redux or to obtain echocardiograms as a consequence of exposure to these drugs; and/or (3) to recover personal injury damages on behalf of classes of persons who took Pondimin and/or Redux. (Tr. 5/2/00 at 20-21 & 36-39.)

To the extent that these actions were filed in the federal judicial system, the Judicial Panel for Multidistrict Litigation entered an order transferring all of the actions to the United States District Court for the Eastern District of Pennsylvania for coordinated and/or consolidated pretrial proceedings under MDL Docket No. 1203. As the transferee court, this court entered an order creating and appointing a Plaintiffs' Management Committee ("PMC") to oversee the conduct of the coordinated/consolidated

pretrial proceedings on behalf of the plaintiffs. See Pretrial Order No. 6.¹

By the summer of 1999, a combination of state court and federal court decisions certified classes to pursue some form of relief on behalf of those persons who had used AHP's diet drugs. See Pretrial Order No. 865, Jeffers v. American Home Prods. Corp., C.A. No. 98-CV-20626 (certifying nationwide medical monitoring class in MDL court); Burch, et al. v. American Home Prods. Corp., C.A. No. 97-C-204(1-11) (certifying medical monitoring and personal injury class in West Virginia); Rhyne v. American Home Prods. Corp., 98 CH 409 (certifying medical monitoring class in Illinois); Vadino, et al. v. American Home Prods. Corp., Docket No. MID-L-425-98 (certifying class seeking medical monitoring and damages for unfair and deceptive trade practices in New Jersey); In re: New York Diet Drug Litig., Index No. 700000/98 (certifying medical monitoring class in New York); In re: Pennsylvania Diet Drug Litig., Master Docket No. 9709-3162 (CCP, Phila.) (certifying medical monitoring class in Pennsylvania); Earthman v. American Home Prods. Corp., No. 97-10-03970 CV, (certifying medical monitoring class in Texas); St. John v. American Home Prods. Corp., 97-2-06368-4 (certifying medical monitoring class in Washington).

By the summer of 1999, the parties in both the state litigation and the federal MDL litigation had virtually completed discovery

¹ Pursuant to Pretrial Order No. 6, the court appointed Arnold Levin, Esq., John J. Cummings, III, Esq. and Stanley Chesley, Esq. as co-chairs of the PMC.

with respect to AHP's conduct. (Tr. 5/2/00 at 21-23.) More than 6,000,000 documents were produced by AHP and carefully reviewed, analyzed and collated by the plaintiffs. Id. In the federal litigation, the PMC took nearly 100 depositions of present and former employees of AHP, Interneuron, the FDA and other third parties. (Tr. 5/2/00 at 21-23; Ex. P-1000.) The state court plaintiffs conducted similar deposition discovery, deposing many of the individuals who were the subject of the MDL discovery effort.

In both the MDL litigation and the state court litigation, the plaintiffs consulted with experts in various subjects related to the litigation, including primary pulmonary hypertension, cardioepidemiology, cardiology, cardio-thoracic surgery, clinical pharmacology, cardiopathology, economics, and the like. These experts revealed their opinions in Rule 26 disclosures and were subject to both discovery depositions and, in many cases, depositions designed to preserve their testimony for use at trial. Thus, by the summer of 1999, the plaintiffs had a thorough understanding of the facts underlying the question of AHP's liability to those individuals and classes of individuals who had used Pondimin and Redux, as well as a firm grasp of the relevant scientific principles pertaining to liability, injury and causation in these cases. Also, by the summer of 1999, cases against AHP had begun to go to trial. The most significant of these was the New Jersey Vadino case in which New Jersey Superior Court Judge Marina

Corodemus presided over a trial of the class claims certified in that action.

B. The Settlement Negotiations

In late April 1999, AHP invited representatives of the varying constituencies of state and federal plaintiffs to begin negotiations with it for a "global resolution" of the Diet Drug Litigation. In response to that invitation, a negotiating coalition was formed among representatives of the PMC in the MDL court and representatives of the plaintiffs in state courts with pending certified class actions. (Tr. 5/2/00 at 40-42; AHP Ex. 629 at 65-66 and 71; AHP Ex. 628 at 60-61.)

The plaintiffs' negotiating coalition presented its initial proposal to AHP in the form of a "term sheet" on June 1, 1999. (Tr. 5/2/00 at 47-48.) AHP responded to that proposal with a counter-proposal on June 28, 1999. (Tr. 5/2/00 at 48-49.) Thereafter, intense, adversarial and arm's-length negotiations ensued for more than four months, during which time: Class Counsel in New Jersey prepared for and began the medical monitoring class action trial before Judge Corodemus; cases in Texas proceeded to trial and, in one case, to a substantial verdict against AHP; and individual cases were poised for remand for trial in the MDL 1203 proceedings. (Tr. 5/2/00 at 39; AHP Ex. 628 at 35.) Altogether, members of the negotiating coalition and representatives of AHP participated in approximately 73 negotiating sessions, over a period extending from April through November 1999. (Tr. 5/2/00 at 59.)

Those negotiating the settlement on behalf of the plaintiffs had no understandings, or even negotiations with AHP with respect to any of their individual cases. (Tr. 5/2/00 at 41 & 58-61.) The terms and conditions of the Settlement Agreement were the product of a bargaining process between the parties involving separately negotiating or "building up" the settlement's benefits and obligations in contrast to a process of negotiating a lump sum dollar amount that would then be allocated or "broken down" among class members. The negotiators proceeded by negotiating the types of screening and compensation benefits to be made available to class members and the eligibility for those benefits. Only when those benefits and compensation amounts had been essentially resolved did the parties negotiate the maximum monetary commitment that AHP would incur in providing those benefits. (Tr. 5/2/00 at 59.) During the negotiations, AHP never offered, and the plaintiffs never requested, payment of a lump sum to resolve the claims of class members. To the contrary, the negotiations were devoted to working out a structure that would appropriately resolve the claims of all individuals who took Pondimin and/or Redux. Only when that structure was agreed upon did the parties determine the amount of money that would be necessary to fund the structure. (Tr. 5/2/00 at 58-61; Tr. 5/3/00 at 210-211; AHP Ex. 628 at 100.) Each of the major benefit features of the settlement was the subject of a separate, independent and, at times, heated negotiation process. Importantly, under the settlement process that was employed, there

was no intra-class trading off of benefits. That is, one benefit of the settlement did not have to be reduced in exchange for the creation or increase of another benefit. (Tr. 5/2/00 at 42-59, 154-61 & 166-67; AHP Ex. 628 at 110-12.) Moreover, the subject of attorneys' fees was not discussed until the end of the negotiations and then only to limit the award of fees that might otherwise be payable, subject to appropriate limitations for the benefit of the class. (Tr. 5/2/00 at 88; AHP Ex. 629 at 208-39.)

Throughout the negotiations, the members of the negotiating coalition were willing to litigate their clients' claims in the event that negotiations broke down. (Tr. 5/2/00 at 49, 60-61.) Members of the negotiating coalition were armed with substantial leverage in their negotiations with AHP as a result of plaintiffs' willingness and ability to litigate their claims should negotiations fail. This leverage derived from, among other things, the pendency of the Jeffers action brought by the PMC in the MDL court, several certified state court medical monitoring class actions in which the negotiators or their constituencies were participating, individual diet drugs cases pending in the MDL proceedings and in state courts seeking compensation for personal injury, and the trial of the Vadino medical monitoring case which was underway when the negotiations were taking place.

By October 7, 1999, the parties had reached an understanding on the principal terms of the settlement, embodied in a Memorandum of Understanding ("MOU"). (Ex. P-49.) After the execution of the MOU,

the parties continued with round-the-clock negotiations with respect to the terms left open by the MOU. (Tr. 5/2/00 at 57.) The court also ordered the PMC to make periodic reports to it on fifteen-day intervals concerning the status of the Settlement Agreement. The court was kept apprised of the status of the negotiations. See Pretrial Order No. 929.

Ultimately, on November 18, 1999, the parties executed a Nationwide Class Action Settlement Agreement with AHP. (Exs. P-3 through P-30.) The Court granted preliminary approval of the Settlement Agreement on November 23, 1999 and set May 1, 2000 as the date to commence a Fairness Hearing regarding the Settlement Agreement. See Pretrial Order No. 997. The Agreement has since been subject to four amendments. (First Amendment, Ex. P-31; Second Amendment with Exhibits, Exs. P-32 through P-48; Third Amendment, Ex. P-47; and Fourth Amendment, Ex. P-278.)

C. Procedural Background and Fairness Hearing

On January 28, 2000, the court entered Pretrial Order No. 1071. That order established a "Special Discovery Court" to convene on a weekly basis commencing Wednesday, February 2, 2000 "for the limited and exclusive purpose of promptly administering discovery requirements and resolving discovery disputes applicable to proceedings before the Court regarding consideration of the judicial approval of the nationwide class action Settlement Agreement." Pretrial Order No. 1071 at 1.

On February 3, 2000, the court entered Pretrial Order No. 1109. That Pretrial Order manifested the court's "intention that an eligible party have the opportunity to conduct, under reasonable terms and conditions: (1) discovery pertinent to the issues to be decided at the Fairness Hearing; or (2) discovery deemed important by the eligible person in order to make the decision whether or not to object to the settlement, appear at the Fairness Hearing to object or provide the Court with written comments without an appearance at the Fairness Hearing." Toward this end, Pretrial Order No. 1109 directed that:

on or before February 20, 2000 class counsel and the defendant shall file with the Court: (i) a statement identifying all fact witnesses to be called to testify at the Fairness Hearing, together with a brief statement on the anticipated substance of the testimony of each witness; (ii) copies of all documents or other exhibits to be offered into evidence; and (iii) the identities of all expert witnesses to be called together with the information required in Federal Rule of Civil Procedure 26(a)(2)(B). On or before April 10, 2000 any person or party who has fulfilled the requirements of paragraph 17 of PTO No. 997 shall provide to class counsel and the defendant: (i) a statement identifying all fact witnesses to be called to testify at the Fairness Hearing together with a brief statement on the anticipated subject of the testimony of each witness; (ii) copies of all documents or other exhibits to be offered into evidence; and (iii) the identities of all expert witnesses to be called, together with the information required in Federal Rule of Civil Procedure 26(a)(2)(B).

Pretrial Order No. 1109. On February 10, 2000, the court entered Pretrial Order No. 1116 modifying Pretrial Order No. 1109 as follows:

PTO No. 1109 is modified to the effect that class proponents shall have until Monday, February 28, 2000, to disclose the names of all their intended Expert Witnesses, provide Curriculum Vitae for each Expert Witness, provide a list of any prior case in which any of the experts have testified, and provide a summary of the expected subject area of each Expert's testimony consistent with Rule 26(a)(2)(B). Also on that date, class counsel shall provide the completed disclosures for at least half of the expert witnesses identified. For any remaining Experts, full disclosures shall be completed on a rolling basis by March 20, 2000.

Pretrial Order No. 1116. Acting as liaison counsel for the plaintiffs in the above-entitled matter, Arnold Levin, Esq. transmitted copies of each of the above orders to each attorney in the United States known or believed to be representing individuals who are members of the class as defined above.

The beginning of the Fairness Hearing was adjourned, by one day, to May 2, 2000. At the Fairness Hearing, the proponents of the Settlement Agreement and the persons who objected to the settlement pursuant to the terms of Pretrial Order No. 997 ("the Objectors") had a full and fair opportunity to offer all of the evidence that they wished to tender to the court concerning the proposed nationwide class action Settlement Agreement.

Class Counsel offered the following witnesses in support of the settlement:

1. Michael D. Fishbein, Esquire. Mr. Fishbein's testimony concerned the litigation background for the Settlement Agreement,

the negotiations leading up to the execution of the Settlement Agreement, and the terms of the Settlement Agreement.

2. Robyn J. Barst, M.D. Dr. Barst is one of the leading experts regarding primary pulmonary hypertension. The subject of Dr. Barst's testimony concerned the proper definition of primary pulmonary hypertension under the Settlement Agreement.

3. Troyen A. Brennan, M.D., J.D. Dr. Brennan was offered as an expert in the fields of public health and epidemiology.

4. Professor John C. Coffee, Jr. Professor Coffee is the Adolf A. Berle Professor of Law at Columbia University Law School. Professor Coffee was offered as an expert in class certification in the mass tort context.

5. Molly Kuehn Watson. Ms. Watson is a media planning consultant with 14 years of experience. Ms. Watson testified as an expert in media planning as it related to class notice.

6. Professor Arthur R. Miller. Professor Miller is a professor of law at Harvard Law School. Professor Miller was offered as an expert on issues related to Federal Rule of Civil Procedure 23.

7. Harvey S. Rosen, Ph.D. Dr. Rosen was offered as an expert in the field of economics.

8. Eric D. Caine, M.D. Dr. Caine was offered as an expert witness in the field of neuropsychiatry, which involves the psychiatric and neuropsychological symptoms and signs of brain diseases.

9. Dean G. Karalis, M.D., F.A.C.C.. Dr. Karalis was offered as an expert in the field of cardiology, valvular heart disease and echocardiography.

10. Steven N. Goodman, M.D., M.H.S., Ph.D.. Dr. Goodman was offered as an expert in the design and analysis of epidemiologic and clinical studies, meta-analysis and methods for making inferences from statistical summaries.

11. Samuel J. Kursh, D.B.A.. Dr. Kursh serves as vice president of the Center for Forensic Economic Studies where his responsibilities include damage modeling and projections in complex litigation.

12. Kenneth R. Feinberg, Esquire. Mr. Feinberg is an attorney and founder of the Feinberg Group, LLP, headquartered in Washington, D.C. Mr. Feinberg was offered as an expert on the resolution of mass tort litigation, particularly under Federal Rule of Civil Procedure 23.

13. Professor Sam Dash. Professor Dash is a professor of law at Georgetown University Law Center. Professor Dash was called to testify as an expert in the area of legal ethics, particularly as they apply in the class action context.

14. Class Counsel also offered other evidence including live testimony by Peter Pakradooni, a Declaration by Deborah A. Hyland, deposition transcripts, and a number of exhibits.

AHP offered a number of witnesses, subject to cross-examination, on matters relevant to the settlement, including:

15. Sanjiv Kaul, M.D.. Dr. Kaul is a professor of medicine and the Frances Myers Ball Professor of Cardiology at the University of Virginia where he is director of its Cardiac Imaging Center.

16. Pravin Shah, M.D.. Dr. Shah is the medical director of the Hoage Heart Institute and professor of medicine at Loma Linda University.

17. Walter F. Stewart, Ph.D., M.P.H.. Dr. Stewart is adjunct associate professor of epidemiology of Johns Hopkins School of Hygiene and Public Health, former consultant to the EPA, OSHA, National Cancer Institute, and the NIH; and a reviewer for the American Journal for Epidemiology, Epidemiology Review, and the American Journal of Public Health.

18. Arthur E. Weyman, M.D.. Dr. Weyman is a professor of medicine at Harvard Medical School, director of the Cardiac Ultrasound Laboratory at Massachusetts General Hospital, former chief of cardiology at Massachusetts General, president of the National Board of Echocardiography, former president of the American Society of Echocardiography, author of the text entitled Echocardiography, and is board certified in internal medicine and cardiology.

19. Professor Peter Schuck. Professor Schuck holds the Simeon E. Baldwin Professorship at Yale Law School. Professor Schuck is a member of the American Law Institute advisory committee on the Restatement of the Law (Third) of Torts: General Principles.

20. Mark McClellan, M.D., Ph.D.. Dr. McClellan holds a Ph.D. in Economics from the Massachusetts Institute of Technology, an M.D. from the Harvard-Massachusetts Institute of Technology Division of Health Sciences and Technology, and an M.A. from the Kennedy School of Government at Harvard University. Dr. McClellan is an Assistant Professor of Economics and an Assistant Professor of Medicine at Stanford University, and recently served as Deputy Assistant Secretary for Economic Policy at the Department of the Treasury.

21. Elizabeth Krupnick. Ms. Krupnick is an expert in communications and President of the Farago & Partners advertising agency. Ms. Krupnick's previous positions in the communications industry include (1) Senior Vice President of Corporate Communications and Advertising at New York Life Insurance Company, (2) Chief Communications Officer and Vice President of The Prudential Insurance Company of America and (3) Senior Vice President of Corporate Affairs for Aetna Life and Casualty.

Less than thirty class member objectors filed objections to the Settlement Agreement. No public interest group filed any objection to the Settlement. No academic filed any objection to the Settlement. Several Objectors cross examined witnesses at the Fairness Hearing. In addition, some objectors entered various documents and articles into the Fairness Hearing Record.

D. The Medical Circumstances of the Class

The record before the court includes a substantial amount of medical testimony and evidence, including approximately ninety

clinical and epidemiological studies, which is the foundation for the various monitoring and compensation provisions of the Settlement. By contrast, no expert for any party or any objector testified that any aspect of the Settlement was contrary to the scientific studies or was not a reasonable response to the medical issues raised in the lawsuits that the Settlement will resolve.

1. The Risk of Valvular Heart Disease

a. The Heart

The principal risk created by use of fenfluramine and dexfenfluramine is the risk of valvular heart disease ("VHD"). The human heart has four chambers. The upper chamber on the right side of the heart (the right atrium) functions to receive deoxygenated blood from the body. The lower chamber of the right side of the heart (the right ventricle) pumps the deoxygenated blood through the pulmonary arteries into the lungs where carbon dioxide is removed from the blood and replaced with oxygen. The upper chamber on the left side of the heart (left atrium) receives and collects oxygenated blood which has been pumped from the lungs to the heart through the pulmonary veins. The lower chamber on the left side of the heart (the left ventricle) pumps oxygenated blood from the heart through the aorta and into the arterial system. (Ex. P-95 ¶4; Tr. 5/2/00 at 216; Ex. P-63.)

Just as the heart has four chambers, it also has four valves. The valve structures function to assure that blood moves through the heart in a forward direction and that effective blood flow is

maintained. The valve located between the right atrium and the right ventricle is the tricuspid valve. The valve between the right ventricle and the pulmonary artery is the pulmonic valve. The valve located between the left atrium and the left ventricle is the mitral valve. The valve located between the left ventricle and the aorta is the aortic valve. (Ex. P-95 ¶¶ 5 & 6.)

b. VHD in General

VHD is a group of different conditions which cause a disruption in the normal structure and/or function of the heart valves. When a patient suffers from VHD, blood that is supposed to move in a forward direction through the heart leaks backward or "regurgitates" through the diseased valve. (Ex. P-95 ¶ 8.) The existence of VHD and the extent of regurgitation associated with it can be diagnosed with echocardiography--a non-invasive study in which ultrasound waves are used to image cardiac structure and blood flow in the heart. (Ex. P-95 ¶ 9.)

Apart from VHD related to the use of diet drugs (which is described below), several other conditions are the principal causes of valvular regurgitation in the left side of the heart. (Ex. P-95 ¶ 10.) Each of these other conditions may be diagnosed with an echocardiogram in accordance with accepted, objective criteria. (Ex. P-95 ¶ 10.)

The prevalence of valvular regurgitation in the general population also varies with the age of the population--with more regurgitation present in older individuals as a result of the normal

aging process, as well as their exposure over time to these various diseases or agents that are known to cause such regurgitation. (Ex. P-95 ¶ 16; AHP Ex. 613 ¶ 9; AHP Ex. 610 ¶ 13.) Because there is such a "background" or "control" rate of valvular regurgitation among the general population who never took diet drugs--and because that rate varies with the age of the patients and various other conditions--it is essential that any demonstration of causation with respect to diet drugs and such regurgitation be predicated on controlled studies which, on a blinded basis, compare the prevalence of such regurgitation among those who took the drugs and a similarly-situated population of others who did not. (AHP Ex. 611 ¶¶ 6-10 & 14-16; AHP Ex. 613 ¶ 18; AHP Ex. 610 ¶¶ 7-9.)

The levels of valvular regurgitation caused by the varying conditions underlying VHD vary in severity. The degree of valvular regurgitation is measured by an echocardiogram in accordance with standardized techniques and criteria. (Ex. P-95 ¶ 11.) Using these techniques of measurement, the degrees of valvular regurgitation are characterized as trace, mild, moderate or severe. (Ex. P-95 ¶ 12.) Such valvular regurgitation occurs to varying degrees in the majority of entirely healthy individuals. As all of the cardiology experts testified, today's echocardiography technology is so sensitive that it can detect even trivial amounts of regurgitation that require no medical treatment and are not a precursor of any disease. (Ex. P-95 ¶ 12; AHP Ex. 613 ¶ 6; AHP Ex. 610 ¶ 11.)

Mild or greater aortic regurgitation ("AR") and moderate or greater mitral regurgitation ("MR") is frequently referred to as "FDA positive regurgitation" based on the FDA's observation that "[m]inimal 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." (Ex. P-95 ¶ 13; Ex. P-182 at 2 & 6 of 13.) All of the experts who testified on this issue agreed that the FDA case definition--which has come to be known as "FDA Positive"--is the appropriate way to define medically relevant valvular regurgitation. Specifically, all the experts testified that the lesser degrees of regurgitation--including mild mitral regurgitation--are common in the general population and have no medical significance. (Ex. P-95 ¶¶ 13, 18; AHP Ex. 613 ¶¶ 6 & 10.)

Although the progression in severity of valvular regurgitation resulting from conditions other than diet drugs has not been subject to rigorous clinical investigation, it is generally accepted that VHD from such other causes is potentially progressive in nature; that is, once significant valvular regurgitation exists, it tends to beget more severe regurgitation in a significant subset of patients. (Ex. P-95 at ¶ 14.) Clinical experience tends to suggest that the risk of progression of valvular regurgitation is related to the severity of regurgitation in the first instance, with mild forms of regurgitation tending not to progress, and moderate to severe levels of regurgitation tending to be progressive. (Ex. P-95 ¶ 15.) Trace

AR, trace MR and mild MR are relatively common conditions, while more severe forms of regurgitation tend to be less common in the general population. See, e.g., Ex. P-95 ¶ 16 (discussing results of Framingham Study).

The existence and degree of symptoms caused by VHD and the medical care required to manage such disease vary significantly depending upon the degree of valvular regurgitation that the patient presents. Trace AR, trace MR, and mild MR are completely asymptomatic conditions that do not impose any limitations on a patient's ability to function normally. Without some additional factor, such as impaired mobility of the valve "leaflets," patients with trace AR, trace MR and mild MR do not require medical management or treatment. (Ex. P-95 ¶¶ 17 & 18.)

Mild AR is an asymptomatic condition that does not impose any limitation on an individual's ability to function normally. However, mild AR poses two distinct health risks. First, the abnormal aortic valve is susceptible to bacteria introduced into the blood stream through invasive procedures, such as surgery or normal dental hygiene. This, in turn, creates an increased risk of the patient suffering an infection of the heart valve and surrounding heart muscle known as "bacterial endocarditis." Bacterial endocarditis is an extremely serious and often fatal condition. Patients suffering from bacterial endocarditis can develop severe regurgitation or peripheral emboli which, in turn, can lead to stroke, loss of an extremity or major organ failure. Second, mild

AR can progress to more severe levels of valvular regurgitation that can impair the functioning of the heart. (Ex. P-95 ¶ 19; Tr. 5/3/00 at 102-103.)

Given these risks, the accepted regimen of medical management for patients with mild AR is the prescription of antibiotic prophylaxis in connection with invasive procedures, such as surgery or normal dental hygiene, and periodic evaluation by a cardiologist to determine if the degree of valvular regurgitation in the patient is progressing. (Ex. P-95 ¶ 20.) Typically, the regimen for following such asymptomatic patients is a yearly examination by a cardiologist and serial echocardiographic testing. Since the risk of progression of valvular regurgitation in diet drug-induced VHD is unknown, an echocardiogram should be performed one year after the diagnosis of valvular regurgitation is made. If the aortic regurgitation remains mild, then follow-up echocardiograms should be performed every two to three years to screen for progressive valvular regurgitation. If the valvular regurgitation is found to be more severe on follow-up echocardiographic studies, then the echocardiogram should be performed yearly. (Ex. P-95 ¶ 21.) Mild AR is difficult to appreciate by merely listening for abnormal heart sounds with a stethoscope (auscultation), particularly in obese individuals. Because of this, and because of the risks of endocarditis and progression of asymptomatic disease described above, many physicians believe that patients who are at risk for

developing AR should receive screening echocardiograms. (Tr. 5/3/00 at 98-99; Ex. P-95 ¶ 41.)

At the other end of the spectrum of VHD, severe AR and severe MR are conditions in which the percentage of blood ejected from the heart (the "ejection fraction") can fall significantly below normal. With chronic severe aortic and mitral regurgitation, patients are often asymptomatic at first and become symptomatic when the heart function begins to fail. (Ex. P-95 ¶ 22.) When such patients are symptomatic, their symptoms will include shortness of breath, fatigue and/or diminished exercise capacity. (Ex. P-95 ¶ 23.)

Severe valvular regurgitation leads to a volume overload of the heart. The size of the left atrium and/or left ventricle tends to increase in response to the volume overload created by severe regurgitation. This phenomenon is described as left ventricular and/or left atrial "dilatation" ("LV/LA"). In addition, the thickness of the walls of the atrium and/or ventricle also tends to increase in response to the volume overload created by severe regurgitation. This process is known as left ventricular hypertrophy and/or left atrial hypertrophy. Over time, heart function will deteriorate, and as the left ventricular ejection fraction decreases, the pressure within the left ventricle increases. This, in turn, will lead to an increase in the pulmonary venous pressures and an increase in the pulmonary artery pressure. This secondary pulmonary hypertension (PH) is a marker of significant cardiac dysfunction and may not return to normal even

after valve surgery. In addition, the hypertrophy and dilatation may also be permanent conditions that may not be corrected medically or surgically following valve repair or replacement. (Ex. P-95 ¶ 24.)

When dilatation and/or hypertrophy progress to a sufficient level of abnormality, the patient is exposed to the following risks, among others:

- The patient is at risk of developing chronic atrial fibrillation in the case of severe MR, that can lead to a stroke or peripheral embolus;
- The patient is at risk of developing ventricular fibrillation or ventricular tachycardia, dangerous arrhythmias, that can precipitate the patient's sudden death;
- The patient has a high risk of developing congestive heart failure, an often fatal condition; and
- The patient is at risk of developing permanent pulmonary hypertension, that can lead to persistent symptoms of shortness of breath, fatigue, congestive heart failure and death.

(Ex. P-95 ¶ 26.)

Drug therapies can be used in the treatment of severe AR and severe MR, particularly before the patient develops symptoms, hypertrophy, dilatation and/or pulmonary hypertension. These include drugs that increase the strength or the contractility of the heart and drugs that decrease the afterload of the heart to allow the heart to beat more easily. (Ex. P-95 ¶ 27.) However, where a patient with severe MR or severe AR exhibits significant symptoms or begins to exhibit hypertrophy, dilatation and/or pulmonary hypertension (PH), surgery is usually the treatment of choice.

Surgery involves the operative repair of the diseased valve, if possible, or the replacement of the diseased valve with either a mechanical valve or a porcine valve. (Ex. P-95 ¶ 28.)

The average cost of valvular repair or replacement surgery, including both physician and hospital fees, ranges between \$30,000-\$50,000. (Ex. P-94 at 7-8 of 41.) Valvular repair/replacement surgery in properly selected patients is a safe procedure. The morbidity/mortality associated with valvular repair/replacement surgery during the intra-operative and post-operative period in low risk patients is between 2 and 4 percent, with a long-term morbidity/mortality for such patients averaging about 3 percent per year. (Ex. P-95 ¶ 29.) Patients who undergo valve repair or replacement surgery are normally able to resume their activities of daily living without significant restriction or disability. (Ex. P-95 ¶ 30.)

However, valvular repair or replacement surgery is not without risk. Patients who receive metallic prosthetic valves must take blood thinning agents for the rest of their lives. Patients who receive tissue valves do not require blood thinners. However, tissue valves are less durable than metallic valves, and over one-third of patients with tissue valves will have valve failure within 11 years of surgery. (Ex. P-95 ¶ 31.) Valve repair/replacement surgery is accompanied by the risk of stroke, peripheral embolus with severe impairment to the kidneys, abdominal organs, or extremities, renal failure, quadriplegia or paraplegia resulting

from cervical spine injury and post-operative infection. (Ex. P-95 ¶ 31.) Therefore, the decision to perform valve repair or replacement surgery involves striking a balance between the risks of surgery and the risks of severe regurgitation. (Ex. P-95 ¶ 32.)

As Dr. Brennan, a public health expert and board-certified internist, testified--and as is well-accepted in the medical literature--the use of echocardiograms to screen and monitor patients who are at some increased risk of developing valvular regurgitation should further reduce the morbidity and mortality associated with possible progression and complications of the disease (which takes years to injure a patient's heart after it can be detected on an echocardiogram) as compared to patients who are not so screened and monitored. Specifically, a higher-risk population that is screened and monitored in this fashion can be treated--either through medication, valve repair or replacement--at the optimal time to reduce the likelihood that they will suffer permanent heart damage or other complications of unchecked valve disease. No expert testified to the contrary. (Tr. 5/3/00 at 101-104, 114-116.)

Given the above, the regimen to be followed in the management of patients suffering from severe AR and severe MR consists of:

1. prescribing antibiotic prophylaxis in connection with any invasive procedures, such as surgery or dental hygiene;
2. frequent examination and evaluation of the patient by a cardiologist, including frequent use of echocardiograms, to assess the degree of regurgitation, the presence and extent of LV/LA dilatation, the presence and extent of LV/LA hypertrophy, the patient's ejection fraction, the

patient's pulmonary artery pressure, the patient's symptom status and other cardiovascular parameters;

3. treatment with medication; and
4. surgery, where indicated.

(Ex. P-95 at ¶ 33.)

Finally, moderate MR and moderate AR are asymptomatic conditions that do not impair an individual's ability to function normally. Typically, these conditions pose the same risk and require the same regimen of medical management as that which is appropriate for the management of mild AR. However, when moderate MR and/or moderate AR approach the level of severe regurgitation, the patient can begin to develop PH, LV/LA dilatation, and LV/LA hypertrophy. When such conditions develop, it is appropriate to treat the patient in the same manner as one would treat a patient who had severe regurgitation with such findings. (Ex. P-95 ¶ 34.)

c. VHD and Diet Drugs

The relationship between the ingestion of the fenfluramine derivatives and VHD has been subject to extensive scientific investigation. Since the withdrawal of Pondimin and Redux from the market in September 1997, a number of investigators have conducted controlled studies that have compared the prevalence of valvular regurgitation among patients who previously took fenfluramine, dexfenfluramine or the Fen/Phen combination to similarly situated subjects (i.e., matched controls) who had not taken diet drugs. There are 14 principal studies and a number of other investigations that studied a total of more than 12,000 patients who took

fenfluramine and/or dexfenfluramine for varying lengths of time. (Exs. P-113, P-127, P-170, P-172, P-173, P-122, P-115, P-153, P-228, P-111, P-118, P-119, P-126, P-138, P-148 & P-149.) As stated in a February 1999 Review article that summarized a number of these studies, "Fenfluramine and more recently its d-isomer Dexfenfluramine have been the most extensively studied anorexic drugs for the past 30 years." (Dunn LT 84 at 123.) Although these studies vary in their design, each is a valid scientific study supported by the undisputed expert testimony as reliable and authoritative.

As a result of the unprecedented amount of study that diet drug-related valvulopathy has received, it is possible to reach reliable conclusions regarding the nature of the disease process, the effect of duration of use, latency, progression, incidence and prevalence. It appears clear that the fenfluramine derivatives, Pondimin and Redux, cause valvular heart disease by producing plaques that become "stuck-on" to the valve structures causing regurgitant lesions. (Ex. P-113.) Equally clear is that there is a duration-response relationship between exposure to the drugs and the development of regurgitant lesions. An enormous body of epidemiologic data from the authoritative, reliable studies described above establishes with a high degree of confidence that the population of patients who took fenfluramine and/or dexfenfluramine for less than three months does not have a significant increased risk of FDA Positive levels of valvular

regurgitation. (Tr. 5/3/00 at 93-96; Ex. P-90 ¶ 5; Tr. 5/8/00 at 24; Ex. P-122; AHP Ex. 587A; Ex. P-115; Ex. P-228; Ex. P-170.)

Moreover, although short-term therapy with Pondimin or Redux was reported to produce an increased risk when both FDA Positive and non-FDA levels of regurgitation were considered, there was no longer a significant difference between exposed and control subjects when the same population was re-evaluated 3 to 5 months after discontinuation of the use of the drugs and again at one year after discontinuation. (Exs. P-172 & P-173.) In contrast, there is epidemiologic evidence that the use of fenfluramine or dexfenfluramine for durations of three to six months or longer produces a significant increased risk of FDA Positive levels of regurgitation and that this risk increases in proportion to the duration of therapy. (Ex. P-90 ¶ 5; Tr. 5/5/00 at 24; Tr. 5/3/00 at 96.)

With respect to the levels of regurgitation which the FDA has defined as medically relevant ("FDA Positive"), the studies are consistent in finding that the only increased risk of such regurgitation among patients who previously took fenfluramine or dexfenfluramine is a risk of mild aortic regurgitation, and that such increased risk does not occur until patients took the drugs for a "threshold" duration of three to six months or more. (Tr. 5/3/00 at 94-95; AHP Ex. 609 ¶ 8; Tr. 5/8/00 at 78-79; AHP Ex. 611 ¶ 17; AHP Ex. 610 ¶ 10.) All of the other clinical studies are consistent with this durational finding with respect to the association between

FDA Positive aortic regurgitation and the use of the drugs. Specifically, in the Ryan-Jollis, Weissman I, Weissman II, Weissman III, Gardin I, Gardin II and Davidoff Studies, there was no statistically significant increase in the prevalence of FDA Positive aortic regurgitation among the patients who had taken fenfluramine, dexfenfluramine, or the fen-phen combination for three months or less. (AHP Ex. 174A at Table 2; AHP Ex. 175 at 10; P-170 at Tables 1 and 2; P-172 at Tables 1 and 2; AHP Ex. 185A at Tables 1-4; P-122 at 1706; AHP Ex. 587A; AHP Ex. 121 at 11, 20 & 28; Tr. 5/3/00 at 94-95; AHP Ex. 609 ¶ 8; Tr. 5/8/00 at 78-79; AHP Ex. 611 ¶ 17; AHP Ex. 610 ¶ 10.)

With respect to the relative prevalence of mitral regurgitation, the controlled clinical studies do not demonstrate a statistically significant increased risk of FDA Positive (moderate or greater) mitral regurgitation regardless of duration of use. For example, the Ryan-Jollis Study found that--in comparison to a background rate of 2 percent of FDA Positive mitral regurgitation among the untreated control subjects--none of the patients treated with the fen-phen combination for 90 days or less, 2 percent of the patients treated for 90 to 180 days, 3 percent of the patients treated 181 to 360 days, 3 percent of the patients treated 361 to 720 days, and 2 percent of the patients treated for 720 days or more had such regurgitation. None of these slight differences was statistically significant for any of the durational subgroups, nor was the rate of FDA Positive mitral regurgitation among all of the

treated patients taken as a whole (2.5 percent) significantly different from the control rate of 2 percent. (AHP Ex. 175 at 12.)

All of the other controlled clinical studies similarly found that there was no statistically significant increased risk of FDA Positive (moderate or greater) mitral regurgitation among patients treated with fenfluramine, dexfenfluramine, or the fen-phen combination, regardless of duration of use. (Exs. P-153 at 2163; P-130 at Table 2; P-170 at Table 2; P-172 at Table 2; AHP Ex. 185A; P-122 at 1707; AHP Ex. 587A; AHP Ex. 121 at 13; AHP Ex. 609 ¶ 8; AHP Ex. 611 ¶ 18; AHP Ex. 610 ¶ 10.) None of the clinical studies have reported an increased risk of either tricuspid or pulmonic regurgitation among patients treated with fenfluramine or dexfenfluramine regardless of duration of use. (Exs. P-170, P-115, P-111 and P-122.)

All of the expert witnesses who testified in this case and expressed an opinion with respect to the increased risk of medically significant valvular regurgitation likewise agreed that increased risk among former fenfluramine or dexfenfluramine patients is limited to the aortic valve and begins at a "threshold" level of at least three months or more. No expert testified to the contrary. (Tr. 5/3/00 at 93-95; AHP Ex. 609 ¶ 8; AHP Ex. 613 ¶¶ 43-58; AHP Ex. 611 ¶¶ 17-32; AHP Ex. 610 ¶ 10.)

The state of scientific knowledge concerning diet drug induced valvular heart disease was recently summarized by a prominent

pharmaco-epidemiologist, Hershel Jick, in a recent editorial in the Journal of the American Medical Association as follows:

[m]illions of patients were prescribed Fenfluramines prior to 1997. For the substantial majority who took the drug for less than three months, the risk of heart valve disorders appears to be minimal. In those who took the drugs longer than three months, many will have developed echocardiographic evidence of cardiac valve disorders, particularly mild AR. In the majority of instances, these abnormalities most likely are benign and are unlikely to lead to clinical disease. However, a small proportion of patients have substantially increased risk for clinically important valvulopathy and cardiovascular consequences as a result of taking anorexigens. However, because Fenfluramines have been unavailable since 1997, judgments about the overall consequences of Fenfluramine use are likely to be limited to the results of those studies already completed.

Ex. P-128 at 2-3.

In sum, the medical situation of individuals who used AHP's products, Pondimin and Redux, is as follows. First, because the population of individuals who took diet drugs for more than three or four months is at an increased risk of asymptomatic valvular heart disease, it is appropriate for them to have a screening echocardiogram to determine if they have developed VHD as a consequence of exposure to Pondimin and Redux. Second, to the extent that diet drug recipients manifest FDA Positive levels of regurgitation, they require antibiotic prophylaxis and ongoing medical surveillance to determine if there is progression in their condition such that further medical treatment or intervention is appropriate. (Tr. 5/3/00 at 102-103.) Finally, if diet drug

recipients have or develop serious levels of regurgitation (defined as either severe regurgitation or moderate regurgitation with dilatation, hypertrophy, reduced ejection fraction, or pulmonary hypertension) then such individuals suffer disabling conditions for which substantial compensation is warranted.

2. The Risk of Primary Pulmonary Hypertension ("PPH")

PPH is a disease that affects pulmonary circulation. PPH is characterized by scarring and fibrosis of the pulmonary arteries which carry deoxygenated blood from the right side of the heart to the lungs. This scarring prevents the blood cells from effectively absorbing oxygen as they pass the alveoli in the lungs. Moreover, the scarring within the pulmonary arteries obstructs the flow of blood within the vessels, causing the blood pressure in the pulmonary arteries pressure to rise. The right ventricle of the heart attempts to overcome the increasing resistance to the flow of blood through the pulmonary arteries by growing larger and more muscular. Ultimately, this dilatation and hypertrophy of the right ventricle will cause the heart to fail and result in the patient's death. (Tr. 5/2/00 at 223-27 & 231-32.)

PPH is a relentlessly progressive disease that leads to death in virtually all circumstances. The only approved treatment for the disease involves the administration of a drug known as Prostacyclin ("Flolan"), which must be administered continuously through an intravenous pump. Flolan is not a cure for the disease. If it is used successfully, it can reduce the patient's symptoms and delay

death for a few years. Administration of the drug is accompanied by a high incidence of serious complications. The drug can cause death if administered to patients who do not suffer from PPH, and is thus contraindicated for use in such patients. (Tr. 5/2/00 at 237-245.)

The proper diagnosis of primary pulmonary hypertension is extremely important for two reasons. First, the diagnosis is accompanied by enormous psychological trauma to the patient because it is a virtual death sentence. Second, proper diagnosis is important because the treatment administered as a result of the diagnosis is extraordinarily dangerous in patients who do not, in fact, suffer from the disease. (Tr. 5/2/00 at 236-38, 242-43.)

The community of physicians with expertise in diagnosing and treating PPH have repeatedly reached a consensus concerning the appropriate criteria for diagnosing and defining the disease. This consensus was expressed at the World Health Organization meeting in 1973, in a statement of the American College of Chest Physicians in 1993 and in the Executive Summary of the World Symposium on Primary Pulmonary Hypertension in 1998. In addition, this "consensus definition" of PPH was expressed in every major epidemiologic study concerning the disease that has ever been done. The consensus for defining and diagnosing PPH has three elements. The first of the three criteria necessary to make a diagnosis of primary pulmonary hypertension is a mean pulmonary artery pressure ≥ 25 mm Hg at rest or ≥ 30 mm Hg with exercise as measured at cardiac catheterization.²

² Doppler echocardiography does not accurately assess pulmonary artery pressure in a consistently reliable way.

(Tr. 5/2/00 at 230-31, 254-55, 259-62, 265 & 268-69; Tr. 5/3/00 at 13.)

There are many conditions aside from PPH that can cause an elevation in pulmonary artery pressure. These include systemic hypertension (i.e., "high blood pressure") and a variety of diseases which affect the left side of the heart including cardiomyopathy, mitral stenosis, pulmonary vein obstruction, a stiff left ventricle, and like conditions. Because PPH is a disease that originates in the pulmonary arterial system, patients with the disease will have normal pressures in the left side of their heart even though they have abnormal pressures in the right side of their heart. In contrast, patients who have conditions other than PPH that result in an elevated pulmonary artery pressure will have an elevation in the "pulmonary capillary wedge pressure" which accurately reflects the pressure in the left atrium. The only way to measure pulmonary capillary wedge pressure is through a cardiac catheterization. Accordingly, the second criterion necessary for the diagnosis and treatment of PPH is the presence of a "normal" pulmonary capillary wedge pressure of ≤ 15 mm Hg. (Tr. 5/2/00 at 230-31, 258-62, 266, 268-69 & 279-80; Tr. 5/3/00 at 13, 53-54.)

Finally, PPH is a diagnosis of exclusion. Therefore, in order to reach the diagnosis, all "secondary" causes of pulmonary hypertension must be excluded. These include diseases known to be associated with pulmonary hypertension such as collagen vascular

Pulmonary artery pressure can, however, be accurately be measured by cardiac catheterization.

disease, congenital systemic to pulmonary shunts, portal hypertension, toxin-induced lung disease, significant obstructive sleep apnea, interstitial fibrosis (such as silicosis, asbestosis, or granulomatous disease), HIV infection and others. (Tr. 5/2/00 at 17, 19-20.)

The normal incidence of PPH in the population is 1 to 2 new cases per million people per year. Two well done epidemiologic studies establish that the use of fenfluramine and dexfenfluramine cause PPH. (Exs. P-209 & P-175.) In 1996, Dr. Abenhaim and his colleagues published the results of the International Primary Pulmonary Hypertension Study. This study demonstrated that the risk of developing PPH in individuals who used fenfluramine longer than three months increased twenty-three fold. (Ex. P-209.) In March of 2000, the journal CHEST published the results of an epidemiologic study entitled the Surveillance of North American Pulmonary Hypertension. This study confirmed the association between the use of fenfluramine derivatives and PPH. (Ex. P-175.)

E. The Legal Circumstances of the Class

Diet drug recipients have faced and will continue to face significant legal obstacles in obtaining appropriate relief. First, the statutes of limitation in various states pose significant obstacles to recovery. Most jurisdictions have a "discovery rule," which holds that an individual must commence suit within a specified period of time after he or she knows, or in the exercise of reasonable diligence, should have known that they have suffered an

injury and that it was caused by the defendant. See e.g., Pearce v. Salvation Army, 674 A.2d 1123, 1125 (Pa. Super Ct. 1996); Cochran v. GAF Corp., 666 A.2d 245 (Pa. 1995); HECI Exploration Co. v. Neel, 982 S.W.2d 881, 886 (Tex. 1998). Pondimin and Redux were withdrawn from the market in September 1997 accompanied by an unprecedented amount of publicity which effectively warned diet drug users that they may have developed valvular lesions which could be detected through non-invasive echocardiograms. Also, these lesions are not latent. If they are going to occur, they are going to occur during drug use (or shortly thereafter) and be demonstrable on echocardiogram. Therefore, AHP has an argument that diet drug users, acting with reasonable diligence, should have learned that they had heart valve damage as a result of using Pondimin and Redux beginning with the withdrawal of the drugs from the market in September 1997. Since most states have statutes of limitation of two years or less, AHP could argue that the statute of limitations has run on claims of valvular heart damage by most diet drug recipients. Even though there are approximately 18,000 individuals who have commenced actions against AHP, at present this means that a substantial number of viable claims by diet drug recipients could be time-barred. (Tr. 5/2/00 at 34-35.)

Moreover, because of vagaries in the law governing recovery for potentially progressive injuries, the damage claims of individuals who are not presently suffering from serious diet drug-induced VHD

are potentially subject to the following types of resolution by the courts:

1. many courts may hold that such plaintiffs are not entitled to any recovery of damages at the present time because they do not have a "symptomatic" injury, but that a cause of action will accrue in the future without a statute of limitations time bar if their disease progresses to a symptomatic level;
2. many courts may hold that plaintiffs can recover compensatory damages for asymptomatic valve disease today and that a separate cause of action may accrue in the future, without a statute of limitations time bar, in the event that their disease progresses to a more serious level; and
3. many jurisdictions may hold that claimants can recover compensatory damages for their asymptomatic valvular heart disease at the present time, but will never recover for the risk of future progression because that risk is too speculative, does not meet "more likely than not" standards, and/or because valvular heart disease is not subject to a "two disease" rule that recognizes the accrual of two separate causes of action where there are more serious manifestations of an underlying disease process.

(Tr. 5/2/00 at 34-35.) Thus, it would be beneficial for diet drug recipients to obtain appropriate legal protections such that they have a viable claim for relief when, as, and if, they discover they have either FDA Positive levels of regurgitation or that they have serious VHD.

F. The Settlement

1. The Class

On October 12, 1999, a complaint entitled Brown v. American Home Products Corporation was filed in this action. (Class Action Compl. Ex. P-1; Am. Class Action Compl. Ex. P-2; Second Am. Class Action Compl. Ex. P-65.) The Brown Complaint was filed as a vehicle

for combining the claims of class members asserted in pending federal and state diet drug litigation throughout the country into a single complaint to facilitate class action treatment of those claims for settlement purposes. (Tr. 5/2/00 at 56-57.) The Settlement Agreement was reached with respect to a class consisting of all persons in the United States who ingested Pondimin and Redux and their associated consortium claimants. (Ex. P-3 at 19 of 148.) The class includes 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.

(Ex. P-3 at 19-21 of 148.)

2. The Benefits of the Settlement

a. Medical Monitoring, Medical Screening and Matrix Compensation Benefits

The Settlement Agreement provides that all persons who took diet drugs for 61 days or more who were not diagnosed as "FDA Positive" by September 30, 1999 (i.e., members of Subclass 1(b) as defined above) are entitled to receive a state-of-the-art transthoracic echocardiogram and a consultation with a cardiologist concerning the results of that echocardiogram. (Ex. P-3 at 34 of 148.) The Settlement Agreement makes certain provisions for members of Subclass 1(a) (those who took diet drugs for 60 days or less) to obtain monitoring relief in certain circumstances. In particular, members of Subclass 1(a) are entitled to recover the net out-of-pocket costs which they incur for echocardiograms conducted during the screening period if they are diagnosed as having FDA Positive valvular regurgitation. (Ex. P-3 at 35-36 of 148.) In addition, the Settlement Trustees may, at their discretion and in appropriate cases for compassionate and humanitarian reasons, provide a transthoracic echocardiogram and an associated interpretive

physician visit for members of Subclass 1(a).³ (Ex. P-3 at 36 of 148.) In addition, the Settlement Agreement provides that members of Class 1(a) and 1(b) can obtain echocardiograms upon trial court approval of the settlement in the case of financial hardship.⁴ (Ex. P-3 at 37 of 148; Ex. P-32 at 2 of 13.)

The period of time provided during which echocardiograms described in the foregoing findings are to be completed under the terms of the Settlement Agreement (the "Screening Period") is 12 months from the date on which the settlement receives "Final Judicial Approval." As defined in the Settlement Agreement, Final Judicial Approval refers to the approval of the Settlement Agreement as a whole by the district court and such approval becoming final by the exhaustion of all appeals, if any, without substantial modification of the order or orders granting such approval. The court may extend the Screening Period for an additional six months for cause shown. (Ex. P-3 at 10 & 12 of 148.) Class members who wish to receive the medical monitoring benefits described above must register to receive such benefits by Date 1, which is 210 days after the date of Final Judicial Approval. (Ex. P-3 at 9 & 34-36 of 148.)

The medical monitoring benefits are to be furnished free of charge by a Trust Fund established under the Settlement Agreement as described in greater detail below. (Ex. P-3 at 34-36 of 148.) It

³ The amount which may be expended under the Settlement Agreement to provide this benefit, in the aggregate, may not exceed \$20 million.

⁴ The aggregate amount available under the settlement to provide this benefit to Class Members is limited to \$10 million.

is expected that the Trust will contract with a network of approximately 10,000 board certified or board eligible cardiologists located throughout the country who are qualified to perform and interpret echocardiograms and to consult with patients concerning the results of those echocardiograms. (Tr. 5/2/00 at 69; Tr. 5/9/00 at 25-31.) This network will be sufficiently extensive to provide class members with the opportunity to choose among several conveniently located cardiologists to perform the monitoring services provided by the Settlement Agreement regardless of whether class members reside in a rural or urban setting. (Tr. 5/2/00 at 69; Tr. 5/9/00 at 25-31.) It is expected that, on average, the Trust's cost to provide an echocardiogram and interpretive physician visit pursuant to the Settlement Agreement will average approximately \$800 per class member. (Tr. 5/2/00 at 69; Tr. 5/9/00 at 31.)

Each class member who is diagnosed as having Mild Mitral Regurgitation by the end of the screening period and who registers as such by a date which is 120 days after the end of the Screening Period (defined in the Settlement Agreement as "Date 2") will be entitled to recover compensatory damages pursuant to a settlement "matrix" in the event that they develop serious levels of mitral regurgitation by the year 2015, or, alternatively, each such person may exercise a "back-end opt-out." (Ex. P-3 at 38-56 & 61-63 of 148.) With respect to any class member who properly and timely exercises a right of back-end opt-out, AHP may not raise a defense

based on a statute of limitations or repose or a defense based on improper splitting of a cause of action. By the same token, any class member exercising a back-end opt-out may not recover punitive, exemplary or multiple damages against AHP, and may not use any prior verdicts or judgments against AHP under the doctrines of collateral estoppel, res judicata, or other doctrine of issue or claim preclusion. (Ex. P-3 at 61-63 of 148.)

If a class member learns that he or she has FDA Positive levels of regurgitation after September 30, 1999 but before the end of the Screening Period, that individual has the right to opt out of the settlement and to pursue a claim for compensatory damages in the tort system without meeting the bar of the statute of limitations or a defense of splitting of causes of action and without relying on any prior verdicts or judgment against AHP under the doctrines of collateral estoppel, res judicata, or other doctrine of issue or claim preclusion. This "intermediate opt-out" right is in addition to the initial opt-out right of all class members. (Ex. P-3 at 57-60 of 148.)

Those individuals who have FDA Positive levels of regurgitation but do not exercise an initial or intermediate opt-out right have the right to receive medical services from the Settlement Trust to the extent appropriate to monitor their VHD. Such services may include periodic medically appropriate echocardiograms, cardiology consultations, chest x-rays, laboratory studies, electrocardiograms and other services necessary and appropriate to determine the

cardiac status of individuals who have FDA Positive levels of valvular regurgitation. (Ex. P-3 at 38 of 148.) Class members may elect to receive cash in lieu of the provision of such services. For class members who took diet drugs 61 or more days and who have FDA Positive levels of regurgitation, the settlement provides that they shall receive \$10,000 in medical services or \$6,000 in cash. For class members who took AHP's diet drugs for 60 days or less, the agreement provides that they shall receive \$5,000 in medical services or \$3,000 in cash.⁵ (Ex. P-3 at 34-36 & 38 of 148.)

Finally, if class members with FDA Positive levels of regurgitation progress to serious levels of VHD by the year 2015, they will have a right, as such conditions occur, to receive compensation pursuant to the terms of the settlement matrices or to exercise a "back-end opt-out" and pursue their claim for compensatory damages (but not punitive damages) in the tort system

⁵ Dr. McClellan concluded that the "additional medical services" benefits provided under Fund A would be more than adequate to pay for the possible medical expenses of class members who are found to be FDA Positive but who do not have Matrix-level conditions. Relying on guidelines for the care of such patients, the reports of other experts in this proceeding and his own clinical experience, Dr. McClellan testified that such patients would need at least one follow-up echocardiogram, minimal additional cardiac screening during their periodic physical examinations, antibiotic drugs prior to certain medical procedures and perhaps additional echocardiograms in the future. Dr. McClellan concluded that the benefits provided to class members are more than adequate to pay for this limited additional care. (AHP Ex. 614 ¶¶ 18-23.) See generally, AHP Ex. 111; AHP Ex. 117; AHP Ex. 577; AHP Ex. 600; and AHP Ex. 601. No evidence was offered at the Fairness Hearing to suggest that the amounts provided under Fund A would be inadequate to pay for necessary medical care for class members qualifying for payments from Fund A.

without any time bar or other defense arising from a statute of limitations, a statute of repose or the like. (Ex. P-3 at 38-56, 61-63 of 148.) Class members who progress to more serious levels of valvular heart disease have the right to "step up" to higher amounts of compensation as those levels occur pursuant to the settlement matrices. (Ex. P-3 at 38-56 of 148.)

There are four matrices under the settlement. Matrix A-1 describes the compensation available to diet drug recipients with serious VHD who took diet drugs for 61 days or longer, who are registered as having FDA Positive levels of valvular regurgitation by Date 2 and who do not have any of the alternative causes of VHD that make the B matrices applicable. (Ex. P-3 at 39-55 of 148.) Matrix A-2 describes the compensation available to spouses, parents, children and significant others of diet drug recipients entitled to compensation on Matrix A-1. (Ex. P-3 at 39-55 of 148.)

Matrix B-1 describes the compensation available to class members with serious VHD who were registered as having only Mild Mitral Regurgitation by the close of the Screening Period, or who took diet drugs for 60 days or less, or who have factors that would make it difficult for them to prove that their VHD was caused by the use of diet drugs. Id. These conditions include most conditions that are objectively identifiable as causes of VHD independent of the use of diet drugs. (Ex. P-3 at 39-55 of 148.) Matrix B-2 describes the compensation available to the spouses, parents,

children and significant others of those entitled to compensation on Matrix B-1. (Ex. P-3 at 39-55 of 148.)

The matrices are composed of cells formed by the intersection of five separate matrix levels of severity and 11 separate age intervals ranging from diet drug recipients who are less than or equal to 24 years old to diet drug recipients who are 70 to 79 years of age. Generally, the amount of compensation provided by the matrices decreases with age both because younger individuals have a longer damage period and because, as discussed above, age increasingly confounds the effects of diet drugs in producing valvular regurgitation. (Tr. 5/2/00 at 76-77.)

The levels of VHD described on the settlement matrices correspond with the medical consensus regarding the stages of serious VHD. Level I describes those individuals who either have severe regurgitation or have suffered bacterial endocarditis. Level II describes those individuals with moderate to severe regurgitation who have evidence of changes in their cardiac status such as hypertrophy, dilatation, reduced ejection fraction, pulmonary hypertension and the like. Level III describes those individuals who have or need valvular repair or replacement surgery. Level IV describes those individuals who suffer from either complications of valvular surgery or whose disease has progressed to the point that surgery is not an effective remedy. Level V describes those individuals whose VHD is so far advanced that it is terminal. (Ex. P-95 ¶ 48; Ex. P-3 at 40-50 of 148.) Each cell formed by the

intersection of an age interval with a severity level describes the amount of compensation to which a claimant meeting those criteria is entitled.

Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred. (Ex. P-3 at 38-56.)

In addition, the amounts specified by each cell of each matrix will be increased by 2% per year to provide protection against inflation for individuals who qualify for such payments in the future. This two percent increase is sufficient protection against inflation given the historical annual rate of change in the consumer price index. (Tr. 5/2/00 at 78; Ex. P-3 at 55-56 of 148; Ex. P-94 at 3 of 41.)

Under the Settlement Agreement, the determination of a matrix benefit is not subject to the exercise of discretion by the Administrators of the Settlement or by any court. Rather, benefits determinations are based on the sworn certification of a board certified physician--primarily a board certified cardiologist or cardiothoracic surgeon--that a class member either has or does not have each of the conditions applicable under the settlement matrices. (Tr. 5/2/00 at 79; Ex. P-3 at 101-02 of 148.)

In order to prevent fraud, the settlement requires the Trustees to perform a quarterly audit of five percent of the total claims for Matrix Compensation Benefits in accordance with a plan of audit adopted by those responsible for administration of the settlement. In addition, the settlement permits AHP to submit additional claims for quarterly audit of up to 10% of the matrix claims submitted and 10% of the non-matrix claims submitted.⁶ (Ex. P-278 ¶ 31.) The audit procedure requires those responsible for administration of the settlement to gather all medical records relevant to the audited claim and forward them to a highly qualified independent board certified cardiologist who is responsible for making a determination as to whether or not there was a reasonable medical basis for the representations made by any physician in support of the claim. (Ex. P-3 at 111-15 of 148.) If the auditing cardiologist makes the determination that there was a reasonable medical basis to support the class member's claim and there is no substantial evidence that fraud was committed in connection with the claim, the claim is to be allowed. Id. If not, those responsible for the administration of the settlement are required to apply to the court for relief. Id. The relief available to the court upon such an application includes an order disallowing the claim, an order directing an additional audit of other claims involving the same attorney and/or physician

⁶ In connection with AHP initiated audits, AHP has a right to obtain, at its expense, an independent transthoracic echocardiogram of a claimant who has made a claim for matrix benefits upon a demonstration of cause as specified in the Settlement Agreement. Id.

who was involved in the claim, an order directing such other additional audits as may be appropriate, an order imposing penalties including the payment of costs and attorneys fees and an order making a referral of the matter to the United States Attorney or other appropriate law enforcement officials for criminal prosecution if there is probable cause to believe that the claim was submitted fraudulently. Id.

b. Prescription Reimbursement Benefits

The average Redux prescription cost \$54.82 per month. The average Pondimin prescription cost \$29.22 per month. Class members arguably had a right to recover these prescription costs under the consumer fraud theories advanced in many jurisdictions. Under the Settlement Agreement, class members who took diet drugs for 60 days or less have the right to receive reimbursement of the costs of purchasing Pondimin and/or Redux at the rate of \$30 per month for prescriptions of Pondimin and \$60 per month for prescriptions of Redux. Eligible class members must register for this benefit by Date 1. (Ex. P-3 at 35 of 148.) Class members who took diet drugs for 61 days or more have the right to receive reimbursement for the cost of their Pondimin and/or Redux prescriptions, subject to a maximum payment of \$500 and further subject to the availability of money within Fund A after payment of all other benefits. Eligible class members must register for this benefit by Date 1. (Ex. P-3 at 35 of 148.)

c. Reimbursement of Echocardiogram Expenses

Under the consumer protection laws of many states, class members arguably had the right to recover the cost of echocardiograms which they incurred as a consequence of their exposure to Pondimin and Redux. Under the Settlement Agreement, class members have the right to be reimbursed the net out-of-pocket expenses of obtaining echocardiograms outside of the medical monitoring program subject to the availability of money within Fund A after payment of all other benefits except prescription reimbursement benefits for those who took diet drugs 61 days or longer. Eligible class members must register for this benefit by Date 1. (Ex. P-32 ¶ 2.)

d. Establishment of a Medical Research Fund

The Settlement Agreement requires the establishment of a \$25 million fund to be used to finance medical research and education related to heart disease. Specifically, the settlement requires the creation of a non-profit corporation named the "Cardiovascular Medical Research and Education Fund" to be managed by a Board of Directors consisting of seven persons. Twenty five million dollars in Settlement Funds are to be provided to the corporation. The corporation is required to solicit proposals for grants to physicians, scientists, researchers, healthcare providers and others for purposes of performing medical research or providing medical education concerning heart disease which will be beneficial to the settlement class. The corporation may provide individual grants not to exceed \$2 million in response to such proposals upon a finding

that the research or educational proposal made by the grant applicant will benefit the members of the class and the grant applicant undertakes, in writing, to submit the results of any research conducted pursuant to any grant proposal for publication by a peer reviewed journal. (Ex. P-3 at 36-37 of 148; Ex. P-7.)

e. Establishment of a Registry/Database

In order to obtain benefits under the Settlement Agreement, all class members must submit one of several claim forms which requires: (1) basic personal information including the age and gender of the claiming class member; (2) information about both the use of Pondimin and Redux and the period of time during which it was used; (3) if the claim is based, in whole or in part, on the results of an echocardiogram, a copy of both the report of the echocardiogram and the videotape or computer disk on which the image of the echocardiogram is stored; and (4) if the claimant is making a claim for matrix benefits, relevant information from a board certified cardiologist on the claimant's condition and certain medical records. (Ex. P-3 at 87-91 of 148; Exs. P-12, P-17, P-24 & P-25.) Class members may either furnish the requested information directly or have the Settlement Administrators obtain it through execution of appropriate authorizations. (Ex. P-3 at 87-91 of 148; Exs. P-12, P-17, P-24, & P-25.)

This information is to be recorded in a computerized database suitable for use with standard medical research software and maintained as a "registry" for purposes of administering the

settlement and for purposes of medical education and research. (Ex. P-3 at 91-95 of 148.) After redaction of all patient identifying information, the registry/database is to be made available to persons who: (1) provide written proof of their training, qualifications and experience to conduct medical research; (2) provide a research protocol setting forth the purposes for which they seek access to the registry, the research methodology, source of funding and a description of how the proposed research will benefit the settlement class; (3) undertake, in writing, to use the information they receive from the registry solely for medical, scientific and educational purposes; (4) undertake upon completion of the research to provide the Settlement Administrators, the court, AHP and Class Counsel with a copy of any publication based in whole or in part on the information contained in the registry; and (5) undertake not to testify at any time on behalf of any party in any lawsuit relating to the use of Pondimin and/or Redux.

(Ex. P-3 at 91-95 of 148.)

f. The Public Health Benefits of the Settlement

The benefits provided by the Settlement Agreement will significantly contribute to the protection and advancement of the public health. Specifically, the provision of screening echocardiograms under the settlement will allow for early diagnosis of individuals with asymptomatic VHD. Such early diagnosis will permit these individuals to receive antibiotic prophylaxis when having dental and surgical procedures, thereby minimizing the risk

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

g. Exit Rights

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

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

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

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

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

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

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

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

3. Creation of a Settlement Trust

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

supervision of the court), administering the trust, providing the benefits contemplated by the Settlement Agreement and conducting the audits contemplated by the Settlement Agreement.⁸ It is also required to issue regular reports to the court concerning these matters. (Ex. P-3 at 22-24, 73-81 & 100-15 of 148; Ex. P-4.) Pending the creation of the Trust, the functions of the Settlement Trust are to be performed by Interim Claims Administrators and an Interim Escrow Agent. (Ex. P-3 at 70-73 of 148.) On November 23, 1999, the Court appointed Gregory P. Miller, Esquire and the Honorable C. Judson Hamlin to serve as Interim Claims Administrators. Mr. Miller is an experienced trial lawyer who has served as Special Discovery Master in MDL 1203. Judge Hamlin served as a judge in the Superior Court of the State of New Jersey handling mass tort litigation until his retirement from that position in 1998. He has functioned as Special Settlement Master with respect to the Diet Drug Litigation pending in the state of New Jersey. (Tr. 5/9/00 at 18-20 & 54-56.) In Pretrial Order No. 1010, dated December 6, 1999, the court appointed PNC Bank to serve as Interim Escrow Agent.

The Settlement Agreement contemplates that there will be seven Trustees who will serve until the year 2005, and that, thereafter, there will be three Trustees for the Settlement Trust. (Ex. P-3 at 22 & 70 of 148.) By Pretrial Order No. 1159, the court appointed

⁸ The Settlement Trust is to be structured and managed to qualify as a Qualified Settlement Fund under Section 468B of the Internal Revenue Code. (Ex. P-3 at 28 of 148.)

the following individuals to serve as Trustees for the Settlement Trust: Joseph L. Castle, II, Radnor, Pennsylvania; George A. Beller, M.D., Charlottesville, Virginia; Honorable Richard S. Cohen, New Brunswick, New Jersey; Senator Chris Harris, Arlington, Texas; Ms. Alison Overseth, New York, New York; Rose-Marie Robertson, M.D., FACC, Nashville, Tennessee; and Honorable Dean M. Trafelet, Chicago, Illinois. Although the court has issued an order appointing Trustees to the Settlement Trust, the Trust had not been formally organized as of the date of the Fairness Hearing. (Tr. 5/9/00 at 49.)

4. The Settlement Fund

The settlement requires the creation of two separate funds to provide benefits to class members. "Fund A" is intended to provide funding to pay for all non-matrix benefits available under the Settlement Agreement to class members and the associated costs of administering those benefits. "Fund B" is intended to provide funding to pay for matrix benefits for class members and the associated costs of administering those benefits.

Under the agreement, AHP is required to make payments into Fund A as follows: (1) \$50 million 5 business days after preliminary approval; (2) \$383 million 5 business days after trial court approval; (3) \$383 million 180 days after the preceding payment of \$383 million; and (4) \$184 million 5 business days after Final Judicial Approval. (Ex. P-3 at 22-23 of 148.)

With respect to Fund B, AHP agrees to have \$2.55 billion

available for Fund B payments which the Trustees may reasonably draw upon. (Ex. P-278 ¶ 4.) In any given quarter, to the extent that the \$2.55 billion is not drawn upon, such amount accrues interest at one and a half percent per quarter or six percent a year, which carries forward to increase the available amount. Any remaining balance from Fund A is also included in Fund B. In addition, AHP receives credits against this amount for payments made to those who exercised an initial opt out right. These credits are capped at \$300 million, which AHP cannot apply until year 5. (Ex. P-278 ¶ 33.) AHP also receives credits for payments made to those who exercise a back-end opt out right. The amount of both of these types of credits is the lesser of the payment AHP makes to the claimant or the matrix level for which such claimant would be entitled to under the Settlement.

Clearly, AHP has adequate financial coverage to meet these obligations. Dr. Rosen, who testified at the May 2000 proceedings and again on August 10, 2000, examined several AHP financial reports and statements and stated that AHP currently has approximately \$2.6 billion in cash and marketable securities. (Tr. 8/10/00 at 107.) In addition, Dr. Rosen testified that AHP continues to generate better than half a billion dollars per quarter, or approximately \$2.3 billion per year.

The court is also satisfied that Funds A and B are sufficient to provide the necessary benefits under the Settlement Agreement. To analyze the adequacy of the funding for Fund A and Fund B, the

experts who testified at the Fairness Hearing relied on a number of considerations, including: (1) the number of potential class members; (2) the participation rate in the Settlement; (3) the proportion of participants who took fenfluramine and/or dexfenfluramine 61 days or more; (4) the proportion of participants who will be diagnosed to have FDA Positive levels of regurgitation; (5) the costs of providing echocardiograms within the Screening Program; (6) the cost of reimbursing certain echocardiograms; (7) administrative costs; (8) costs for the registry and research funds; (9) rates of possible progression to severe levels of regurgitation among class members with FDA Positive levels of regurgitation or mild mitral regurgitation; (10) progression among class members who will receive Matrix-level benefits to higher levels of the Matrix grid; and (11) the proportion of patients who have conditions entitling them to Matrix-level benefits who will receive benefits from the B Matrix rather than the A Matrix. (AHP Ex. 614 ¶¶ 9-16, 24, 26, 32-37; Ex. P-94 at 3-7.)

The experts used conservative assumptions likely to overstate the demands on Fund A and Fund B. Dr. McClellan (1) assumed a higher participation rate in the Settlement than has been seen to date; (2) assumed that a significantly higher proportion of class members who used the diet drugs for 61 days or longer would participate in the Settlement than would class members who used the drugs for 60 days or less; (3) did not take into account scientific evidence of regression of regurgitation in Diet Drug Recipients; (4)

assumed higher prevalence rates of regurgitation than have been seen in Diet Drug Recipients; and (5) assumed progression to Matrix-level conditions despite the lack of evidence supporting appreciable progression among users of fenfluramine and dexfenfluramine. Dr. Kursh used similar assumptions. (AHP Ex. 614 ¶¶ 10, 16 & 32; Tr. 5/9/00 at 133-35; Ex. P-94 at 3-7.)

Employing these conservative assumptions, Dr. McClellan concluded that Fund A would not come close to exhaustion. Under Dr. McClellan's "base case," only \$786 million of the \$1 billion committed for Fund A would be used. (AHP Ex. 614 ¶ 25, Ex. C; Tr. 5/9/00 at 125.) The remaining funds would be available to pay for drug refunds to class members who used fenfluramine and/or dexfenfluramine for 61 days or longer and to reimburse class members for echocardiograms obtained outside the Screening Period. (Ex. P-32 at 2-3 of 13.)

With respect to Fund B, Dr. Kursh testified that, assuming a 100% participation rate in the settlement, the cost of paying matrix level benefits was \$3.88 to 4.55 billion present value. (Tr. 8/10/00 at 97.) Dr. Kursh relied on previous analyses done by Drs. Karalis and Goodman, whose declarations were admitted at the Fairness hearing held in this court in May 2000. Dr. Rosen testified that \$2.55 billion was a sufficient amount to cover all of the matrix claims likely to be filed in this Settlement. (Tr. 8/10/00 at 102.) Dr. Rosen relied on Dr. Kursh's testimony, the provisions in the Fourth Amendment to the Settlement Agreement, the

prior declarations and analyses of Drs. Karalis and Goodman and a comparison of participation rates in other classes. Dr. Rosen concluded the payment structure contemplated under the Fourth Amendment would be sufficient to bear a 76%-90% participation rate. Dr. Rosen testified that prior to the Fourth Amendment, the amount provided under the Agreement was sufficient to bear 66%-79% participation. (Tr. 8/10/00 at 105-06.) Dr. Rosen also testified that, considering other classes in other cases, a participation rate of 30%-40% was considered a high participation rate. Id. (Tr. 8/10/00 at 105-06.)

No evidence was offered at the Fairness Hearing suggesting that the amounts to be paid into Fund A or Fund B are, or are likely to become, inadequate to pay for the benefits to be provided under the Settlement. No evidence was offered at the Fairness Hearing suggesting that the assumptions employed by the experts would understate the demands for benefits under the Settlement. Based on the methods and evaluations employed by these experts, the court is satisfied the amounts provided in Funds A and B are sufficient to provide all likely benefits under the Settlement Agreement.

5. Treatment of PPH Under the Settlement Agreement

Under the terms of the Settlement Agreement, PPH is defined as follows:

For a diagnosis based on examinations and clinical findings prior to death:

Mean pulmonary artery pressure by cardiac catheterization of ≥ 25 medical monitoring Hg at rest or ≥ 30 medical monitoring Hg with

exercise with a normal pulmonary artery wedge pressure \leq 15 medical monitoring Hg; or
A peak systolic pulmonary artery pressure of \geq 60 medical monitoring Hg at rest measured by Doppler echocardiogram utilizing standard procedures; or

Administration of Flolan to the patient based on a diagnosis of PPH with cardiac catheterization not done due to increased risk in the face of severe right heart dysfunction; and

Medical records which demonstrate that the following conditions have been excluded by the following results:

- (a) Echocardiogram demonstrating no primary cardiac disease including, but not limited to, shunts, valvular disease (other than tricuspid or pulmonary valvular insufficiency as a result of PPH or trivial, clinically insignificant left-sided valvular regurgitation), and congenital heart disease (other than patent foramen ovale); and
- (b) Left ventricular dysfunction defined as LVEF $<$ 40% defined by MUGA, Echocardiogram or cardiac catheterization; and
- (c) Pulmonary function tests demonstrating the absence of obstructive lung disease ($FEV_1/FVC >$ 50% of predicted) and the absence of greater than mild restrictive lung disease (total lung capacity $>$ 60% of predicted at rest); and
- (d) Perfusion lung scan ruling out pulmonary embolism; and
- (e) If, but only if, the lung scan is indeterminate or high probability, a pulmonary angiogram or a high resolution angio computed tomography scan demonstrating absence of thromboembolic disease; and

- (f) Conditions known to cause pulmonary hypertension, including connective tissue disease known to be causally related to pulmonary hypertension, toxin induced lung disease known to be causally related to pulmonary hypertension, portal hypertension, significant obstructive sleep apnea, interstitial fibrosis (such as silicosis, asbestosis, and granulomatous disease) defined as greater than mild patchy interstitial lung disease, and familial causes, have been ruled out by a Board-Certified Cardiologist or Board-Certified Pulmonologist as the cause of the person's pulmonary hypertension.

-OR-

For a diagnosis made after the individual's death:

Autopsy demonstrating histopathologic changes in the lung consistent with primary pulmonary hypertension and no evidence of congenital heart disease (other than a patent foramen ovale) with left-to-right shunt, such as ventricular septal defect as documented by a Board-Certified Pathologist; and Medical records which show no evidence of alternative causes as described above for living persons.

(Ex. P-3 at 12-15 of 148.)

This definition is consistent with the long standing consensus in the medical community with respect to the proper definition of the disease, except to the extent that it permits the diagnosis of PPH based on pulmonary artery pressure ≥ 60 mm Hg as determined by Doppler echocardiography--and is thus somewhat over-inclusive. The evidence before the court, including the testimony of all three experts who addressed this issue and the consensus statements in the

relevant medical literature, confirm that the definition of PPH set forth in the Settlement Agreement is the accepted definition in the field. (Tr. 5/2/00 at 267; Tr. 5/3/00 at 15 & 16.)

Dr. Barst, an expert in cardiology and pulmonary medicine with a specialty in the treatment of primary and secondary pulmonary hypertension, testified that: (1) the definition of PPH in the Settlement Agreement is the definition that has been accepted by experts in the field of cardiology since 1973; (2) right heart catheterization is the appropriate test to assess elevated pulmonary pressures in the context of diagnosing PPH; and (3) the other alternative causes of elevated pulmonary pressure must be excluded to arrive at a proper diagnosis of PPH. (Tr. 5/2/00 at 266; Tr. 5/3/00 at 15; P-97 ¶ 8.) Dr. Weyman, an expert in the fields of cardiology and echocardiography, also testified that the definition of PPH in the Settlement Agreement is medically appropriate and includes what cardiologists would recognize as PPH. (AHP Ex. 610 ¶ 27.) Dr. Shah, an expert in the fields of cardiology and echocardiography, who also treats PPH cases, similarly testified that the PPH definition included in the Settlement Agreement is reasonable. (AHP Ex. 613 ¶ 78.)

Indeed, Drs. Barst, Shah and Weyman all agreed that, if anything, the definition of PPH included in the Settlement Agreement is over-inclusive in that the Settlement Agreement definition allows a class member with an "exceedingly mild case" of PPH to maintain an action against AHP on the basis of his or her PPH claim. (Tr.

5/2/00 at 268; AHP Ex. 613 ¶ 78; AHP Ex. 610 ¶ 27.) There was no expert testimony contradicting the opinions of Drs. Barst, Weyman and Shah or to challenge the definition of PPH in the Settlement Agreement. Moreover, because PPH is a relentlessly progressive disease and because the definition contained in the Settlement Agreement includes individuals with very mild forms of the disease, it is inevitable that any individual who actually has PPH will meet the definition by the time they develop symptoms. (Tr. 5/2/00 at 268, 281-82.)

Under the Settlement Agreement, claims based on PPH, including claims for compensatory, punitive, exemplary or multiple damages based on PPH are not "settled claims." Thus, class members are not precluded by the settlement from instituting, prosecuting or maintaining claims against AHP and the AHP Released Parties with respect to the development of PPH. (Ex. P-3 at 17-18 of 148.) Moreover, the Settlement Agreement provides that "for purposes of any statutes of limitations or similar time bar, the AHP Released Parties shall not assert that a Class Member actually had PPH unless and until the condition of the Class Member meets the definition of PPH set forth in [the Settlement Agreement]." (Ex. P-3 at 119 of 148.) Moreover, the Settlement Agreement provides that "in the event that a Class Member initiates a claim based on PPH, the AHP Released Parties shall not assert a defense based on 'splitting' of claims, causes of action and/or parties by virtue of the fact that Class Member is included in the settlement. . . ." (Ex. P-3 at 119

of 148.) Although the Settlement Agreement does not provide any direct benefits for PPH, it fully preserves the rights of class members to recover against AHP if they have or develop PPH as a result of taking Pondimin and/or Redux. Indeed, the settlement protects Class Members against the running of any statute of limitations with respect to such claims. (Tr. 5/2/00 at 64-65.)

6. Release and Bar Provisions

Effective upon Final Judicial Approval, the Settlement Agreement will release all Settled Claims against Released Parties. (Ex. P-3 at 119 of 148.) Settled Claims are 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. (Ex. P-3 at 17-18 of 148.) Class members are barred from asserting any Settled Claim against AHP or any other Released Party except those class members who timely and properly exercise opt-out rights. (Ex. P-3 at 119 of 148.)

The Released Parties under the Settlement Agreement are AHP, 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. (Ex. P-3 at 15-16 of 148.) Servier, Interneuron, and any manufacturer, seller, wholesaler or distributor of phentermine are not Released Parties.⁹ (Ex. P-3 at 16 of 148.)

7. Attorneys' Fees

The Settlement Agreement provides two vehicles for an award of counsel fees and reimbursement of litigation expenses that serve to limit the amount of class funds which can be paid to compensate class counsel for their services in achieving the relief provided by the settlement. With respect to the benefits afforded by Fund A, the Settlement Agreement requires that AHP deposit the sum of \$200 million in an escrow account to pay for the services of counsel in creating that fund. The amount that will actually be awarded from this escrow account as counsel fees in relation to Fund A is to be determined by the court in accordance with applicable provisions of law. To the extent that any balance remains in the escrow account after payment of any fee awarded by the court, that balance will be returned to AHP. (Ex. P-3 at 134-135 of 148.) The court may order reimbursement of all out-of-pocket costs reasonably related to the creation of Fund A from the fund itself. (Ex. P-3 at 23 of 148.)

⁹ To the extent that any distributor that distributed Pondimin or Redux also distributed phentermine, such distributor is released to the extent it distributed Pondimin or Redux. (Ex. P-278 ¶ 8.)

The Settlement Agreement provides that for purposes of awarding attorneys' fees from Fund B, attorneys' fees should be awarded and paid as a percentage of or otherwise based on the net present value, as of the date of Final Judicial Approval, of the maximum amounts AHP may be legally obligated to pay to Fund B for the benefit of the settlement class pursuant to the principle of law expressed in Boeing v. Van Gemert, 444 U.S. 472 (1980). (Ex. P-3 at 135-136 of 148.) For this purpose, the parties have stipulated and the court finds that the net present value of the maximum amounts which AHP may be legally obligated to pay for the benefit of the class is \$2,550,000,000.00. The amount of the actual attorneys' fees to be awarded to counsel for their services in creating Fund B and securing the benefits that it provides is subject to determination by the court under applicable principles of law. However, Class Counsel have agreed that the amount of such fees shall not exceed \$229 million which is nine percent of the \$2,550,000,000.00 present value amount of Fund B. (Ex. P-3 at 135-136 of 148.)

This cap on the award of common benefit fees in relation to Fund B is consistent with a prior determination by the court that it was appropriate to set aside nine percent of the amount recovered by plaintiffs in MDL 1203 and coordinated state litigation to pay "common benefit fees." See Pretrial Order Nos. 467 & 517. In addition, Class Counsel have the right to apply to the court for reimbursement of costs expended for the common benefit of class members from Fund B. (Ex. P-3 at 28 of 148.) Attorneys for

individual class members who recover Matrix Compensation Benefits are entitled to recover the total attorneys' fees due under the terms of any valid written contingent fee agreement with such class member less the percentage amount awarded by the court to Class Counsel and other attorneys for their services in creating Fund B and securing the benefits it provides. (Ex. P-3 at 135-136 of 148; Ex. P-278 ¶ 37.)

8. The Accelerated Implementation Option

The Settlement Agreement provides an Accelerated Implementation Option ("AIO"). (Ex. P-3 at 59-69 of 148.) For class members who are satisfied with the settlement and who are willing to waive their initial, intermediate and back-end opt-out rights, the AIO provides a means for such class members to obtain the benefits of the settlement without regard to Final Judicial Approval. Id. The AIO may be exercised by any class member. In order to do so, the class member must submit a signed PINK FORM in which the class member waives all opt-out rights and executes a release in favor of AHP and the other Released Parties. (Ex. P-3 at 64 of 148; Ex. P-12.) Upon execution and submission of the completed PINK FORM, AHP is deemed to have entered into a private contract to provide all of the benefits that the class member would be entitled to receive under the Settlement Agreement regardless of whether or not the settlement receives Final Judicial Approval. Id. The start date for receiving benefits pursuant to the AIO is the date on which the trial court

rules (favorably or unfavorably) on whether or not to approve the settlement. (Ex. P-3 at 64 of 148.)

9. Jurisdiction

The United States District Court for the Eastern District of Pennsylvania has original jurisdiction over all provisions of the Settlement Agreement including the creation and operation of the Settlement Trust and the award of attorneys' fees and reimbursement of litigation expenses, pursuant to 28 U.S.C. § 1332. (Ex. P-3 at 130 of 148.)

However, the Settlement Agreement calls upon the court to create a "State Court Judicial Advisory Committee" consisting of the judges from the state courts which, as of October 7, 1999, had issued any order certifying state-wide class actions in relation to the effects of Pondimin and/or Redux. (Ex. P-3 at 130-131 of 148.) The duties of the State Court Judicial Advisory Committee are to provide advice and counsel to the court on all matters pertinent to the settlement, including approval of the settlement, which affect class members residing in the states of each committee member.¹⁰ Id. In addition, prior to making any award of counsel fees and reimbursement of litigation expenses, the court is to consult with and give substantial deference to the views of the members of the State Court Judicial Advisory Committee concerning the actual contribution that was made to the overall resolution of the

¹⁰ A State/Federal Coordination Conference was held in Philadelphia on January 13, 2000, at which the terms of the Settlement were presented to members of the State Court Judicial Advisory Committee.

litigation by the attorneys with whom the members of the committee are familiar. Id. Finally, during the period of time from the date on which Settlement Trust is established until December 31, 2004, the majority of Trustees serving the Trust are to be approved by the State Court Judicial Advisory Committee. Id. On December 7, 1999, by Pretrial Order No. 1014, this court appointed the Honorable Stephen Levin, the Honorable Marina Corodemus, the Honorable Fred Edwards, the Honorable Helen E. Freedman, the Honorable Fred Risovich, II, the Honorable Richard J. Schroeder and the Honorable Ellis E. Reid to serve as members of the State Court Judicial Advisory Committee which has since operated in accordance with the above described provisions of the Settlement Agreement.

II. DISCUSSION

A. Subject Matter Jurisdiction

This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332. The named class representatives are all citizens of Pennsylvania. (Third Am. Compl. ¶¶ 3-8.) Defendant AHP is a Delaware corporation with its principal place of business in Madison, New Jersey. Id. ¶ 9. Thus, complete diversity exists among the parties.

The \$75,000.00 amount in controversy requirement is also met. Plaintiffs seek a comprehensive medical monitoring program. Id. ¶¶ 87-95; see supra, at § II.B.2.a.. In addition, the settlement

provides for a \$25 million medical research fund to examine the relationship between diet drugs and VHD.

In Jeffers v. American Home Products Corporation, the court found that a similar request in a class complaint for medical monitoring which included a research fund was sufficient to meet the jurisdictional amount. See 1999 WL 673066 (E.D. Pa. Aug. 26, 1999); Pretrial Order No. 865 at 9-13 (finding that request for medical monitoring which included research fund met jurisdictional amount); see also Katz v. Warner Lambert Co., 9 F. Supp. 2d 363, 364 (S.D.N.Y. 1998) (holding that request for medical research fund satisfied jurisdictional amount). Here, the court adopts the reasoning in Jeffers and the authorities cited therein in support of its having subject matter jurisdiction. See Pretrial Order No. 865 at 9-13.

B. Personal Jurisdiction and Notice Requirements Under Federal Rules of Civil Procedure 23(c)(2) and 23(e).

1. Legal Standards

a. Personal Jurisdiction

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

b. Rule 23(c)(2)

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(c)(2) and 23(e). See Carlough v. Amchem Prods., Inc., 158 F.R.D. 314, 324-25 (E.D. Pa. 1993) (stating that requirements of Rule 23(c)(2) are stricter than requirements of Rule 23(e) and arguably stricter than due process clause). Under Rule 23(c)(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(c)(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(c)(2).

c. Rule 23(e)

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) (holding that settlement notice that failed to detail distribution plan was not inadequate); Grunin v. International House of Pancakes, 513 F.2d 114, 122 (8th Cir. 1975) (stating that "[c]lass members are not expected to rely upon the notices as a complete source of settlement information"); Greenspun v. Bogan, 492 F.2d 375, 382 (1st Cir. 1974) (stating that notice need not indicate arguments in favor of and against proposed settlement); Carlough, 158 F.R.D. at 332 (stating that notice need not include entire settlement agreement). 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) (stating that due process requires "notice reasonably calculated under all the circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections").

2. The Notice Plan

The Settlement Agreement provides for an elaborate and extensive plan of notice. This plan was approved by the court in

Pretrial Order No. 997 as "the best notice practicable under the circumstances" and was implemented by the parties pursuant to the terms of the Settlement Agreement and Pretrial Order Nos. 997 and 998. The notice program had two essential parts. The first part of the notice program was designed to make class members aware of the potential risks posed by Pondimin and Redux, of the legal rights arising from the use of those drugs, of the proposed nationwide class action settlement which would resolve such claims and of their opportunity to opt out or object to the Settlement. In addition, the first part of the notice program was designed to inform class members of the opportunity to obtain a court authorized "notice package" describing their legal rights in relation to the settlement by registering to receive the notice package through a 1-800 number (1-800-386-2070) or through the world wide web (www.settlementdietdrugs.com). The second part of the notice program was to provide a detailed "notice package" to each person who had registered through the 1-800 number or web site and to all other class members whose names and addresses were known to the parties.

a. Dissemination

The first part of the notice campaign employed sophisticated media techniques designed to reach all class members. A television commercial was developed.¹¹ This television message was broadcast

¹¹ The text of this television commercial message was as follows:

If you took the diet drug combination known as FenPhen or the diet drugs Pondimin or Redux, you may have heart valve problems and not know it. As a result of a proposed class

106 times over a period of five weeks on network television. The television commercial message was also broadcast 781 times, for six consecutive weeks on various cable networks. (Ex. P-68 at 7-8 of 88.)

A summary notice was prepared for use in the print media. (Exs. P-36; P-81; P-68 at 8-10 of 88.) The summary notice appeared repeatedly in several magazines between January and March 2000.¹² The summary notice appeared as a one-third page black and white ad in four national newspapers, 77 local newspapers, 3 newspapers distributed throughout the U.S. Territories and four newspapers targeted to the Hispanic market.¹³ These newspapers were selected

action settlement, you could be eligible for free medical testing and compensation. But you must act promptly. You must decide whether to participate in this settlement by March 30, 2000. If you do nothing, your legal rights will be affected. Call 1-800-386-2070 today.

The television advertisement also displayed the address of the website that class members could contact in order to obtain the notice package. The text of this television message was approved by the court. (Pretrial Order No. 997; Tr. 5/4/00 at 18; Ex. P-68 at 7-8 of 88; Ex. P-20; Ex. P-52.)

¹² The summary notice appeared ten times between January and February 2000 in the form of a full page black and white advertisement in Parade, People and Time magazines. A full page black and white version of the summary notice was inserted into eight monthly magazines during the month of February including Better Home & Gardens, Ladies Home Journal, Family Circle, McCalls, Women's Day, Redbook, Good Housekeeping and Ebony. Additional insertions of the summary notice appeared as a full page black and white advertisements in the March editions of Better Home & Gardens and Good Housekeeping. In addition, a two page black and white version of the summary notice was placed in Reader's Digest during the months of February and March 2000. (Ex. P-68 at 9 of 88.)

¹³ Each newspaper received four insertions: one in December 1999, two in January 2000, and one in February 2000.

because they were national publications, or because they represented the principal newspapers in the top 15 markets in the United States, or because they were published in geographic areas having the highest usage of Pondimin and Redux and/or because they were targeted to African-American or Spanish speaking populations. (Ex. P-68 at 9-10 of 88.) In addition, the summary form of notice was published in a variety of publications targeted to healthcare providers and pharmacists.¹⁴ Banner ads were also developed for use on the Internet, directing potential class members to the official settlement web site where class members could receive information concerning the settlement and obtain a notice package. These banner advertisements were placed within several media categories on a variety of Internet publishers.¹⁵

In addition to the above, notice was transmitted by mail to all pharmacists in the United States and to doctors who were likely to have prescribed Pondimin or Redux or treated patients for complications resulting from the use of those drugs. Notices to these healthcare providers contained a "notice package," a letter of explanation and a counter card reflecting the summary form of notice described above, which pharmacists and physicians could display to

¹⁴ These included nine primary care physician publications, two internist publications, one baratriitian publication, two endocrinology journals, one psychiatry journal, seven publications targeted to cardiologists and/or echocardiographers, and four pharmacists' publications. Each of these insertions ran throughout January and February 2000. (Ex. P-68 at 10 of 88.)

¹⁵ Specifically, the categories included Keyword Searches, Message Boards, Clubs & Chat, Health Channels and Women's and Health destination sites. Publishers included AltaVista, GoTo, Yahoo, Deja.com, Egroups.com, Women.com., DRKoop.com, Flycast.com., I-village, and Gainesville. (Ex. P-68 at 10 of 88.)

alert patients about the existence of the settlement and the opportunity to obtain a "notice package" by contacting the 1-800 number or official web site. These counter cards contained "tear sheets" that referenced the settlement and contained the 1-800 number and website address which class members could contact to gain further information concerning the settlement. Such mailings were transmitted to 784,128 physicians and to 108,288 pharmacists. (Exs. P-8, P-21, P-40 and P-210; Tr. 5/9/00 at 79-80.)

The media program described above was highly successful.¹⁶ Ms. Krupnick testified that the effectiveness of the publication notice plan was greatly enhanced by the enormous publicity that has surrounded the diet drugs involved in this litigation and the publicity of this Settlement. According to Ms. Krupnick, it is well-understood in the advertising field that a campaign is more effective when there is an existing understanding about an issue or

¹⁶ A sophisticated media analysis demonstrated that 97% of women between the ages of 25 and 54 viewed one or more forms of televised or printed notice an average of 10 times. A reach and frequency analysis indicated that almost 80% of women between the ages of 25 and 54 were exposed to the message contained in the televised or printed forms of notice a minimum of five times. Women between the ages of 25 and 54 account for a vast majority of the use of diet drugs Pondimin and Redux. (Ex. P-68 at 10 of 88.) In addition, a reach and frequency analysis indicated that the settlement message reached 97% of women 35 years and older an average of 11.4 times and that it reached 81% of women 35 years and older a minimum of five times. With respect to African-American women between the ages of 25 and 54, the reach and frequency analysis shows that the settlement message reached 97% of those women an average of 10.2 times and that 79% of African-American women between the ages of 25 and 54 viewed the message a minimum of five times. With respect to men age 25 through 54, 94% viewed the settlement message an average of 6.2 times and 54.3% were reached with the settlement message a minimum of five times. (Ex. P-68 at 10-11 of 88.)

a product. Ms. Krupnick testified that the publicity that occurred prior to the announcement of the proposed Settlement would have given users of Pondimin and Redux a base of knowledge and some understanding of the health concerns associated with the use of these drugs and the fact that they had potential legal remedies in some instances because of their use of the drugs. The coverage of the Settlement itself would also have enhanced the effectiveness of the publication notice of this Settlement. (AHP Ex. 608 ¶¶ 23-24; AHP Ex. 511; AHP Ex. 616.) As of the date of the settlement hearing, 735,289 people had called 1-800-386-2070 and registered to receive a notice package. The notice package was transmitted to each of these 735,289 people. (Tr. 5/9/00 at 80-82.)

The website, www.settlementdietdrugs.com, became fully available on the World Wide Web in January 2000. Individuals could access the website and view and/or download the following: (1) the Settlement Agreement in its entirety; (2) the Table of Exhibits to the Settlement Agreement; (3) Amendments to the Settlement Agreement; (4) the forms (English or Spanish); (5) the class members' Guide (English or Spanish); (6) the Settlement Matrix Guide for Physicians, Attorneys, and class members; (7) the Official Legal Notice (English or Spanish); and (8) a summary of the benefits available to class members. Furthermore, one could sign up to receive the notice package on the website. (AHP Exs. 7 & 507.) Class members were also able to view, download or register to receive the notice package at the official settlement website.¹⁷

¹⁷ As of the date of the hearing, there had been 1,485,371 "page views" of the website, the website was subject to 536,486

In addition, the parties had in their possession or control the names and addresses of 287,108 individuals who had taken Pondimin and Redux, either because such individuals had filed claims against AHP, because they had filed claims against Interneuron, or because their identity was reflected in AHP's corporate records. Notice packages were transmitted by first class mail to each of these 287,108 individuals. (Tr. 5/9/00 at 75-76 & 85; Tr. 5/8/00 at 125-126; Ex. P-287; AHP Ex. 618.)

b. Content

The official notice package approved by the court and transmitted to class members was optimally designed to be read and understood by class members. The Official Court Notice and the brochure were sent in a red and blue 8 ½" by 11" envelope bearing a picture of Pondimin and Redux pills. The text on the envelope read: "Attention: Anyone Who Took 'Fen-Phen,' Pondimin and/or Redux-- Important Notice Inside." The envelope advised recipients that it contained an Official Court Notice and that the information contained within "may have an impact on your legal rights, your health and your future medical expenses." (Ex. P-211.)

The notice itself consisted of several elements. The first component of the notice was a colorful brochure entitled "A Class Member's Guide to Settlement Benefits." It was designed to describe

"user sessions," 349,410 forms had been downloaded from the website; and 87,908 individuals registered on the website to receive notice packages by mail. (Tr. 5/9/00 at 80-84.) As of August 8, 2000, there had been 1,741,720 "page views" of the website, the website was subject to 673,375 "user sessions," 369,093 forms had been downloaded from the website; and 93,778 individuals registered on the website to receive notice packages by mail. (AHP Ex. 646; Tr. 8/10/00 at 56-58.)

the background of the Diet Drug Litigation and the Settlement Agreement in a way that would be read and understood by all class members. Towards this end, it was written in plain English and contained a number of pictures, charts and graphs. (Exs. P-211, P-42 & P-34.) The next element of the notice package was the Official Court Notice of the nationwide Diet Drug Class Action Settlement. This "official notice" contained a detailed description of the Settlement Agreement, typeset in the manner traditionally used to provide legal notice. (Exs. P-211, P-54 & P-35.)

The notice package also included a PINK FORM that class members were required to complete if they elected AIO benefits. The deadline for completing the PINK FORM was either the date on which Final Judicial Approval was obtained or the date on which it was determined that Final Judicial Approval would not be obtained. (Exs. P-211, P-44 & P-33.) The notice package also contained a BLUE FORM that class members were required to complete in order to register to receive settlement benefits in the event that the settlement received Final Judicial Approval. The deadline for completing the BLUE FORM was open-ended. (Exs. P-211, P-24, P-46 & P-38.) The notice package also contained a GREEN FORM that class members and physicians were required to complete in order for class members to obtain Matrix Compensation Benefits now or in the future. This form included a comprehensive guide to Matrix Compensation Benefits to assist class members in completing the form and understanding class members' rights to Matrix Compensation Benefits. This guide contained quotations and illustrations from standard medical texts

which were used to define the concepts relevant to a determination of Matrix Compensation Benefits. (Exs. P-211, P-45 & P-22.)

The notice package also contained a simple one page ORANGE FORM that class members could complete to exercise their initial opt-out rights. In the alternative, class members could exercise an initial opt-out right by transmitting any written manifestation of their intent to do so to the Interim Claims Administrators. (Exs. P-211, P-43 & P-9.) The court directed that class members be given the right to opt-out by March 30, 2000, which was 120 days from the date that class notice commenced. (Pretrial Order No. 997 ¶ 11; Ex. P-31 ¶ 2.) Finally, the notice package contained a postage-prepaid business reply envelope that class members could use to return the relevant forms. (Exs. P-211 & P-48.)

The notice packages were not the only source of information concerning the settlement. The Interim Claims Administrators employed the Official Settlement Website to post answers to frequently asked questions about the settlement, to reply to questions submitted via E-mail, to provide a news letter regarding the settlement, and to otherwise communicate with class members concerning the settlement. In addition, the Interim Claims Administrators established a separate 1-800 number and provided staff to answer questions submitted via telephone concerning the settlement. (Tr. 5/9/00 at 32-34 & 37-38.)

c. Response

Altogether, notice packages were transmitted by first class mail to 944,723 individuals. (Tr. 5/9/00 at 85-86; AHP Ex. 618.)

As of May 8, 2000, 44,423 people had signed and submitted ORANGE FORMS (or the substantial equivalent) exercising the right of initial opt-out under the settlement. (Tr. 5/9/00 at 89; and AHP Ex. 618.) Although there is currently no deadline for the submission of PINK FORMS or BLUE FORMS, as of May 8, 2000, 119,011 class members had executed PINK FORMS registering for AIO benefits and 97,544 class members had executed BLUE FORMS registering for settlement benefits in the event that the settlement received Final Judicial Approval. (Tr. 5/9/00 at 89; AHP Ex. 618.) In addition, as of May 8, 2000, 12,253 people had submitted GREEN FORMS manifesting an intent to receive Matrix Compensation Benefits. By August 8, 2000, 51,467 ORANGE FORMS, 164,291 PINK FORMS, 108,572 BLUE FORMS and 12,014 GREEN FORMS were submitted. (AHP Ex. 646.) However, it appears that many of these forms need more complete information. (Tr. 8/10/00 at 65 & 80.)

The response by members of the class to the notice is significant in three ways. First, it demonstrates that the plan of notice was highly effective in meeting its goals to make class members aware of the circumstances leading up to the proposed settlement, the nature of the settlement and the potential impact of the settlement on their legal rights. Second, the response to the notice clearly indicates that the notice program was sufficient to afford all class members a full, informed and effective opportunity to exercise their initial opt-out rights under the Settlement Agreement. Finally, the response to the class notice shows that although there are a number of class members who chose to opt-out of

the settlement, the class overwhelmingly supports the settlement as fair and equitable.

3. Analysis

Under these circumstances, the notice plan implemented here satisfies the requirements of personal jurisdiction, due process and Federal Rules of Civil Procedure 23(c)(2) and 23(e). The notice plan was implemented by experienced specialists and utilized a wide variety of media to disseminate notice, including mailings to individual class members where possible, mailings to physicians and pharmacists, publication in magazines, newspapers and on the Internet, and through use of cable and network television, a toll free phone number and the Internet. This notice was amplified by the wide publicity that followed the controversy surrounding the diet drugs. This comprehensive notice program fulfills the "best notice practicable" requirement of Rule 23(c)(2), as articulated in Shutts. See Shutts, 472 U.S. at 812. In addition, the settlement agreement clearly provided an opportunity for members to exclude themselves from the class by exercising their initial opt out right by March 30, 2000. In fact, class members may become eligible for three subsequent opt out rights under the settlement agreement. Thus, this notice program, coupled with opt out opportunities, is sufficient to warrant this court's exercise of personal jurisdiction over the class. See In re Prudential Ins. Co. of Am. Sales Practices Litig., 148 F.3d at 306.

In Amchem Products, Inc. v. Windsor, the Supreme Court recognized that adequate notice to the class could be impeded where

many class members were not even aware of their exposure to a defendant's product. Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 628 (1997). The initial opt out right in Amchem was not meaningful due to the fact that some asymptomatic class members were unaware that they were even exposed to asbestos. Id. Here, however, there are no class members unwittingly exposed to the diet drugs, which were available only through a doctor's prescription and had to be consciously ingested. In addition, class members were made aware of the risks these drugs posed in 1997, when AHP withdrew them from the market. Moreover, Class Counsel employed an expansive notice plan to inform class members of their initial opt out right. In sum, unlike Amchem, the initial opt out right has meaning because all class members were aware of their exposure to the diet drugs. In Amchem, the Supreme Court also raised the concern that even if class members "fully appreciate the significance of class notice, those without current afflictions may not have the information or foresight needed to decide, intelligently, whether to stay in or opt out." Amchem, 521 U.S. at 628. Here, the instant settlement's intermediate and back-end opt out rights allow class members to make informed choices about whether to remain in or opt out of the settlement. Moreover, the settlement's provisions of medical monitoring provide the mechanism to inform class members of their injury status.

In addition, the content of the notice is sufficient to satisfy the requirements of Rules 23(c)(2) and 23(e). The notice package contains a "plain language" description of the settlement and class

members' rights thereunder, in addition to the more traditional class action notice. More generally, the class notice details the nature of the litigation and the right of class members to opt out. It further indicates that those who do not opt out will be bound by a final judgment, that complete information is available in the court files and that any class member could have appeared and been heard at the Fairness Hearing. For the reasons set forth above, the court finds that it has personal jurisdiction over this settlement class, and that the accompanying notice plan comports with the requirements of due process under the Fifth Amendment and Federal Rules of Civil Procedure 23(c)(2) and 23(e).

C. Article III Case or Controversy Requirement

The Brown Complaint was filed for settlement purposes only. Nevertheless, the court's jurisdiction over this settlement class does not violate the Article III case or controversy requirement. Settlement class actions have been held by several courts to present a case or controversy. See In re Asbestos Litig., 90 F.3d 963, 988 (5th Cir. 1996), rev'd on other grounds, Ortiz v. Fibreboard Corp., 527 U.S. 815 (1999); In re Orthopedic Bone Screw Prod. Liab. Litig., 176 F.R.D. 158, 172 (E.D. Pa. 1997); Carlough v. Amchem Prod., Inc., 834 F. Supp. 1437, 1462-66 (E.D. Pa. 1993), rev'd on other grounds sub nom., Georgine v. Amchem Prods., Inc., 83 F.3d 610 (3d Cir. 1996), aff'd sub nom., Amchem Prods., Inc. v. Windsor, 521 U.S. 591 (1997).

This settlement resolves highly contentious litigation that has been conducted in state and federal courts, including this MDL No. 1203, since 1997. See supra, at § I.A.. This litigation includes several classes certified in state courts as well as the Jeffers action before this court. Based on this litigation background, the court is confident that these claims would have been pursued to trial in the absence of settlement. Class Counsel's choice to file the Brown Complaint as the procedural mechanism for bringing this settlement class before the court does not transform this into a "friendly" suit for which there is no jurisdiction. See Carlough, 834 F. Supp. at 1465 (stating that "[l]ooking at the nature of the controversy, and not the timing of the settlement agreement, it is clear that the plaintiffs and the . . . defendants are true adversaries. . . . [and that] [t]he proposed settlement simply represents a compromise of a genuine dispute"). Thus, the court finds that the Brown action meets the case or controversy requirement of Article III of the Constitution.

D. Rule 23 Class Certification Requirements

Federal Rule of Civil Procedure 23 governs class action certification in the federal courts. Under Rule 23(a), four threshold requirements must be met in all class actions: (1) numerosity; (2) commonality; (3) typicality; and (4) adequacy of representation. Fed. R. Civ. P. 23(a). In addition to Rule 23(a)'s requirements, parties seeking class certification must meet the requirements of either Rule 23(b)(1), (2) or (3). See e.g., Fed.

R. Civ. P. 23(b)(2) (permitting class actions for declaratory or injunctive relief where the "party opposing the class has acted or refused to act on grounds generally applicable to the class"); Fed. R. Civ. P. 23(b)(3) (permitting class actions where common questions of law and fact predominate and where class treatment is superior to other available methods).

In Amchem Products, Inc. v. Windsor, the Supreme Court held that settlement is relevant to class certification. 521 U.S. at 619. The Court stated that: "[c]onfronted with a request for settlement-only class certification, a district court need not inquire whether the case, if tried, would present intractable management problems, see Fed. R. Civ. Proc. 23(b)(3)(D), for the proposal is that there be no trial." Id. at 620. Nonetheless, other requirements of Rule 23, "those designed to protect absentees by blocking unwarranted or overbroad class definitions--demand undiluted, even heightened, attention in the settlement context." Id. Importantly, federal courts may not substitute a finding that a settlement is fair under Rule 23(e), for a finding that certification is proper under Rule 23(a) and (b). See id. at 621-22 (finding that Rule 23(e)'s fairness criteria function as additional requirement to findings under Rules 23(a) and (b) that class has sufficient unity).

1. Rule 23(a) Numerosity

Rule 23(a)(1) permits class treatment where "the class is so numerous that joinder of all members is impracticable." Fed. R.

Civ. P. 23(a)(1). Potentially six million people nationwide were exposed to Pondimin or Redux (four million Pondimin prescriptions and two million Redux prescriptions). The vast number of class members and their dispersed geographic locales exceeds the threshold for a conclusion that joinder is impracticable. See Eisenberg v. Gagnon, 766 F.2d 770, 785-86 (3d Cir. 1985) (holding that 90 geographically dispersed plaintiffs met numerosity requirement); Lerch v. Citizens First Bancorp., Inc., 144 F.R.D. 247, 250 (D.N.J. 1992) (stating that "[i]mpracticability does not mean impossibility, but rather that the difficulty or inconvenience of joining all members of the class calls for class certification"). Indeed, no objector has disputed that Rule 23(a)(1)'s numerosity requirement is met here. Based on the vast size and geographical dispersement of the class, the court finds that Rule 23's numerosity requirement is met.

2. Rule 23(a)(2) Commonality and 23(b)(3) Predominance

Rule 23(a)(2) requires that there are questions of law or fact common to the class.¹⁸ Fed R. Civ. P. 23(a)(2). Rule 23(b)(3) requires that common questions of law or fact predominate over questions affecting individual class members. The court will treat these requirements together "[b]ecause 23(b)(3)'s predominance requirement incorporates the commonality requirement" of Rule

¹⁸ The commonality requirement is satisfied "if the named plaintiffs share at least one question of fact or law with the grievances of the prospective class." Baby Neal v. Casey, 43 F.3d 48, 56 (3d Cir. 1994); see Georgine, 83 F.3d at 627 (identifying commonality requirement as low threshold).

23(a)(2). Georgine, 83 F.3d at 626. The predominance inquiry "trains on the legal or factual questions that qualify each class member's case as a genuine controversy, questions that preexist any settlement." Amchem, 521 U.S. at 623; see id. (stating that benefits to be gained from settlement's establishment of compensation scheme is not pertinent to predominance inquiry). Common issues need only predominate, not outnumber, individual issues. The Third Circuit has instructed:

[t]here may be cases in which class resolution of one issue or a small group of them will so advance the litigation that they may fairly be said to predominate. Resolution of common issues need not guarantee a conclusive finding on liability, . . . nor is it a disqualification that damages must be assessed on an individual basis.

In re School Asbestos Litig., 789 F.2d 996, 1010 (3d Cir. 1986) (citations omitted). "Even mass tort cases arising from a common cause or disaster may, depending upon the circumstances, satisfy the predominance requirement." Amchem, 521 U.S. at 625.

Here, there exist several common issues to the class to support a finding of predominance and cohesiveness. With regard to common questions of fact, the diet drugs at issue here are essentially a single product--in that Pondimin and Redux are chemically related--marketed by a single major manufacturer--AHP. In addition, use of the diet drugs spanned a finite and relatively short period of time. Moreover, there is, in general, a common injury type to heart valves, albeit to varying degrees. Moreover, there is a common body

of science establishing the causal connection between the diet drugs and heart valve injuries.

In addition, plaintiffs' claims in this litigation all stem from allegations involving a common course of conduct followed by AHP. See In re Prudential Ins. Co. of Am. Sales Practices Litig., 148 F.3d at 314-15 (agreeing with district court's predominance finding where common interest existed in determining whether defendant's course of conduct was actionable). Plaintiffs' negligence and failure to warn claims will revolve around AHP's conduct and knowledge in developing and marketing Pondimin and Redux. Although there are some individual differences among class members, the common class-wide focus on AHP's knowledge and conduct predominate such that judicial efficiency will be improved through the class mechanism as opposed to relitigating these same issues in a series of individual cases. Furthermore, the class wide need for medical monitoring, as evidenced by the classes certified by this court in Jeffers, and in several state courts throughout the country, establish another concern common to the class. In sum, these common concerns which preexisted the settlement confirm the cohesiveness of the class.

The instant class is more cohesive than the classes sought to be certified in the asbestos and tobacco litigation arenas. For example, this class is not as "sprawling" as the class rejected by the Supreme Court in Amchem. Where Amchem involved class members exposed to asbestos in differing ways and through a wide range of

different asbestos-containing products, the instant class was exposed to only two diet drugs, which are chemically related, and through a single method of exposure--oral ingestion of the drugs. See Amchem, 521 U.S. at 624. Where Amchem involved 20 asbestos defendants, the instant class involves a single manufacturer defendant--AHP. Where Amchem involved a wide variety of injuries including pleural scarring, lung cancer, asbestosis and mesothelioma, the instant class involves essentially a single type of injury--heart valve injury. See id. at 624. Additionally, unlike Amchem, the instant class involves one scientific theory of causation.

The instant class also differs from the class decertified by the district court and affirmed by the Third Circuit in Barnes v. American Tobacco Company, 161 F.3d 127 (3d Cir. 1998), cert. denied, 526 U.S. 1114 (1999). In Barnes, the Third Circuit affirmed the decertification of a medical monitoring class involving tobacco litigation due to the presence of too many individual issues. See id. at 143. Where Barnes involved the entire tobacco industry, which manufactured hundreds of different products containing different ingredients, the class here involves a single defendant with essentially a single diet drug product. See id. at 135. In Barnes, plaintiffs claimed that defendants manipulated nicotine levels. Thus, nicotine levels in different products at different times became an individual issue destroying class cohesion. See id. at 144-45. No such individual issues divide the instant class.

Moreover, addiction, an inherently individual issue, worked to further splinter the tobacco class in Barnes. No such individual issue exists with respect to the instant class.

Moreover, when taking the settlement into consideration for purposes of determining class certification, individual issues which are normally present in personal injury litigation become irrelevant, allowing the common issues to predominate. For example, differences in state law with regard to contributory negligence and comparative fault, learned intermediary doctrine, medical monitoring, punitive damages and the statute of limitations do not destroy class cohesion because the settlement agreement provides for distribution of benefits based on the objective criteria described therein. Similarly, individual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation. The court notes that this is not the same as finding that the benefits of the settlement itself provide a common issue which satisfies the predominance requirement. Rather, the court finds that the common issues that preexisted this settlement--involving a common product, defendant and course of conduct--when considered in light of the proposed settlement, predominate over any individual issues between class members.¹⁹

¹⁹ With respect to Rule 23(b)(2), although there is no predominance requirement, it is well settled that the class claims must be cohesive and that an analysis of whether individual issues that exist among class members destroy the cohesive nature of the class. See Barnes, 161 F.3d 127, 142-43 (3d Cir. 1998). The court's findings with respect to

3. Rule 23(a)(3) Typicality

Rule 23(a)(3) requires the named plaintiffs' claims to be typical of the claims of the class. Fed. R. Civ. P. 23(a)(3). The typicality requirement "is intended to assess whether the action can be efficiently maintained as a class and whether the named plaintiffs have incentives that align with those of absent class members so as to assure that the absentees' interests will be fairly represented." Baby Neal, 43 F.3d at 57. The Third Circuit has stated:

"Typicality entails an inquiry whether 'the named plaintiff's individual circumstances are markedly different or . . . the legal theory upon which the claims are based differs from that upon which the claims of other class members will perforce be based.'"

Id. at 58 (quoting Hassine v. Jeffes, 846 F.2d 169, 177 (3d Cir. 1988) (quoting Eisenberg, 766 F.2d at 786)). Courts have found that typicality is satisfied where the claims of the class representatives and class members arise from the same alleged course of conduct by the defendant. See Baby Neal, 43 F.3d at 58 (stating that factual differences "will not render a claim atypical if the claim arises from the same event or practice or course of conduct that gives rise to the claims of the class members, and if it is based on the same legal theory"); Eisenberg, 766 F.2d at 786 (stating that "typical" is not same as "identical").

Here, the claims of the class representatives are aligned with those of the class members. Both the class representatives and

predominance extend to its finding that this class has the "cohesion" necessary for certification under Rule 23(b)(2).

class members either ingested the diet drugs over the relatively short time those drugs were available on the market or have a personal or legal relationship with such a class member. Each class member's claim alleges a common defect in the diet drugs and a common course of conduct by AHP with regard to developing and marketing those diet drugs. Thus, the court finds that Rule 23(a)(3)'s typicality requirement is satisfied.

4. Rule 23(a)(4) Adequacy of Representation

Rule 23 requires that the class representatives "will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). This inquiry encompasses two prongs. First, the adequacy or representation inquiry "tests the qualifications of the counsel to represent the class." In re General Motors Corp. Pick-up Truck Fuel Tank Prods. Liab. Litig., 55 F.3d 768, 800 (3d Cir. 1995); see In re Prudential Ins. Co. of Am. Sales Practices Litig., 148 F.3d at 312. Second, the adequacy of representation inquiry "serves to uncover conflicts of interest between named parties and the class they seek to represent." Amchem, 521 U.S. at 625; see In re Prudential Ins. Co. of Am. Sales Practices Litig., 148 F.3d at 308 (stating that "the key to Amchem appears to be the careful inquiry into adequacy of representation").

Rule 23(a)(4)'s adequacy of representation requirement "'tend[s] to merge' with the commonality and typicality criteria of Rule 23(a), which 'serve as guideposts for determining whether . . . maintenance of a class action is economical and whether the named

plaintiff's claim and class claims are so interrelated that the interests of the class members will be fairly and adequately protected in their absence.'" Amchem, 521 U.S. at 2251 n.20 (quoting General Telephone Co. of Southwest v. Falcon, 457 U.S. 147, 157 n.13 (1982)).²⁰ Several considerations here confirm that the interests of these class members will be fairly and adequately represented.

a. Qualifications

Each of Class Counsel and Subclass Counsel satisfy the adequacy of representation requirement as it respects these attorneys' qualifications to represent the class. Class Counsel are Arnold Levin, John J. Cummings, III, Stanley Chesley, Michael D. Fishbein, Gene Locks, Sol Weiss and Charles Parker ("Class Counsel"). (Ex. P-276 at 32.) Each of the Class Counsel are experienced in the conduct of class litigation, mass tort litigation and complex personal injury litigation involving products liability, medical malpractice, drugs and medical devices. Messrs. Levin, Fishbein, Chesley and Cummings served as counsel for the class certified by this court in Jeffers. Messrs. Locks and Weiss served as class counsel in those actions that were certified to proceed as class actions to recover medical monitoring and other relief from AHP by Judge Corodemus in New Jersey, by Judge Levin in Pennsylvania

²⁰ For this reason, the court's reasoning discussed above with respect to typicality and commonality also apply to its reasoning regarding adequacy of representation.

and by Judge Freedman in New York. Charles Parker was one of the attorneys for the class certified by Judge Edwards in Texas.

As set forth in the Settlement Agreement, Pretrial Order No. 997 and the Third Amended Complaint, Dianne Nast is counsel for Subclass 1(a), Richard Lewis is counsel for Subclass 1(b), Mark Tanner is counsel for Subclass 2(a), Eric Kennedy is counsel for Subclass 2(b) and Richard Wayne is counsel for Subclass 3 ("Subclass Counsel"). Each of the Subclass Counsel referred to above are highly skilled competent attorneys with substantial experience in mass tort litigation, class actions and complex personal injury litigation involving medical malpractice, products liability, drugs and medical devices. (Ex. P-270 at 7-8; AHP Ex. 626 at 8; AHP Ex. 629 at 17, 116-20; Tr. 5/2/00 at 53-54.) Based on their experience in personal injury litigation, mass tort litigation, class action practice and their involvement in diet drug litigation, the court finds that each of the Subclass Counsel is well qualified to represent his or her respective Subclass. These attorneys were also qualified to make assessments of the extent to which he or she needed to be involved in the negotiations on behalf of his or her respective subclass in order to protect its interests in connection with any potential or actual antagonism or conflict with the interests of any other subclass.

b. Conflicts

(i) Class Counsel Were Not Disarmed in Their Negotiations.

Both Amchem and Ortiz caution against any "side agreements" or "inventory settlements," where class counsel negotiate a separate settlement of their individual cases, contingent upon the success of the global settlement. See Ortiz, 527 U.S. at 852-53 (stating that prospect of inventory settlements provides great incentive to reach any agreement in global settlement negotiations rather than best possible arrangement for global settlement class); Amchem, 521 U.S. at 627-28 (agreeing with Third Circuit finding that there was no assurance in terms of settlement or structure of negotiations that named plaintiffs operated under proper understanding of their representational responsibilities); Georgine, 83 F.3d at 630 (noting objectors' argument that class counsel cannot adequately represent class where their separate inventory settlements are contingent upon successful resolution of global settlement). With regard to the instant class, it is clear from the evidence introduced at the Fairness Hearing that there were no side deals or inventory settlements entered into by Class Counsel. (Tr. 5/2/00 at 41 & 58-61.)

Neither were Class Counsel disarmed by a lack of leverage in their negotiations. In Amchem, the Supreme Court rejected the notion that in a settlement class context, a fairness inquiry under Rule 23(e) could eclipse the certification requirements under Rules 23 (a) & (b). Amchem, 521 U.S. at 621. The court held that such an approach would disarm both class counsel and the court. Id. The Court stated that "[c]lass counsel confined to settlement

negotiations could not use the threat of individual litigation to press for a better offer, . . . and the court would face a bargain proffered for its approval without the benefit of adversarial investigation." Id. (citations omitted). Here, Class Counsel were armed with leverage in their negotiations, including the threat of imminent and ongoing litigation. By the time settlement negotiations were underway, thousands of individual personal injury and medical monitoring suits were proceeding through discovery and toward trial. Several other class actions were certified in the states and before this MDL No. 1203 transferee court. Also, the class action medical monitoring trial in New Jersey was underway. Thus, throughout the negotiations, Class Counsel were able to use the threat of present and continuing litigation as a bargaining chip in reaching the best possible deal they could achieve for the class.

(ii) There are No Improper Allocations or Trade-Offs Involved.

The settlement classes in Amchem and Ortiz failed in part because they suffered from disabling intraclass conflicts. In Amchem, the Supreme Court detected an intraclass conflict between those class members with immediate injuries and those class members who were merely exposed to asbestos. The conflict was amplified because some of the exposure-only class members were not even aware of their exposure. In addition, there was a long latency period associated with asbestos diseases. Under these circumstances, the Supreme Court noted that the goal of generous immediate payments for the currently injured tugged against the goal of ensuring an ample,

inflation-protected fund for the future for exposure-only plaintiffs. Amchem, 521 U.S. at 526. The Supreme Court found that the terms of the settlement reflected "essential allocation decisions designed to confine compensation and to limit [the] defendants' liability." Id. at 627. Specifically, the Supreme Court pointed out that the settlement included no adjustment for inflation, only a few claimants per year could opt out at the back end and that loss of consortium claims were to be extinguished without compensation. Thus, under those circumstances, the Court held that the settling parties "achieved a global compromise with no structural assurance of fair and adequate representation for the diverse groups and individuals affected." Id. Unlike Amchem, the named class representatives' interests are closely aligned with those of the class, such that fair and adequate representation of the class is ensured. Specifically: the instant class is not as sprawling as that in Amchem; the "futures" problem that existed in Amchem does not exist here; and the settlement provides for structural protections which make it fair to bind absent class members here.

(A) The Class is Cohesive.

As discussed above, the instant class has a great deal of cohesion in that the class was basically exposed to one substance, manufactured by one defendant over a relatively short period of time and suffers or is at risk of suffering one particular type of injury. See supra, at § II.D.2..

(B) There Is No "Futures" Problem Similar to the One Encountered in Amchem.

The instant class does not suffer from the same problems that exposure-only class members suffered from in Amchem. In Amchem, the Court found that class members could not fairly be bound by a settlement where some members were unaware of their exposure to asbestos or where their potential injuries could have a latency period of 30 to 40 years. Here, all class members are aware of their exposure to Pondimin or Redux, which have been off the market since September 1997. In addition, the class members have a diagnosable condition that can be detected through an echocardiogram.

Objectors argue that a "futures" problem similar to that in Amchem exists here because issues regarding the latency and progression of VHD remain vague. The clinical and epidemiological studies demonstrate--and all the experts agree--that insofar as the use of fenfluramine or dexfenfluramine results in an increased prevalence of valvular regurgitation, that regurgitation is detectable by echocardiogram shortly after the patients discontinue use of diet drugs. Conversely, there is no evidence that the use of the drugs results in any increased risk of regurgitation that is "latent" and not detectable by today's sophisticated echocardiographic technology. (Ex. P-95 ¶ 42; Tr. 5/3/00 at 82 & 86; AHP Ex. 613 ¶¶ 59-65; AHP Ex. 610 ¶¶ 10 & 20; AHP Ex. 611 ¶ 41; Tr. 5/8/00 at 79.)

The absence of a latency period between ingestion of fenfluramine and/or dexfenfluramine and the development of clinically detectable VHD is also confirmed by a number of studies that have followed former fenfluramine/ dexfenfluramine patients for a number of years, either through the use of echocardiograms or comprehensive medical record review.²¹ Each of these studies finds that there was no emergence of new disease after some latency

²¹ The studies that have tracked former fenfluramine/dexfenfluramine patients in this manner and did not find latency or progression--and more often found improvement in patients who had previously been FDA Positive--are as follows: Weissman II Study (Ex. P-172 at Table 4) (no progression or latency observed in comparison of dexfenfluramine patients' echocardiograms taken three to five months after cessation of drugs to echocardiograms of same patients one month after cessation; improvement noted in number of patients who had previously been "FDA positive"); Weissman III Study (AHP Ex. 185A) (comparison of echocardiograms one year after cessation to prior echocardiograms of same dexfenfluramine patients one month after cessation--no progression, additional improvement); Gardin II Study (AHP Ex. 587A) (one year follow-up of patients who had taken fen-phen combination or dexfenfluramine--no progression; improvement in some patients); Hensrud Study (Ex. P-126 at 1, Table 1) (comparison of echocardiograms one year after cessation of use to initial echocardiograms at time of cessation--no progression; improvement in some patients); D. H. Ryan Study (Ex. P-149) (comparison of echocardiograms of same fen-phen patients over twenty-four months following cessation of use at six month intervals--no progression; improvement in about one-third of cases); Davidoff Study (AHP Ex. 121 at 21) (no increased prevalence of aortic regurgitation--and hence no latent effect--among treated patients who were given echocardiograms four years after their use of fenfluramine, as compared to untreated control patients); Jick Study (P-127 at 1, Table 3) (comprehensive medical record review of 8900 patients identifying only eleven cases of any new evidence of valvular regurgitation, and no surgeries, over five year period after their use of fenfluramine/dexfenfluramine); and Eichelberger Study (P-118) (evaluation of patients who had taken fen-phen combination on long-term basis some fifteen years after they had used drugs--finding no severe regurgitation, no valve surgeries, and no greater degree of regurgitation than would be expected in such patients).

period. Moreover, these studies suggest that regurgitation attributable to diet drug-induced VHD remains stable or regresses in a substantial portion of the exposed population, but that there may be progression of the severity of the disease among a small percentage of those who have developed FDA Positive levels of VHD after being exposed to diet drugs, particularly those who develop moderate or greater levels of regurgitation while taking the drugs. (Exs. P-95 ¶ 43, P-118, P-119, P-126, P-153, P-138, P-149, P-172 & P-173.) The studies show that a patient who is diagnosed with mild aortic regurgitation shortly after he or she ceased the use of the drugs is thus more likely to improve than to progress to a more severe level of regurgitation. (Ex. P-172 at Table 4; AHP Ex. 185A; AHP Ex. 587A; Ex. P-126 at 1, Table 1 & Ex. P-149.)

The objectors presented no evidence from any study to support the contrary view that such valvulopathy is either latent or that it progresses in most former patients. The absence of any evidence of latent onset of regurgitation or significant progression of regurgitation in former fenfluramine and dexfenfluramine patients is also consistent with both the general observation that progression of valvular regurgitation occurs primarily in patients who already have moderate or severe disease--but not in patients who have only mild regurgitation--as well as studies with other drugs which are known to cause valvular regurgitation but which cease to do so once a patient stops taking the drug. (AHP Ex. 613 ¶ 61; Ex. P-95 ¶ 15; AHP Ex. 107.)

All of the experts who testified in this case agreed that fenfluramine, dexfenfluramine and the fen-phen combination do not cause latent valvular regurgitation; that there is no evidence of significant progression among such patients after they cease taking the drugs; and that there has been clear evidence of improvement in the mild regurgitation previously noted in some former patients. No expert testified to the contrary. (Tr. 5/3/00 at 81-82, 85-86; Ex. P-95 ¶ 43; AHP Ex. 609 ¶ 8; Tr. 5/8/00 at 79; AHP Ex. 613 ¶¶ 62-70; AHP Ex. 611 ¶¶ 33-40; AHP Ex. 610 ¶ 10.) In sum, as it relates to latency, the "futures" problem present in Amchem is not present here.

(C) Objections Pertaining to Neurotoxic Injuries.

The Objectors also argue that an improper "allocation" similar to the allocations made in Amchem exists here in that class counsel "agreed to 'fold in' claims for neurotoxic injuries without procuring any benefit for those whose claims were extinguished." (Dunn Proposed Finding of Fact ¶ 82.) A neurotoxic effect occurs where exposure to a potentially toxic substance has caused an organic effect in the brain which is expressed in some abnormal behavior or mood change. (Ex. P-93 at 2-4 of 26.) There is suggestive evidence that fenfluramine, dexfenfluramine and their combination with phentermine cause neurotoxic brain damage in a variety of tests involving animal species. However, there is also a significant degree of controversy in the available literature, with findings depending on the types of animals used, the dosages

and routes of administration, the duration of exposure and the experimental laboratory methods used to detect the changes in neuronal elements. (Ex. P-93 at 3 of 26.) There is also debate as to whether drug induced changes are permanent or transient and whether damaged neurons can sprout anew portions that have apparently "died back" due to toxic effects. Indeed, there is debate about how to define neurotoxicity in these animal models, and whether findings can be generalized to human beings. (Ex. P-93 at 3 of 26.)

In human beings, neurotoxic effects are characterized by disturbances in mood or behavior such as depression, memory defects, and the like. (Ex. P-93 at 2-4 of 26.) Such alterations or disturbances in behavior and mood are common and can result from both organic and non-organic factors including various life circumstances. (Ex. P-93 at 2-4 of 26.) Therefore, in order to determine whether or not exposure to a potentially toxic substance, such as a pharmaceutical product, has caused an adverse psychological outcome or whether the patient's behavioral manifestations are the result of other factors such as life circumstances, it is essential to conduct clinical investigations systematically comparing well defined psychologic outcomes of interest in a population exposed to a potentially toxic pharmaceutical compound with outcomes in a matched population which has not been exposed to the drug. (Ex. P-93 at 2-4 of 26.)

Despite the fact that the fenfluramine derivatives have been marketed in this country and in Europe since at least the early 1970s, there is very little clinical information concerning any association between the ingestion of fenfluramine derivatives and what might be described as neurotoxic clinical manifestations in human beings. There are episodic case reports of individuals who had disturbances in mood or behavior who have taken fenfluramine derivatives. However, these case reports are "anecdotal" at best and do not provide any credible information from which a reasonable scientist could conclude that diet drugs are neurotoxic. (Ex. P-93 at 4 of 26.)

Significantly, there have been no controlled or systematic studies evaluating the claimed neurotoxic effects of the fenfluramine derivatives. Specifically, there have been no studies comparing defined psychological outcomes in diet drug users with outcomes in a matched population not exposed to such drugs or in the form of studies following a population of individuals exposed to diet drugs to determine who developed neuropsychiatric symptoms and signs and compare the characteristics of affected and unaffected individuals. (Ex. P-93 at 4 of 26.) There is no reliable scientific evidence that fenfluramine or dexfenfluramine, when given at normal therapeutic doses, is neurotoxic in humans, i.e., causes lasting central nervous system impairment. No expert testified to the contrary. (Ex. P-93 at 3; Dunn LT-160 at 670.)

Although the issue of whether fenfluramine and dexfenfluramine are neurotoxic has been studied for over twenty-five years, the very articles relied upon by objectors acknowledge that, as recently as 1998--after the drugs were no longer on the market--no studies have ever shown any neurotoxic effects in humans. (LT-160 at 669-70.) There have been a number of well-designed clinical studies on fenfluramine and dexfenfluramine--including randomized, double-blind, placebo-controlled studies involving thousands of patients--that included evaluation of potential central nervous system side effects in which there were no significant differences between the subjects who took the drugs and subjects who received placebos on neuropsychological and psychiatric assessments. (AHP Ex. 559.)

While there were some reports of adverse neurological or psychiatric effects after use of fenfluramine or dexfenfluramine among the millions of people who used them from 1973 to 1997, even the review article cited by the objectors notes that "a causal link cannot be established" because those are individual reports rather than controlled epidemiological studies. Specifically, because neuropsychiatric problems sometimes occur spontaneously in the general population, individual reports cannot establish a cause and effect relationship between the use of fenfluramine or dexfenfluramine and development of neuropsychiatric difficulties. (LT-160 at 669; P-93 at 3.)

All of this data on the neurological effects of both fenfluramine and dexfenfluramine was reviewed by the FDA between

1993 and 1996, when Redux was approved for distribution in the United States. Most notably, in October 1995 the FDA reviewed data submitted by Interneuron on the "neurologic, psychometric, behavioral [and] cognitive data included in 17 controlled clinical trials, of 10 years of post-marketing spontaneous reports and of 55 reports in the published literature . . . to evaluate the human risk for adverse psychologic, neurologic or psychiatric effects associated with dexfenfluramine . . . treatment." (AHP Ex. 559.) That review of all the available data showed that "at the clinical dose recommended for the treatment of obesity, dexfenfluramine is safe and well tolerated and is without risk of acute or delayed adverse effects involving the central nervous system." (AHP Ex. 559.) Shortly thereafter, the expert panel convened by the FDA to study this issue recommended that the FDA approve dexfenfluramine for sale in the United States--and the FDA ultimately did so. (Tr. 5/11/00 at 51; AHP Ex. 559.) In the absence of such studies, it is not possible to establish that exposure to the fenfluramine derivatives resulted in the development of neuropsychiatric symptoms or signs in any human beings. (Ex. P-93 at 4 of 26.)

The Settlement Agreement does not provide any benefits for neurotoxic injuries alleged to result from ingestion of Pondimin and Redux. However, claims for neurotoxic injury are "settled claims" such that class members release and discharge these claims in the event they have not exercised their initial opt-out right by March 30, 2000. (Ex. P-3 at 17-18 of 148.)

In this regard, the colorful, consumer oriented notice which was sent to class members stated:

Some people believe that a very subtle kind of brain damage - neuropsychiatric or neurotoxic injury - may be caused by the use of Pondimin and/or Redux. However, the question of whether such brain injury can occur as a result of diet drug use is controversial. Also, there are presently no published clinical studies that show that people who took Pondimin or Redux have any brain injury as a result. The settlement provides no benefits for such neuropsychiatric or neurotoxic injuries. If you do not opt-out of the settlement, you will not be able to pursue in Court any claim for neuropsychiatric or neurotoxic injury.

(Ex. P-211 at 14; Ex. P-15 at 13 of 14.) In light of this clear statement and in light of the fact that there is absolutely no clinical evidence that Pondimin or Redux cause neuropsychiatric injury, class members who have not exercised an initial opt-out right have properly relinquished any claim for neurotoxic or neuropsychiatric injury against AHP and the AHP Released Parties.

(D) Structural Protections.

The settlement provides for structural protections that were absent in Amchem. To the extent that some class members can be characterized as "futures" because their existing injuries may progress over time, they are protected by the settlement in that they may "step up" to higher amounts of compensation on the matrices as their level of disease progresses. In, addition, unlike Amchem, there are no case flow maximums designed to limit defendants' payments. See Amchem, 521 U.S. at 604. Also, unlike Amchem, the

settlement matrices here are indexed for inflation. See id. at 604. Moreover, the settlement's fraud prevention mechanism protects against fund depletion.

Most importantly, unlike Amchem, where only a small number of class members per year had the opportunity to reject the settlement and pursue their claims in court, the instant class has several meaningful opt out rights accompanied by protections against statute of limitations and claims splitting defenses.²² See Amchem, 521 U.S.

²² Under the Settlement, class members who exercise an intermediate or back-end opt out are prohibited from seeking punitive or multiple damages. In return, AHP has given up its right to assert statute of limitations and claims-splitting defenses. Objectors argue that this represents an inappropriate trade-off. This argument is illusory.

First, class members had an opportunity to preserve their punitive damages claims by exercising the initial opt out. Second, the Settlement's provisions prohibiting AHP from asserting statute of limitations and claim-splitting defenses serve to protect the class against some of the main risks they face toward recovery. Many class members might be barred from filing suit, "given that there were only about 18,000 claims filed out of six million people as of the time" the Settlement was negotiated. (Tr. 5/2/00 at 196-97.) Statute of limitation defenses could also have the effect of requiring class members to bring suit before determining the state of their health. Id. Last, punitive damage claims are often illusory. See Broussard v. Meineke Discount Muffler Shops, Inc., 155 F.3d 331, 346 (4th Cir. 1998) (stating that award of punitive damages is always "necessarily uncertain"); Haynes v. Logan Assistance Corp., No.Civ.90-1800, 1994 WL 66701, at *19 (E.D. Pa. March 4, 1994) (stating that even where jury awards punitive damages, "it is always speculative as to how much a jury will award in punitive damages"). Moreover, in the case of punitive damage awards, which are intended to punish the defendant, plaintiffs run the risk that a defendant may have already been punished enough, thus barring any further award of punitive damages. See Dunn v. Hovic, 1 F.3d 1371, 1388 (3d Cir. 1993) (en banc) (finding arguments against multiple punitive damage awards "powerful"); In re School Asbestos Litig., 789 F.2d 996, 1005 (3d Cir. 1986) (stating that "as a matter of constitutional law or substantive tort law, the courts should shoulder some responsibility for preventing repeated awards of punitive damages for the same acts

at 604-05; see supra, at § I.F.2.g.. The centrality of the medical monitoring relief sought by the class enhances these opt out rights by allowing class members to make an informed choice about whether to remain in the settlement or pursue their claims in court.

(E) There Have Been No Lump Sum Allocations or Financial Trade-Offs.

In Ortiz, part of the fund of the settlement was comprised of an insurance policy that covered the defendant for pre-1959 asbestos claims. See Ortiz, 527 U.S. at 850. However, the proposed settlement class included those exposed to the defendant's asbestos products both before and after 1959. See id. at 857. Class counsel used those insurance assets, which should have benefitted only the pre-1959 claimants, to cover the post-1959 claimants as well. See id. The Supreme Court found that this type of allocation decision-- where class counsel was forced to allocate a lump sum among

or series of acts"); In re "Agent Orange" Prods. Liab. Litig., 100 F.R.D. 718, 728 (E.D.N.Y. 1983) (stating that, in theory, "when a plaintiff recovers punitive damages against a defendant, that represents a finding by the jury that the defendant was sufficiently punished for the wrongful conduct" and that "[t]here must, therefore, be some limit either as a matter of policy or as a matter of due process, to the amount of times defendants may be punished for a single transaction").

Consequently, courts have approved settlements even where some plaintiffs might have recovered additional punitive damages. See Petrovic v. Amoco Oil Co., 200 F.3d 1140, 1150 (8th Cir. 1999) (finding that speculative possibility of punitive damages was not enough to find that district court abused its discretion in approving settlement). In sum, the court finds that Class Counsel's agreement to waive punitive damage claims on intermediate and back-end opt outs in exchange for protection against statute of limitations and claim-splitting defenses represents a fair and wholly appropriate trade-off. These provisions do not represent an improper allocation, nor do they affect the procedural fairness of the settlement.

different class members--represented an intraclass conflict that revealed the lack of structural protection for the class as required by Rule 23(a)(4). Unlike Ortiz, Class Counsel here has not been forced to allocate a lump sum amongst different class members. See supra, at § I.B. (describing settlement negotiations).

The Objectors have pointed to several documents to support their position that allocations were made in achieving this settlement.²³ The Objectors point to a July 3, 1999 letter from Class Counsel to AHP setting forth a "term sheet" of Class Counsel's proposal for settlement that set out \$4,243,000,000 as the total cost of their June 1 settlement proposal. (Dunn Ex. 20 at 14-15.) The Objectors characterize this term sheet as Class Counsel's request to AHP for a lump sum. However, the evidence introduced at the Fairness Hearing does not support that characterization. In fact, the July 3 letter merely quantifies the amounts AHP would be required to pay for the separately negotiated benefits.

The Objectors also point to plaintiffs' economist's estimates of the amount it would cost to provide matrix benefits, a document representing AHP's estimate of the amount which would cost to provide all benefits under the agreement, a spread sheet proposing a schedule of periodic payments to provide the benefits and a document showing the position of the parties on various issues at

²³ At the Fairness Hearing, the Objectors did not attempt to impeach Mr. Fishbein's testimony regarding the style of the negotiations. In fact, they did not present him with a document, fact or circumstance suggesting that lump sum demands or trade-offs occurred.

one point during the negotiations. (Dunn Exs. 99, 188, 189, 101, 118, 191, 187 & 117.) Each of these documents is consistent with the unimpeached testimony of Mr. Fishbein that the parties reached an agreement on what benefits would be provided to class members, without an allocation being made, before an assessment of the aggregate amount necessary to pay for those benefits was made. In sum, the Objectors have not shown that any intra-class financial trade-offs were made in these negotiations. The court finds that these documents do not support the Objectors' view, but instead confirm the style of negotiations as set forth in the testimony of Class Counsel Michael D. Fishbein, Esquire.

(F) Issues Involving Subclasses and Subclass Counsel.

The Objectors have also argued that the settlement negotiations were conducted almost exclusively by Class Counsel, that Subclass Counsel's involvement in the negotiations was negligible, that the class representatives played no role in the negotiations and that Class Counsel "allocated" benefits between groups of claimants. Initially, these arguments are diluted by the fact that the Objectors were unable to point to any lump sum allocations or intra-class trade-offs, and thus, no disabling conflicts requiring subclassing arose in this instance. The Eighth Circuit's recent decision addressing the propriety of subclasses provides this court with guidance:

[i]f the objectors mean to maintain that a conflict of interest requiring subdivision is created when some class members receive more than other class members in a

settlement, we think that argument is untenable. It seems to us that almost every settlement will involve different awards for various class members. Indeed, even if every class member were to receive an identical monetary award in settlement, the true compensation would still vary from member to member since risk tolerance varies from person to person.

Petrovic v. Amoco Oil Co., 200 F.3d 1140, 1146 (8th Cir. 1999); In re Prudential Ins. Co. of Am. Sales Practices Litig., 148 F.3d at 294-97 (noting that different claims were weighted according to strength and given different benefits accordingly); Elkins v. Equitable Life Ins. Co. of Iowa, No.Civ.A. 96-296-Civ-T-17B, 1998 WL 133741, at *15 (M.D. Fla. Jan. 27, 1998) (stating that "nor is an impermissible intra-Class conflict or antagonism created by [a] settlement" that compensates class members based on the strength of their claim rather than trading off theoretical subgroup's interests "to the benefit of any other theoretical subgroup").

Nonetheless, subclasses were created here as a structural protection to be employed if such a conflict situation arose. With regard to the class representatives, the Objectors' chief complaint is that they were inactive and that three of the five were replaced. In a massive class action, however, "it is counsel for the class who has the laboring oar. The class representatives furnish the factual basis to invoke jurisdiction of the court and provide the outline of the controversy, but the lawyers shape the claims . . . by the compilation of factual and expert testimony and the presentation of . . . evidence." Goodman v. Lukens Steel Co., 777 F.2d 113, 124 (3d Cir. 1985). The class representatives are not expected to have

detailed knowledge or participate integrally in complex settlement negotiations. See Lewis v. Curtis, 671 F.2d 779, 789 (3d Cir. 1982) (stating that "adequacy of representation test is not concerned with whether plaintiff personally derived the information pleaded in the complaint or whether he will personally be able to assist his counsel"); Greenfield v. Villager Indus., Inc., 483 F.2d 824, 832 n.9 (3d Cir. 1973) (stating that "[e]xperience teaches that it is counsel for the class representative and not the named parties, who direct and manage these actions . . . [and that] [e]very experienced federal judge knows that any statement to the contrary is sheer sophistry"). Nor does replacement of class representatives destroy adequate representation of the class. See e.g., Kremens v. Bartley, 431 U.S. 119, 134-35 (1977) (remanding action to district court, for, among other things, substitution of class representatives with live claims); Schlick v. Penn-Dixie Cement Corp., 551 F.2d 531, 533 (2d Cir. 1977) (recognizing court's ability to substitute class representative if it finds named plaintiff "to be in a conflicting or untenable position either for the conduct of the trial or settlement").

With regard to subclass counsel, the Objectors' chief complaint is that they were not sufficiently involved and adversarial in negotiations. Subclass counsel are deemed adequate where they are competent and have no interest that conflicts with the class they represent. See Amchem, 521 U.S. at 625-26; In re Prudential Ins. Co. Sales Practices Litig., 148 F.3d at 312; In re GM Motors Corp.

Pickup Truck Fuel Tank Prods. Liab. Litig., 55 F.3d at 800; Barnes, 161 F.3d at 141. Nothing in Rule 23 requires that subclass counsel fight among one another or attend every negotiation session in attempting to work out a global resolution.

Initially, the court finds that each of Subclass Counsel is competent and experienced in handling class actions and mass tort litigation. (AHP Ex. 639 at 7-16; AHP Ex. 627 at 6-12; AHP Ex. 637 at 7-9; AHP Ex. 626 at 7-8, 16-17, 21 & 23-24; Ex. P-270 at 7-11.) In addition, Subclass Counsel have no disabling conflicts of interest that prevent them from serving as Subclass Counsel. Last, their participation in the negotiations satisfies their fiduciary obligation to protect the interests of the subclasses they represent. Subclass Counsel began serving in that capacity in late July or early August 1999. (Ex. P-270 at 15-16 & 123; Tr. 5/2/00 at 54-55.) From the point in the negotiations where the parties decided to create subclasses, Subclass Counsel agreed to serve. By late July, prior to the signing of the MOU, Eric Kennedy, Dianne Nast and Richard Lewis had agreed to serve. As the subclass structure was in a nascent stage, Ms. Nast and Mr. Lewis were initially asked to represent those persons who had not received echocardiograms (and those who were not diagnosed FDA Positive), and Mr. Kennedy was asked to represent those who had been diagnosed FDA Positive). This was an appropriate division of responsibilities. These three Subclass Counsel actively participated in the negotiations in late July and early to mid-August prior to the

submission of the MOU that led to the current subclass structure and basic compensation scheme. In fact, all three testified that well before they met with members of AHP's defense team in late July or early August 1999, they had numerous discussions with the PMC about the settlement and what they thought it should include. At meetings among Class Counsel, Subclass Counsel and AHP during late July and early to mid-August, the subclass definitions were refined and the benefits surrounding the fundamental distinctions were solidified. Soon thereafter, Mark Tanner and Richard Wayne were selected to be Subclass Counsel. At this point: Ms. Nast represented Subclass 1(a), Mr. Lewis represented Subclass 1(b), Mr. Tanner represented Subclass 2(a), Mr. Kennedy represented Subclass 2(b), and Mr. Wayne represented Subclass 3. (AHP Ex. 629 at 132; AHP Ex. 627 at 35-37 & 39-40; AHP Ex. 630 at 24 & 31-32; AHP Ex. 626 at 34 & 37.)

These Subclass Counsel assisted in negotiating one of the key elements of the Settlement Agreement--the duration of use that would distinguish group "a" from group "b," which impacted the benefits that persons would receive under the settlement. In addition, the distinction between persons who had been diagnosed with FDA Positive valvular regurgitation by September 30, 1999, and persons who had not been so diagnosed by that date was also successfully negotiated with the assistance of Subclass Counsel. Finally, in September of 1999, when plaintiffs believed that the parties were coming close to agreement, a draft of the MOU was circulated to Subclass Counsel for their comments. Subclass Counsel commented on that draft, and the

individuals who were directly involved in the negotiation with AHP at that point took direction from Subclass Counsel and made sure to obtain their approval regarding the remaining details of the agreement. (AHP Ex. 633 at pp. 24-25 & 48; AHP Ex. 630 at 42-43; AHP Ex. 629 at 133-35; Ex. P-270 at pp. 21-22.)

In sum, the court finds a sufficient amount of involvement by Subclass Counsel. Although some Subclass Counsel were less active than others, this alone does not cause the court to find that Subclass Counsel shirked their obligations to the subclasses they represented.

(G) Attorneys' Fees.

Objectors assert that Class Counsel negotiated their attorneys fees simultaneously with the class, that they reached a deal to divide the fee among themselves, that lead counsel used their leverage to coerce Subclass Counsel to go along with the settlement, that the settlement does not provide for a mechanism to award fees and that the Agreement does not provide a separate fee structure for Subclass Counsel. (Dunn Proposed Conclusions of Law ¶¶ 21-24.) Objectors argue that, thus, Class Counsel and Subclass Counsel had a conflict in that they were economically motivated to simply enact a global settlement and share in the \$429 million pot of attorneys' fees that AHP agreed to provide. Objectors' assertions are off the mark.

First, the court determines whether and to what extent Class Counsel are entitled to fees for services performed in generating a

common fund. In the Third Circuit, common benefit fees are appropriately determined by both a Lindy approach and a percentage of the fund approach. See Report of the Third Circuit Task Force, "Court Awarded Attorneys Fees", 108 F.R.D. 237, 255 (1985); In re Prudential Ins. Co. of Am. Sales Practices Litig., 148 F.3d at 333 (stating that it is sensible to use both Lindy approach and percentage approach as "cross-check"); GM Trucks, 55 F.3d at 820 (same). Also, Class Counsel may agree to limit the amount of fees awarded by the court or negotiate with defendants to create a separate fund for the payment of attorneys' fees to be awarded by the court and it is permissible for counsel to do so prior to the conclusion of negotiations regarding the benefits of the settlement itself. See Ashley v. Atlantic Richfield Co., 794 F.2d 128, 138 (3d Cir. 1986).

Here, while Class Counsel reached an understanding among themselves with regard to the relative contributions made by attorneys, they did not make a deal to split fees. The determination of fees is for the court. Also, it is clear that Class Counsel did not make a deal with AHP for the payment of attorneys' fees. The \$200 million fee cap on Fund A was negotiated after the benefits for Fund A were determined. (Tr. 5/2/00 at 88.) With regard to Fund B, Class Counsel voluntarily agreed to limit their fee request to a maximum of 9% of the value of Fund B. (Tr. 5/2/00 at 95-97.) Last, there is no evidence that lead counsel possessed any leverage with regard to counsel fees which would allow

them to pressure Subclass Counsel into acceding to the terms of the settlement. In fact, such a suggestion ignores the fact that it is the court that controls the award of attorneys' fees. In sum, the cap on fees provided for in the Settlement Agreement does not constitute a disabling force upon Class or Subclass Counsel which destroys their ability to adequately represent the class.

5. Rule 23(b)(2)

A class action is maintainable under Rule 23(b)(2) when "the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole." Fed. R. Civ. P. 23(b)(2). Subsection (b)(2) class actions are "limited to those class actions seeking primarily injunctive or corresponding relief." Barnes v. American Tobacco Co., 161 F.3d 127, 142 (3d Cir. 1998) (quoting 1 H. Newberg, Newberg on Class Actions, § 4.11, at 4-39). Plaintiffs here seek "equitable, injunctive and declaratory relief" to create a court-supervised fund to provide medical screening, medical services, medical research and education, and a medical/legal registry to assure that Diet Drug Recipients receive prompt and proper diagnosis and treatment of Diet Drug induced health problems. (Ex. P-2 ¶¶ 2, 31-34 & 87-95.) Establishment of a court-supervised program through which class members would undergo periodic medical examinations in order to promote early detection of diseases is a

"paradigmatic request for injunctive relief." Barnes v. American Tobacco Co., 161 F.3d at 132.

The Third Circuit examined the medical monitoring remedy in Barnes and articulated the following elements for recovery: (1) plaintiff was significantly exposed to a proven hazardous substance through the negligent actions of the defendant; (2) as a proximate result of exposure, plaintiff suffers a significantly increased risk of contracting a serious asymptomatic disease; (3) that increased risk makes periodic diagnostic medical examinations reasonably necessary; (4) monitoring and testing procedures exist that make the early detection and treatment of the disease possible and beneficial; and (5) a reasonable physician would prescribe a monitoring regime different than the one that would have been prescribed in the absence of that particular exposure. Barnes, at 138 n.10 (citing In re Paoli Railroad Yard PCB Litig., 916 F.2d 829, 852 (3d Cir. 1990); In re Paoli Railroad Yard PCB Litig., 35 F.3d 717, 788 (3d Cir. 1994)). These legal requirements correspond with various public health criteria identified in the hearing testimony by Troyen Brennan, J.D., M.D., M.P.H. as prerequisites for implementing a medical monitoring program: (1) asymptomatic progression of disease following toxic exposure; (2) the existence of a test with high sensitivity; (3) exposed population with relatively high prevalence; (4) the test has a high predictive value; (5) the test is relatively low cost; (6) monitoring is capable of integration into standard clinical follow-up of those

with disease; (7) monitoring should allow early preventive care; and (8) monitoring should allow appropriate timing of definitive care. (Tr. 5/3/00 at 80-104.) The legal and medical requirements are met here. Integration of these elements into the settlement between the parties demonstrates the important public policy and public health objectives achieved by this settlement.

The same public policy objectives are often poorly served by tort litigation. As Dr. Brennan explained, the tort system often fails to accurately identify injured individuals. The economics of tort litigation means that intervention can only occur after a litigant has already sustained an injury. There are no incentives for the tort system to screen asymptomatic individuals, since such persons generally have limited compensation rights. Medical monitoring, on the other hand, suits public health goals of prevention and early treatment, because it seeks to preserve health and prevent injury rather than maximize damages, thereby ameliorating the harsh dynamics of an injury-compensation based tort system. Equally important, in the context of a class action settlement achieved in the midst of an ongoing public health emergency, medical monitoring allows for informed choice about medical and legal options.

6. Rule 23(b)(3) Superiority

Rule 23(b)(3) requires that a class action be "superior to other available methods for the fair and efficient adjudication of

the controversy." Fed. R. Civ. P. 23(b)(3). In making a finding under this rule, the court should consider:

(A) the interest of members of the class in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; [and] (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum.

Id. As discussed, the difficulties likely to be encountered in the management of a class action is not a relevant consideration in the class action settlement context. See Fed. R. Civ. P. 23(b)(3)(D); Amchem, 521 U.S. at 620 (stating that district court need not inquire whether case, if tried, would present intractable management problems). With regard to the interest of class members individually controlling their litigation, the Settlement honors that concern through its multiple opt out rights, which are further enhanced by the information class members can receive about their injury status through the Settlement's medical monitoring provisions. In essence, the combination of medical monitoring and unprecedented opt out rights allows a class member to make informed choices about how to control their own destinies, whether it be through settlement or through litigation. In addition, from the perspective of judicial efficiency, there is a strong desirability in implementing a settlement in this MDL No. 1203 transferee court, the jurisdiction with the most individual and class actions pending.

The Settlement's Accelerated Implementation Option also weighs in favor of superiority here as it further expands the amount of

choice individual class members may exercise through the provisions of the Settlement. Under the AIO, class members may enjoy the benefits under the settlement without waiting for the conclusion and outcome of any appellate process. The AIO presents a unique opportunity in that class members may accept the benefits of the Settlement without having to await court approval of the class.

Another factor weighing in favor of superiority is that the relief provided in the Settlement would not practically be available in the absence of class treatment. The Fifth Circuit has recognized that the "'most compelling rationale for finding superiority in a class action . . . [is] the existence of a negative value suit.'" Allison v. Citgo Petroleum Corp., 151 F.3d 402, 420 (5th Cir. 1998) (quoting Castano v. American Tobacco Co., 84 F.3d 734, 748 (5th Cir. 1996)). Negative value claims are claims in which the costs of enforcement in an individual action would exceed the expected individual recovery. Here, the small monetary amount involved with a medical monitoring claim makes an individual claim for monitoring prohibitive in the absence of class treatment.

Objectors argue that this settlement involves an immature mass tort, and thus, fails the superiority prong of Rule 23. See Castano, 84 F.3d at 746-47 (stating that immature certification dramatically affects the stakes for defendants); see also Arch v. American Tobacco Co., Inc., 175 F.R.D. 469, 494 (E.D. Pa. 1997). Specifically, Objectors assert that because there are only a limited number of verdicts and settlements involving diet drugs, it is more

difficult for claimants to assess the reasonableness of the settlement offered here by AHP. Objectors' reliance on the immature tort theory is unpersuasive. In Castano, the Fifth Circuit noted the dangers of early certification:

[i]n the context of mass tort class actions, certification dramatically affects the stakes for defendants. Class certification magnifies and strengthens the number of unmeritorious claims. Aggregation of claims also makes it more likely that a defendant will be found liable and results in significantly higher damage awards.

In addition to skewing trial outcomes, class certification creates insurmountable pressure on defendants to settle, whereas individual trials would not.

Castano, 84 F.3d at 746. Here, none of these concerns are present. In fact, it appears that the objectors have turned the immature tort argument--typically a defense theory against certification--on its head.

In addition, the science underlying this litigation is sufficiently mature. While superiority concerns may exist where litigation involves a novel legal theory or where injuries have a considerable latency period or where there is inadequate evidence to support liability, causation and damages, none of those concerns exist here. In that regard, Objectors' views of the science are refuted by the record developed at the Fairness Hearing with regard to the following topics: progression, latency, severity of injury, duration of exposure, tricuspid claims, neurotoxicity claims and PPH claims.

a. Progression and Latency

As discussed above, the scientific evidence does not indicate a long latency period or slow progression of VHD. See supra, at II.D.4.b.(ii)(B). Objectors have cited two studies--the Eichelberger and Fischer studies--in support of their assertion that diet drugs may have a history of slow progression. (Ex. P-118; Ex. P-119.) Neither of these studies support Objectors' arguments. In fact, the exact conclusion of the Eichelberger study was that:

the prevalence and severity of fenfluramine/phentermine associated valvulopathy fifteen years after exposure is similar to published reports of patients with recent exposure, suggesting a lack of significant regression or progression of valvulopathy over the time period examined. Most patients have only mild regurgitation associated with the aortic valve, and no patient in this study developed significant valvular complications.

(Ex. P-118.) Likewise, the Fischer study concluded that "[i]n a subset of patients with FDA defined clinically relevant valvular regurgitation, there does not appear to be progression off anorexic agents." (Ex. P-119.)

Objectors have also cited to the Jick study and asserted that VHD may emerge years after ingestion because that study reported that four of 8900 patients evaluated were not clinically diagnosed with regurgitation until a few years after they had taken the drugs. (Ex. P-127.) This study does not support Objectors' views of the evidence. The Jick Study focused on VHD detected in clinical practice based upon the presentation of symptoms. The study did not employ echocardiography in evaluating the exposed population. All of the experts who testified at the Fairness Hearing agreed that echocardiography can accurately diagnose diet drug induced VHD

substantially before it progresses to the point of producing symptoms. (Ex. P-95 ¶ 9 & 12; AHP Ex. 613 ¶ 6; AHP Ex. 610 ¶ 11.)

b. Severity of Injury

Objectors argue that FDA positive is not the appropriate benchmark for clinically significant VHD. They cite to the Kahn Study, which detected trace aortic valve insufficiency in some patients, suggesting that FDA thresholds for may be too high to detect all valvular damage. (Dunn LT 81 at 717.) However, studies performed since the Kahn study and introduced into this record demonstrate that increased incidence of non-FDA positive levels of valvular regurgitation disappear within six months after exposure to the drugs. (Ex. P-172 at 1 of 8; Ex. P-173 at 2 of 23; AHP Ex. 587A; Ex. P-126 at 1, Table 1; Ex. P-149; AHP Ex. 609 ¶ 8; Tr. 5/8/00 at 79; AHP Ex. 613 ¶¶ 62-70; AHP Ex. 611 ¶¶ 33-40; & AHP Ex. 610 ¶ 10.)

c. Duration of Exposure

At least six experts testified in person or by declaration that individuals who took diet drugs for less than three months did not have an increased risk of FDA positive levels of regurgitation. (Tr. 5/3/00 at 93-96; Tr. 5/8/00 at 24; AHP Ex. 609 ¶ 8; Tr. 5/8/00 at 78-79; AHP Ex. 611 ¶ 17; and AHP Ex. 610 ¶ 10.) Despite the evidence introduced at the Fairness Hearing as discussed above, the Objectors argue that 60 days of diet drug exposure is an inappropriate benchmark for settlement benefits. This argument is without merit.

First, the Objectors cite to the PMC's response to a paper AHP submitted to the FDA which pointed out that there was a "higher prevalence of VHD reported with exposures [to diet drugs] as brief as one month." (Dunn Proposed Findings of Fact ¶¶ 93 & 96.) Although this is true, it is also true that there is no increased prevalence of FDA regurgitation in individuals who used diet drugs for less than three to six months and that the increase in non-FDA levels of regurgitation manifested for short term users disappears within six months to one year after cessation of diet drug use. (Tr. 5/3/00 at 93-96; Ex. P-90 ¶ 5; Tr. 5/8/00 at 24; Ex. P-122; AHP Ex. 587A; Ex. P-115; Ex. P-228; Ex. P-170; Ex. P-172; & Ex. P-173.)

Second, Objectors cite to the Biswas report, which involved a single patient. (Dunn Proposed Finding of Fact ¶ 93.) Such anecdotal evidence is insufficient to support an inference about increased risk. Third, Objectors cite to a study by Dr. Jick. Id. However, this study caused Dr. Jick, as well as every other expert who reviewed that study, to conclude that individuals who used diet drugs for less than three months were not at increased risk of VHD. (Ex. P-128 at 2-3; Tr. 5/3/00 at 112-14.) Fourth, the Objectors cite to Dr. Goodman's declaration stating that the duration-response relationship of diet drugs is an "open scientific question." (Ex. P-90 ¶ 5.) However, Objectors ignore Dr. Goodman's declaration that "if there is an excess risk in the class of persons with less than 60 days of exposure, it is likely to be substantially smaller" and that there is a "scientifically justifiable separation of

individuals into different classes with regard to the strength of evidence for causation and with regard to screening practices." Id. Last, Objectors point to the fact that a one-month cut-off date was used to define the class in Jeffers. However, the one month cut-off used in Jeffers has no evidentiary significance. That certification decision was made without the benefit of scientific studies that have been published over the last year showing that a thirty day cut-off period was too short.

d. Injury to the Tricuspid Valve

Objectors further argue that there are indications that diet drugs may also affect the tricuspid valve. (Dunn Proposed Finding of Fact ¶ 97.) In support, Objectors cite to the Connolly Study, a case series involving 24 patients which detected some tricuspid regurgitation in patients. However, there was no confirmation that such tricuspid regurgitation was caused by the same kind of stuck-on plaques that characterize diet drug induced VHD. (Ex. P-113 at Table 1.) On the other hand, at least four epidemiologic studies confirmed that fenfluramines did not produce an increased risk of tricuspid regurgitation. (Ex. P-170; Ex. P-115; Ex. P-111; & Ex. P-122.) In keeping with these studies, several experts offered opinions that diet drugs did not pose an increased risk of tricuspid regurgitation. (AHP Ex. 611 ¶ 18.) The Objectors did not attempt to prove otherwise through cross-examination or direct testimony.

e. Neurotoxicity

The court has already discussed the science with regard to neurotoxicity. See supra, at II.D.4.b.(ii)(C). Although the neurotoxicity hypothesis has been advocated for several years, no evidence suggests that the drugs are neurotoxic in humans.

f. PPH

The Objectors argue that the definition of PPH in the Settlement Agreement precludes individuals who have non-cardiac related secondary causes of pulmonary hypertension (such as collagen vascular disease) from pursuing PPH claims against AHP if they manifest pulmonary hypertension as a result of taking diet drugs. (Dunn Proposed Findings of Fact ¶¶ 101-03.) This is a misreading of the Settlement Agreement. Under the definition of PPH in the Settlement Agreement, a person with pulmonary hypertension which is not related to left-sided VHD, obstructive lung disease or pulmonary embolism has the right to make a claim against AHP for PPH provided that a board certified cardiologist or pulmonologist determines that diet drugs were the cause of the person's pulmonary hypertension. (Ex. P-3 at 14 of 148.) Thus, the Agreement does not foreclose those with secondary causes of pulmonary hypertension from making claims that they developed pulmonary hypertension as a result of taking the drugs.

g. Summary

The Objectors assert that there are a number of scientific uncertainties that undermine the superiority of this class action settlement. Nonetheless, several scientific experts testified otherwise at the Fairness Hearing. The Objectors did not cross-examine these witnesses, challenge their credentials, or question the studies that they argue are contrary to the experts' views. Moreover, the Objectors neglected to offer any expert testimony of their own. Instead, they offer their own interpretation of studies, absent any expert explanations supporting these interpretations. Under these circumstances, the court is satisfied that the scientific state of this litigation is not so underdeveloped as to destroy the superiority of class treatment under Rule 23.

In conclusion, and for the reasons discussed above, the court finds that this proposed class meets the requirements of Rule 23(a) and 23(b)(2) and (3) of the Federal Rules of Civil Procedure and that the "'proposed class has sufficient unity so that absent members can fairly be bound by decisions of class representatives.'" In re Prudential Ins. Co. of Am. Sales Practices Litig., 148 F.3d at 316 (quoting Amchem, 521 U.S. at 621).

E. Rule 23(e) Fairness Requirements

As a separate inquiry, the court must determine the fairness of any class action settlement. Fed. R. Civ. P. 23(e). Where the parties simultaneously seek certification and settlement approval, a court should "'be even more scrupulous than usual'" when examining the fairness of the proposed settlement. In re Prudential Ins. Co.

of Am. Sales Practices Litig., 148 F.3d at 317 (stating that heightened standard ensures that class counsel demonstrate sustained advocacy throughout proceedings and protect interests of class members) (quoting G.M. Trucks, 55 F.3d at 805). In Girsh v. Jepson, 521 F.2d 153 (3d Cir. 1975), the Third Circuit set out the traditional factors to consider in evaluating the fairness of a class action settlement:

(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 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 . . .; [and] (9) the range of reasonableness of the settlement fund to a possible recovery in light of all the attendant risks of litigation. . . .

In re Prudential Ins. Co. of Am. Sales Practices Litig., 148 F.3d at 317 (quoting Girsh, 521 F.2d at 157).

In addition, the Third Circuit has expanded the Girsh factors in the mass tort context to include, when appropriate, a consideration of:

the maturity of the underlying substantive issues, as measured by experience in adjudicating individual actions, the development of scientific knowledge, the extent of discovery on the merits, and other factors that bear on the ability to assess the probable outcome of a trial on the merits of liability and individual damages; the existence and probable outcome of claims by other classes and subclasses; the comparison between the results achieved by the settlement for individual class or subclass members and the results achieved--or likely to be achieved--for other claimants; whether class or subclass members are accorded the right to opt out of the

settlement; whether any provisions for attorneys' fees are reasonable; and whether the procedure for processing individual claims under the settlement is fair and reasonable.

In re Prudential Ins. Co. of Am. Sales Practices Litig., 148 F.3d at 323. The court now turns to an examination of these factors.

1. Complexity, Expense and Likely Duration of the Litigation.

This factor is "intended to capture the probable costs, in both time and money, of continued litigation." G.M. Trucks, 55 F.3d at 812 (internal quotations omitted). This court, sitting as the MDL No. 1203 transferee court, has presided over hotly contested discovery and motion practice for over two years. See supra, at § I.A. (discussing MDL No. 1203 proceedings). Litigation of these cases would require great time and expense in concluding discovery, obtaining numerous expert witnesses and in setting trial dates throughout the country. See supra, at § I.A. (discussing diet drug litigation in general). Given the complexity and number of cases involved, this litigation would place a strain on court dockets throughout the nation. Consequently, many plaintiffs could wait substantial periods of time before their cases reach trial. This factor weighs in favor of settlement.

2. Reaction of the Class to the Settlement.

This factor must be analyzed by examining the number and vociferousness of the objectors, as well as gauging whether members of the class support the settlement. See G.M. Trucks, 55 F.3d at 812. Of the potential class size of six million, over 200,000 class

members have already registered for settlement benefits. Approximately 160,000 of those class members have elected the AIO. On the other hand, approximately 50,000 class members have opted out of the settlement and less than thirty objections to the settlement were filed. The court finds that these numbers represent a low number of objectors and strong reaction by the class in favor of the settlement. Thus, this factor weighs in favor of settlement.

3. Stage of Proceedings and Amount of Discovery Completed.

"To ensure that a proposed settlement is the product of informed negotiations, there should be an inquiry into the type and amount of discovery the parties have undertaken." In re Prudential Ins. Co. of Am. Sales Practices Litig., 148 F.3d at 319. It is appropriate to measure the stage of proceedings either in the class action at issue or in some related proceeding. G.M. Trucks, 55 F.3d at 813. As discussed above, litigation in both MDL No. 1203 and in state court proceedings had progressed to a point that allowed those plaintiffs negotiating the settlement to appreciate the merits of their claims against AHP. See supra, at § I.A. (discussing progression of discovery and litigation in general). In fact, litigation had proceeded to the point of mid-trial in the Vadino medical monitoring class action in New Jersey. In light of the extensive discovery undertaken in state and federal courts, the court finds that Class Counsel were informed of the merits of this litigation. This factor weighs in favor of settlement.

4. Risks of Establishing Liability and Damages

"The fourth and fifth Girsh factors survey the possible risks of litigation in order to balance the likelihood of success and the potential damage award if the case were taken to trial against the benefits of the immediate settlement." In re Prudential Ins. Co. of Am. Sales Practices Litig., 148 F.3d at 319. Initially, the court recognizes that "the risks surrounding a trial on the merits are always considerable." Weiss v. Mercedes-Benz of N. Am., Inc., 899 F. Supp. 1297, 1301 (D.N.J. 1995); see In re Prudential Ins. Co. of Am. Sales Practices Litig., 962 F. Supp. 450, 539 (D.N.J. 1997) (quoting Weiss), aff'd, 148 F.3d 283 (3d Cir. 1998).

Here, the risks of establishing liability and damages are readily apparent. Although the court makes no determination of the merits of the claims of plaintiffs, it notes several obstacles that they would have to overcome:

- damages for pain and suffering and future medical expenses are often speculative and pose an uncertainty that plaintiffs may be able to prove these damages at trial;
- while plaintiffs assert that AHP was aware of information confirming the association between diet drugs and VHD, AHP argues that such information did not indicate such an association and the regulatory agencies including the FDA evaluated similar information and did not perceive the association;
- based on the studies discussed above, several causation issues pose a risk, especially for class members who used diet drugs for less than three to six months;
- the scientific complexity of this case is likely to lead to a battle of expert testimony which enhances the unpredictability of a trial outcome. See In re Warner Communications Sec. Litig., 618 F. Supp. 735, 744-45 (S.D.N.Y. 1985) (discussing "virtual[] impossib[ility]" of

predicting which testimony will be credited in battle of experts);

- several class members may face difficulty in establishing present or future damages, such as those who took the drug and are uninjured or have only mild aortic regurgitation, an asymptomatic condition that does not affect a person's ability to function normally;
- depending on the jurisdiction, other asymptomatic class members may not be able to recover damages; and
- AHP has asserted several other defenses in individual cases, including the statute of limitations, claim-splitting, res judicata, contributory negligence, comparative negligence, pre-existing condition, Daubert challenges to plaintiffs' experts and attacks against plaintiffs' damages evidence.

These risks to establishing liability and damages show that plaintiffs' success at trial can not be guaranteed. Thus, these factors weigh in favor of settlement.

5. Risk of Maintaining Class Action Throughout Trial

Under Rule 23, the court has authority to decertify a class that proves unmanageable, and thus, there is always a risk that the class may not be maintained throughout trial. In re Prudential Ins. Co. of Am. Sales Practices Litig., 148 F.3d at 321. AHP has also represented that it would contest certification if this case proceeds to trial. AHP has also sought review of the Jeffers class and has challenged and defeated class certification in some state court actions. Thus, this factor weighs in favor of settlement. However, the court finds that this factor is insignificant and does not figure prominently in the court's decision. Amchem's directive to take settlement into consideration negated the inquiry into whether case, if tried, would present intractable management

problems. Amchem, 521 U.S. at 620. Thus, the Third Circuit has stated that "after Amchem the manageability inquiry in settlement-only class actions may not be significant." In re Prudential Ins. Co. of Am. Sales Practices Litig., 148 F.3d at 321.

6. Ability of AHP to Withstand Greater Judgment

This factor does not require that the defendant pay the maximum it is able to pay. In re Prudential Ins. Co. of Am. Sales Practices Litig., 148 F.3d at 321-22 (finding that defendant's declining credit rating during litigation supported settlement). "Where the ability of the defendant to take a bigger hit is in doubt . . . the courts generally view this as a major factor weighing in favor of the settlement." In re Chambers Dev. Sec. Litig., 912 F. Supp. 822, 839 (W.D. Pa. 1995). Where a defendant has resources to pay a larger judgment, courts often accord this factor little weight. See G.M. Trucks, 55 F.3d at 818 (agreeing with district court determination that although defendant could withstand a greater judgment, no significance would be attributed to this factor); Lazy Oil Co. v. Witco Corp., 95 F. Supp. 2d 290, 318 (W.D. Pa. 1997) (presuming defendants would have resources to withstand greater judgment but according factor little weight in light of risks that plaintiffs would not be able to achieve greater recovery at trial).

Here, AHP has committed a substantial portion of its book value toward this settlement. While the court presumes that AHP could withstand a greater judgment, it accords little weight to this Girsh factor in light of the attendant risks plaintiffs would face if

these cases proceeded to trial. See infra, at § II.F.7. (discussing attendant risks of litigation).

7. Range of Reasonableness of the Settlement Fund in Light of the Best Possible Recovery and All the Attendant Risks of Litigation.

"The last two Girsh factors ask whether the settlement is reasonable in light of the best possible recovery and the risks the parties would face if the case went to trial." In re Prudential Ins. Co. of Am. Sales Practices Litig., 148 F.3d at 322. Objectors argue that the matrix benefits are substantially below the real world settlement value in comparison to certain individual settlements reached in the diet drug litigation. This reasoning is flawed. First, this argument incorrectly assumes that all class members will want to pursue the risk of proceeding toward trial. See id. at 322 (stating that present value of damages must be discounted for risk of not prevailing). Second, variables such as the specific nature of the proceeding, the venue, the skill of attorneys and several other factors render individual settlements or verdicts incapable of direct comparison with the nationwide resolution contemplated here. Third, the fact that over 120,000 class members have chosen the AIO option (which, in essence, is a separate agreement with AHP to receive the same benefits as provided for in the Settlement) is a strong indication that the settlement's benefits are within the range of reasonableness.

The court has already noted the other obstacles to plaintiffs' success if the case were to proceed to trial. See supra, at §

II.E.4. (discussing risks to establishing liability and damages). While the settlement avoids these risks, it also offers choice. Class members who wish to bear the risks of trial had an initial opt out right, and may have additional opt out rights in the future. The court finds that the benefits offered here are within the range of reasonableness considering the best possible recovery and all the attendant risks of litigation, and thus, these factors weigh in favor of settlement.

8. Remaining Prudential Considerations.

a. Maturity of Underlying Substantive Issues as Measured by Experience in Adjudicating Individual Actions.

As discussed above, the discovery conducted in both state and MDL courts has progressed to the point of general "trial readiness" for plaintiffs. See supra, at § I.A. (discussing progression of discovery and litigation). The substantive issues involved here are sufficiently shaped, as seen through the risks of establishing liability and damages as outlined earlier by the court. See supra, at § II.E.4. (discussing risks). This "trial readiness" allowed Class Counsel to negotiate this Settlement from a position of strength. This factor weighs in favor of settlement.

b. Development of Scientific Knowledge.

As discussed above, there has been extensive investigation into the relationship between diet drugs and VHD. See supra, at § I.D. (discussing medical circumstances and scientific issues affecting class). There have been at least thirteen major scientific

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

c. Comparison of Class Recovery to Individual Claimant Recovery.

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

d. Whether Class Members Have Opt Out Rights.

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

e. Reasonableness of Attorneys' Fees.

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

f. Fairness of Procedure for Processing Individual Claims.

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

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

9. Provision for Joint Tortfeasor Liability.

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

The settling parties also agreed that class members "shall reduce any judgments" that class members may obtain from non-settling defendants to the extent necessary to "relieve AHP and the Released Parties of liability for contribution or non-contractual indemnity" to any non-settling defendant. Id. The express terms of the Settlement Agreement further provide that non-settling defendants, at a minimum, retain the set-off or judgment reduction rights to which they are entitled by operation of applicable law. Id. at 121-22 of 148. In the event that non-settling defendants' rights are not extinguished by operation of law, any class member who recovers a judgment against such a non-settling defendant "shall reduce his judgment against the Non-Settling Defendant by the amount, percentage, or share of such judgment necessary, under applicable law, to relieve AHP and the Released Parties of liability for contribution or non-contractual indemnity." Id. at 122-23 of 148.

The Settlement Agreement also expressly incorporates what is known in Pennsylvania as a "Griffin release" and/or known in Wisconsin and elsewhere as a "Pierringer release." In this provision, class members agree that the lack of a judicial determination that the settling defendant is a joint tortfeasor does not preclude non-settling defendants from obtaining set-off or judgment reduction rights they would otherwise have under applicable law in the absence of the Settlement Agreement. (Ex. P-3 at 123-24 of 148 (citing Griffin v. United States, 500 F.2d 1059 (3d Cir.

1974); Pierringer v. Hoyer, 124 N.W.2d 106 (Wis. 1963)). The Settlement Agreement states that the settling parties intended to obviate the need, and eliminate the expense, of having AHP and Released Parties added or remain as parties or participate in trials merely for the purpose of determining if in fact they were joint tortfeasors. The settling parties state in the Agreement that the "Griffin release" and/or "Pierringer release" was incorporated in the Agreement to "facilitate the adjudication" of non-settling tortfeasors' set-off and judgment reduction rights in any verdict. (Ex. P-3 at 123-24 of 148.)

In light of the set-off and judgment reduction rights provided to the non-settling defendants, the Settlement Agreement provides for a bar order to be entered, prohibiting the assertion of claims of contribution or non-contractual indemnity. (Ex. P-3 at 133 of 148.) The Settlement Agreement defines "non-contractual indemnity" as "a right of indemnity based upon the relationship between or conduct of the parties." Non-contractual indemnity includes "a contractual indemnification voluntarily assumed by AHP to the extent AHP would have been liable to such claimant for indemnity in the absence of such contractual indemnification." (Ex. P-3 at 126-27 of 148.)

As further protection for the non-settling defendants' interests, the settling parties provided a mechanism in the Agreement by which non-settling defendants may apply to the court for relief from the bar order. A non-settling defendant may obtain

relief from the bar order when necessary to "protect set-off or judgment reduction rights to which the Non-Settling Defendants would be entitled under applicable law but for the provisions of the Settlement Agreement." (Ex. P-3 at 126 of 148.) These provisions in the Settlement Agreement are taken almost verbatim from the comparable provisions of the settlement agreement approved by this Court in In re Orthopedic Bone Screw Prod. Liab. Litig., 176 F.R.D., 158, 182 (E.D. Pa. 1997). As in that case, the "set-off and reduction provisions [in the Diet Drug Settlement Agreement] assure that the non-settling defendants will pay no more than they would have paid had they been able to seek contribution or indemnity." Id.

Non-settling defendant Interneuron Pharmaceuticals, Inc. ("Interneuron") asserts that its substantive state law contribution and indemnity rights cannot be altered by the Settlement Agreement. Initially, the court recognizes that the law "favors settlement, particularly in class actions and other complex cases where substantial resources of the parties and the judiciary can be conserved by avoiding" further litigation. G.M. Trucks, 55 F.3d at 784. Consequently, courts have encouraged the use of devices such as bar orders against contribution and indemnity claims. See id.; Eichenholtz v. Brennan, 52 F.3d 478, 486 (3d Cir. 1995); In re Orthopedic Bone Screw Prod. Liab. Litig., 176 F.R.D. at 181.

Interneuron argues that the Settlement's contribution and indemnity bar provisions are at odds with the Rules Enabling Act.

28 U.S.C. § 2072(b); see Ortiz, 527 U.S. at 845 (stating that no reading of Rule 23 can ignore the Rules Enabling Act's mandate that "rules of procedure shall not abridge, enlarge or modify any substantive right"); Amchem, 521 U.S. at 629 (stating that Rule 23 must be interpreted with fidelity to Rules Enabling Act). Here, however, the Settlement Agreement does not affect any of Interneuron's substantive rights to reduce any liability it might have to a class member through contribution or indemnity claims. The Settlement Agreement preserves Interneuron's set-off or judgment reduction rights which it has in some jurisdictions, accords it any additional set-off or judgment reduction rights necessary under applicable law in other states to extinguish its claims and, as a fall back, in jurisdictions which would not extinguish such claims, provides that the class member will reduce his or her judgment against Interneuron by the amount, percentage or share of such judgment necessary to relieve AHP of any liability. (Ex. P-3 at 121-23 of 148.) Moreover, if any applicable state law did not permit the parties' intentions to be effectuated, the Settlement Agreement provides that a non-settling defendant may apply to this court for relief from the bar order. Further, the Griffin/Pierringer release provisions make it unnecessary for the non-settling defendant to obtain a determination that AHP was a joint tortfeasor and provide that class members waive any rights they might have against the non-settling defendant, the assertion of which might permit the non-settling defendant to add or retain AHP

in the litigation for adjudicating such setoff or judgment reduction rights.²⁴

Both non-settling defendants Interneuron and Les Laboratoires Servier ("Servier") object to the Settlement Agreement's definition of "non-contractual indemnity." They argue that their contractual rights of indemnity would be affected to the extent that they overlapped with non-contractual rights because they would first have to pursue those rights through judgment reduction against class members and only then sue AHP for any additional sums to which they might be entitled. Again, the court finds that the Settlement Agreement does not deprive Servier or Interneuron of any indemnity rights against AHP, but merely transfers financial exposure for such claims to the class members. Indeed, should a particular state law have any other effect, non-settling defendants have the ability to apply to this court for relief from the bar order.

²⁴ Interneuron argues that the Griffin/Pierringer release provisions have the effect of altering some of Interneuron's substantive state law rights. In support they cite only to Maine law. See Petit v. Key Bancshares of Me., Inc., 614 A.2d 946, 947 (Me. 1992) (holding that order dismissing contribution claims based on Pierringer release cannot be entered over objection of non-settling defendant). However, AHP has represented that it is unaware of any diet drug cases pending in the state courts of Maine or case transferred to this court from federal courts in Maine. (AHP's Objs. to and Comments on Other Parties' Findings of Fact and Conclusions of Law at 28-29.) In addition, if such a case is brought in Maine, or any other state which did not permit the procedures contemplated by the Settlement Agreement, Interneuron may seek relief from the bar order in this court. The court also notes that recently, the Maine legislature has overruled the decision in Petit. See 2000 Me. Legis. Serv. Ch. 633 (S.P. 630 (L.D. 1795) (amending 14 Me. Rev. Stat. Ann. tit. 14, §§ 156 & 163).

In sum, the Settlement Agreement provides that class members will reduce any judgment obtained against any non-settling defendant to the extent necessary to extinguish any claims the non-settling defendant may have against AHP for contribution and non-contractual indemnity, and that non-settling defendants would be barred from asserting any such claims against AHP. For the reasons set forth above, the court finds that in doing so, the Settlement Agreement treats the Contribution and Indemnity Claims of Non-Settling Defendants in a fair, adequate and reasonable manner without affecting the non-settling defendants' rights to reduce any liability they might have to a class member.

10. Treatment of Subrogation Interests

The Settlement Agreement carefully preserves the rights of subrogees under applicable law. First, and most importantly, the agreement specifically provides that claims by subrogees against AHP and class members can only be barred, released and discharged to the extent permitted by applicable law. (Ex. P-3 at 128 of 148.) Thus, to the extent that any principle of federal or state law does not permit a settlement to preclude the assertion of a subrogation claim without the subrogee's consent, such claims are preserved. (Tr. 5/2/00 at 95; Ex. P-3 at 128 of 148.)

Second, the Settlement Agreement provides a mechanism to adjudicate subrogation claims with respect to Matrix Compensation Benefits. (Ex. P-3 at 96-106 & 128 of 148.) In order to qualify for Matrix Compensation Benefits, class members are required to

notify the Trustees of the identity of any insurer, HMO, government agency, or other third party payor who has paid or provided healthcare benefits related to the conditions which are the basis for the class member's matrix compensation claim. Upon receiving that information, the Trustees are required to contact the putative subrogee and afford it an opportunity to demonstrate to what extent it has a right of subrogation with respect to the class member's claim for Matrix Compensation Benefits. The Trustees are required to adjudicate that claim under applicable law. If either the class member or the subrogee is not satisfied with the Trustee's adjudication of the claimed subrogation right, then there is an opportunity to appeal de novo--first to an arbitrator appointed by the court and then to the court itself. In distributing Matrix Compensation Benefits to class members, the Trustees are required to

pay the subrogation claims adjudicated through this process.²⁵ (Ex. P-3 at 96-106 & 128 of 148.)

Objectors representing subrogation interests have made a number of arguments in opposition to the Settlement. The subrogees argue that they have a right of participation in the Settlement negotiations and that the Class Representatives are not typical or representative of the subrogees. However, a right of subrogation is wholly derivative of the subrogees' insureds. The subrogees only "stand in the shoes" of their insureds.

The subrogees also argue that their subrogation rights cannot be released or compromised by their insureds. (Blue Cross Conclusions of Law ¶ 63.) However, the cases cited in support of this proposition state that an insured may indeed release subrogation claims, except in the event that the tortfeasor had

²⁵ Objectors representing subrogation interests quarrel with the mechanisms established for resolving subrogation claims with respect to Fund B payments. These objectors characterize these mechanisms as inefficient and burdensome. The court, however, has reviewed the provisions in the Settlement Agreement which provide for resolution of subrogation claims and is satisfied that this represents a fair and reasonable treatment of these claims. In fact, the Settlement's subrogation mechanism has certain benefits. In a normal subrogation context, an insurer would have to show that the medical expense paid was incurred to the injury as well as show that the alleged tortfeasor was liable. Here, subrogees are relieved of the burden of showing that AHP engaged in conduct that constituted a basis for liability.

While the subrogee objectors have offered ways to make the process even more convenient for them, the court notes that it does not have the duty to be assured that the Settlement Agreement is carefully tailored to meet subrogation concerns. Instead, the court must evaluate whether the procedures in place represent and fair and reasonable treatment of subrogation interests. The court so finds.

notice of the specific subrogation claim at the time of release. See e.g., Commercial Union v. Blue Cross and Blue Shield of Alabama, 540 So.2d 1368, 1370 (Ala. 1989) (stating that "if the tortfeasor has notice or knowledge of the insurer's rights as subrogee at the time the release is executed by the insured, that release will be regarded as subject to the rights of the insurer-subrogee" and that "[i]f, on the other hand, the tortfeasor is without notice or knowledge of those rights at the time of execution of the release, the release will act as a bar to the insurer-subrogee's claim"); Home Ins. Co. v. Hertz Corp., 375 N.E.2d 115, 118 (Ill.)(1978) (holding that "an unlimited release executed by an insured-subrogor for consideration not specifically including an amount designated as covering the insurer's subrogation interest does not bar a subsequent subrogation action by an insurer-subrogee against the tortfeasor, if the tortfeasor or his insurance carrier had knowledge of the insurer-subrogee's interest prior to the release"). The Objector subrogees here have not provided notice to AHP of any insureds for whom they claim subrogation rights.

The subrogee Objectors also complain that Fund A has no comparable mechanism for resolving subrogation interests. However, Fund A primarily provides for future medical services to class members. Thus, these subrogees cannot yet claim any interest in such future medical benefits. The subrogee Objectors also claim rights with respect to Fund A's reimbursement of the purchase prices of Pondimin and Redux. AHP argues that a valid subrogation interest

does not arise unless a subrogee's payment was related to personal injury to an insured caused by the tortfeasor. AHP further asserts that the cost of diet drugs was not a payment related to a personal injury caused by AHP, but rather a payment used to treat a pre-existing malady--obesity. The subrogee objectors, however, argue that subrogation is routinely applied to causes of action other than personal injury actions. Without resolving this dispute, the court notes that the subrogation bar order would not prohibit the assertion of a such a claim. See Ex. P-3 at 128-29 of 148 (barring subrogation claims "except to the extent that it would be impermissible to bar such claims under provisions of applicable law").

The subrogee Objectors also argue that the Settlement may not be approved until it knows how much of the Settlement amounts will go to each insured and how much each insured might owe to subrogees. The court finds that such a task would be nearly impossible and would have the effect of indefinitely suspending the class. Here the class has been informed that subrogation is an issue and that the Settlement seeks to deal with the issue:

[t]o the extent that any person has rights of subrogation by virtue of payments made for the benefit of any specific Class Member who has not exercised a right of opt-out, such rights of subrogation may be asserted only with respect to the obligation under the Settlement Agreement to make Compensation Payments from Fund B to that Class Member. Subrogation claims may not be asserted directly against AHP and/or the Released Parties except to the extent required by law. Notice of a subrogation claim will be provided to an affected Class Member, and the Class Member will be given an opportunity to object to the

subrogation claim. Subrogation claims will be paid only to the extent that they are recognized by applicable law.

(Ex. P-211 at 10.)

11. Summary

In conclusion, upon consideration of the factors set forth in Girsh v. Jepson, 521 F.2d 153, 157 (3d Cir. 1975) and In re Prudential Ins. Co. of Am. Sales Practices Litig., 148 F.3d 283 (3d Cir. 1998), the court finds this Settlement to be fair, adequate and reasonable. Thus, it will approve this Settlement in accordance with Federal Rule of Civil Procedure 23(e).

III. CONCLUSION

For the reasons set forth above and pursuant to Federal Rule of Civil Procedure 23, the court will grant the Joint Motion of the Class Representatives and American Home Products Corporation ("AHP") for an order certifying and approving the nationwide settlement class embodied in the Settlement Agreement entered into between the parties on November 19, 1999.

An appropriate Pretrial Order follows.

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 :
: :
THIS DOCUMENT RELATES TO: :
: :
----- :
SHEILA BROWN, et al. :
: :
v. :
: :
: :
AMERICAN HOME PRODUCTS :
CORPORATION : CIVIL ACTION NO. 99-20593

PRETRIAL ORDER NO. 1415

The court has conducted extensive proceedings to determine whether the proposed class action settlement set forth in the Nationwide Class Action Settlement Agreement with American Home Products Corporation and Amendments thereto (the "Settlement Agreement") filed with the court in the above-captioned action merits final approval, and if the plaintiff class previously certified by the court in Pretrial Order No. 997 should be confirmed for purposes of effectuating the Settlement. For the reasons set forth in the attached Pretrial Memorandum and upon consideration of all papers filed, all evidence and testimony presented and the presentations and arguments on pertinent issues in the Fairness Hearing Proceedings conducted herein, the court has determined that the proposed class action settlement should be approved pursuant to Federal Rule of Civil Procedure 23(e) as fair, reasonable and adequate.

Accordingly, IT IS ORDERED that:

1. The court's findings of fact and conclusions of law are incorporated herein as though fully set forth in this Final Order and Judgment. The definitions and terms set forth in the Settlement Agreement are incorporated herein as though fully set forth in this Final Order and Judgment.
2. The court has jurisdiction over the subject matter of this action with respect to all claims, and has jurisdiction over all parties to this action, including all members of the settlement class and subclasses as defined below.
3. The court hereby confirms that this action is properly certified as a class action for settlement purposes, in compliance with the applicable Rule 23 criteria; and that the settlement merits final approval under the criteria articulated in Girsh v. Jepson, 521 F.2d 153 (3d Cir. 1975) and In re Prudential Ins. Co. of Am. Sales Practices Litig., 148 F.3d 283 (3d Cir. 1998), cert. denied sub nom., Krell v. Prudential Ins. Co. of Am. Litig., 525 U.S. 1114 (1999). The settlement class and its subclasses are defined as:

All persons in the United States, its possessions and territories who ingested Pondimin® and/or Redux™ ("Diet Drug Recipients"), or their estates, administrators or other legal representatives, heirs or beneficiaries ("Representative Claimants"), and any other persons asserting the right to sue AHP or any Released Party independently or derivatively by reason of their personal relationship with a Diet Drug Recipient,

including without limitation, spouses, parents, children, dependents, other relatives or "significant others" (Derivative Claimants"). The Settlement Class does not include any individuals whose claims against AHP and/or the AHP Released Parties, arising from the use of Diet Drugs, have been resolved by judgment on the merits or by release (other than releases provided pursuant to this Settlement).

- "Subclass 1(a)" - All Diet Drug Recipients in the Settlement Class (1) who ingested Pondimin® and/or Redux™ for 60 days or less, and (2) who have not been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and September 30, 1999, and all Representative and Derivative Claimants in the Settlement Class whose claims are based on their personal or legal relationship with a Diet Drug Recipient (1) who ingested Pondimin® and/or Redux™ for 60 days or less, and (2) who has not been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and September 30, 1999.
- "Subclass 1(b)" - All Diet Drug Recipients in the Settlement Class (1) who ingested Pondimin® and/or Redux™ for 61 or more days, and (2) who have not been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and September 30, 1999, and all Representative and Derivative Claimants in the Settlement Class whose claims are based on a personal or legal relationship with a Diet Drug Recipient (1) who ingested Pondimin® and/or Redux™ for 61 or more days, and (2) who has not been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and September 30, 1999.
- "Subclass 2(a)" - All Diet Drug Recipients in the Settlement Class (1) who ingested Pondimin® and/or Redux™ for 60 days or less, and (2) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram which was performed between the commencement of Diet Drug

use and September 30, 1999, and all Representative and Derivative Claimants in the Settlement Class whose claims are based on a personal or legal relationship with a Diet Drug Recipient (1) who ingested Pondimin® and/or Redux™ for 60 days or less, and (2) who has been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram which was performed between the commencement of Diet Drug use and September 30, 1999.

- "Subclass 2(b)" - All Diet Drug Recipients in the Settlement Class (1) who ingested Pondimin® and/or Redux™ for 61 or more days, and (2) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram which was performed between the commencement of Diet Drug use and September 30, 1999, and all Representative and Derivative Claimants in the Settlement Class whose claims are based on a personal or legal relationship with a Diet Drug Recipient (1) who ingested Pondimin® and/or Redux™ for 61 or more days, and (2) who has been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and September 30, 1999.
- "Subclass 3" (which may include persons also included in Subclasses 1(a) and 1(b)) - All Diet Drug Recipients in the Settlement Class who have been diagnosed by a Qualified Physician as having Mild Mitral Regurgitation by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening, but who have not been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, and all Representative and Derivative Claimants in the Settlement Class whose claims are based on a personal or legal relationship with a Diet Drug Recipient who has been diagnosed by a Qualified Physician as having Mild Mitral Regurgitation by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, but who has not been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between

the commencement of Diet Drug use and the end of the Screening Period.

4. The court has determined that the Class Representative plaintiffs named in the operative Third Amended Complaint (Brenda Chambers, Donna Jarrell, Vivian Naugle, Quentin Layer, Joan S. Layer and Isabel Connor), have standing to represent, and adequately represent, the Class and their respective Subclasses, and they are confirmed as representatives of the Settlement Class and of each of their respective Subclasses. Class and Subclass counsel are likewise confirmed as follows:

Class Counsel:

John J. Cummings
Cummings, Cummings & Dudenhefer

Arnold Levin
Levin, Fishbein, Sedran & Berman

Michael D. Fishbein
Levin, Fishbein, Sedran & Berman

Stanley Chesley
Waite, Schneider, Bayless & Chesley

Sol H. Weiss
Anapol, Schwartz, Weiss, Cohan, Feldman & Smalley,
P.C.

Charles R. Parker
Hill & Parker

Gene Locks
Greitzer & Locks

Subclass Representatives and Counsel:

- Subclass 1(a)
Subclass Representative: Brenda Chambers

Subclass Counsel: Diane M. Nast, Roda & Nast,
P.C.

- Subclass 1(b)
Subclass Representative: Donna Jarrell
Subclass Counsel: Richard S. Lewis, Cohen,
Milstein, Hausfeld & Toll, P.L.L.C.
- Subclass 2(a)
Subclass Representative: Vivian Naugle
Subclass Counsel: Mark W. Tanner, Feldman,
Shepherd & Wohlgelertner
- Subclass 2(b)
Subclass Representative: Quentin Layer & Joan S.
Layer
Subclass Counsel: R. Eric Kennedy, Weisman,
Goldberg & Weisman Co., L.P.A.
- Subclass 3
Subclass Representative: Isabel Connor
Subclass Counsel: Richard Wayne, Strauss & Troy

5. The court hereby approves the settlement as set forth in the Nationwide Class Action Settlement Agreement with American Home Products Corporation (including the First through Fourth Amendments thereto) in its entirety and finds and determines that said settlement is, in all respects, fair, reasonable and adequate to the Class, within the authority of the parties, and non-collusive.
6. The court hereby dismisses, with prejudice and with each party to bear their own costs, the Third Amended Complaint in this action, as well as all other claims or actions asserting Settled Claims against American Home products Corporation ("AHP") pending before the court. These dismissals are to be vacated, and the complaints

reinstated, in the event that this Order and Judgment is reversed or vacated, in whole or material part, on appeal.

7. The court hereby bars and enjoins all class members who have not, or do not, timely and properly exercise an Initial, Intermediate, Back-End or Financial Insecurity Opt-Out right from asserting, and/or continuing to prosecute against AHP or any other Released Party any and all Settled Claims which the class member had, has or may have in the future in any federal, state or territorial court.
8. The court hereby bars and enjoins the commencement and/or prosecution of any claim for contribution and/or non-contractual indemnity, pursuant to Section VII.C of the Settlement Agreement and subject to the provisions of Section VII.C.2 of the Settlement Agreement, in any federal, state or territorial court against AHP or any other Released Party by any Non-Settling Defendant arising from or relating to any Settled Claim asserted by any class member.
9. The court hereby bars and enjoins the commencement and/or prosecution of any claim or action against AHP in any federal, state or territorial court based on rights of subrogation by virtue of a payment or payments made to or for the benefit of a class member arising out of or in relation to any Settled Claims, except to the extent that

it would be impermissible to bar such claims under provisions of applicable law.

10. This Order and Judgment is binding upon AHP and upon all members of the Settlement Class and Subclasses, as defined herein above, who have not timely effected exclusion from the class under the procedures set forth in the Class Notice. A final list of timely and proper exclusions shall be filed herein by the Interim Claims Administrators as soon as practicable. This Final Order and Judgment is without prejudice to the prospective exclusion rights of the class members as set forth in the Settlement Agreement.
11. Without affecting the finality of this Final Order and Judgment in any way, the court hereby retains continuing and exclusive jurisdiction over this action and each of the Parties, including AHP and the class members, to administer, supervise, interpret and enforce the Settlement in accordance with its terms; to supervise the operation of the Settlement Trust; to determine applications for and make reasonable awards of attorneys' fees and reimbursement of costs to Class and Subclass Counsel, the Plaintiffs' Management Committee, and others for work contributing to the common benefit of the class; and to enter such other and further orders as are needed to effectuate the terms of the Settlement.

12. There is no just reason for delay of the entry of this Final Order and Judgment as set forth herein, and it is therefore directed that judgment be entered.

SO ORDERED, this 28th day of August, 2000.

BY THE COURT:

LOUIS C. BECHTLE, J.