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

IN RE DIET DRUGS (Phentermine/Fenfluramine/Dexfenfluramine) PRODUCTS LIABILITY LITIGATION	MDL NO. 1203
THIS DOCUMENT RELATES TO:	
SHEILA BROWN, SHARON GADDIE, JOSE GADDIE, VIVIAN NAUGLE, QUENTIN LAYER, JOAN S. LAYER, JOBY JACKSON-REID and HARVEY E. REID, Individually and all others similarly situated,	CIVIL ACTION NO. 99-20593
Plaintiffs,	
v.	
AMERICAN HOME PRODUCTS CORPORATION,	
Defendant.	

PRETRIAL ORDER NO. 2383

PROCEDURES FOR RESOLVING MOTIONS TO ENFORCE PARAGRAPH 7 OF PRETRIAL ORDER NO 1415 AGAINST CLASS MEMBERS WHO ASSERT CLAIMS ALLEGEDLY BASED ON PPH

RECITALS

A. On August 28, 2000, the Honorable Louis C. Bechtle entered Pretrial Order No. 1415 ("PTO 1415"), which certified this action as a class action and approved the Nationwide Class Action Settlement Agreement (the "Settlement Agreement"). In approving the Settlement Agreement, Judge Bechtle determined that it was a fair, reasonable and adequate resolution of all claims and potential claims against American Home Products Corporation ("AHP") by approximately 6,000,000 members of the class, as defined in Section II.B of the Settlement Agreement.[1] PTO 1415 further provided that the Court retained continuing and exclusive jurisdiction over this action and each of the parties, including Class Members, to administer, supervise, interpret and enforce the settlement in accordance with its terms and to enter such other orders as needed to effectuate the terms of the Settlement Agreement. See PTO 1415, ¶ 11.

B. PTO 1415 also barred and enjoined those Class Members who have not timely and properly exercised an Initial, Intermediate, Back-End or Financial Insecurity Opt-Out right, as respectively defined in the Settlement Agreement, from

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[1] The Settlement Class consists of:

> 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).

Settlement Agreement, § II.B.

asserting and/or continuing to prosecute Settled Claims against AHP or any other Released Party. See PTO 1415, ¶ 7. See also Settlement Agreement, §§ I.48 (defining "Released Parties") and I.53 (defining "Settled Claim"). Any Class Member may assert a claim based on Primary Pulmonary Hypertension ("PPH"), however, with certain exceptions as set forth in Section I.53,[2] if the Class Member has that medical condition as specifically defined in Section I.46. See Settlement Agreement, §§ I.46 (defining "PPH") and I.53.

C. Recently, AHP filed a motion to enforce PTO 1415 against certain Class Members who had commenced lawsuits against AHP, in which the plaintiffs had asserted that their claims were based on PPH. In its motion, AHP contends that these Class Members are attempting to prosecute Settled Claims that are barred by Paragraph 7 of PTO 1415, because their medical conditions do not meet the criteria of Section I.46 of the Settlement Agreement.

D. A determination of whether a putative PPH plaintiff has been diagnosed with PPH, as defined by Section I.46 of the Settlement Agreement, is a threshold question that determines the eligibility of that Class Member to assert such a claim. Under the Settlement Agreement, AHP and any other Released Party should not

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[2] Pursuant to Section I.53 of the Settlement Agreement, "Settled Claims" do not include claims based on PPH, as defined by Section I.46, provided that:

> if a Class Member receives settlement benefits from Fund B, he/she may not bring a lawsuit based upon a claim for PPH, unless the Class Member was diagnosed with PPH before the Class Member had left-sided heart valve abnormalities (other than those which produce trivial, clinically insignificant left-sided regurgitation) or Endocardial Fibrosis.

Settlement Agreement, § I.53.

be required to litigate a claim allegedly based on PPH that is initiated by a person whose medical condition does not meet the criteria of Section I.46.

E. AHP, as well as any other Released Party, may seek relief from this Court to enforce PTO 1415, including, but not limited to, injunctive relief against any Class Member who has asserted a claim allegedly based on PPH, but whose medical condition does not meet the criteria of Section I.46.

F. The Court has determined that it would be efficient to adopt standardized procedures to resolve motions filed by AHP and any other Released Party, in which they challenge a Class Member's right to continue litigating a putative PPH claim.

G. The Court enters this Order to govern the resolution of motions relating to any Class Member's purported PPH claim under its continuing *in personam* and subject matter jurisdiction over the Class Members and the claims to which this Order relates. That jurisdiction derives most fundamentally from the Court's retained exclusive jurisdiction to implement the Settlement Agreement, as specified in PTO 1415, ¶ 11, and Section VIII.B.1 of the Settlement Agreement, together with the Court's supplemental jurisdiction to enforce its orders. This Court further has the authority to enter this Order to implement PTO 1415 under the All Writs Act, 28 U.S.C. § 1651, which empowers the Court to enter orders in aid of its retained jurisdiction and to protect and effectuate the Court's judgment in PTO 1415. See In re Prudential Ins. Co. Sales Practice Litig., 261 F.3d 355 (3d Cir. 2001). The Court also has inherent power to provide for the orderly implementation of the Settlement Agreement and PTO 1415 and, as to those actions brought by Class Members before this Court or which are transferred

to this Court pursuant to 28 U.S.C. § 1407, to provide for the processing and resolution of those actions.

Accordingly, the Court hereby enters the following Order:

ORDER

1. The Court hereby appoints Gregory P. Miller, Esquire, as Special Master pursuant to this Order, and authorizes and directs him to carry out the functions of the Special Master in accordance herewith.

2. All Class Members filing suits allegedly based on PPH are required, upon written request of AHP or any other Released Party named as a defendant in such suit ("the underlying action"), to provide AHP or such Released Party with all medical evidence, including medical records and tests, that relate to a diagnosis that the Class Member has PPH as defined by the criteria set forth in Sections I.46 and I.53 of the Settlement Agreement. Such medical evidence shall be disclosed within thirty (30) days of receipt of a written request and must be accompanied by a certification stating that the information being produced to the requesting party is a complete set of medical evidence upon which the Class Member is relying to establish PPH as defined by Sections I.46 and I.53 of the Settlement Agreement.

3. For the convenience of the parties and the Special Master, this Order attaches as Appendix A Sections I.46 and I.53, and as Appendix B a chart that sets forth the requirements of Section I.46.a (the requirements for diagnosis made prior to death) in a checklist form.

4. In the event that a Class Member fails to comply with the disclosure requirements of Paragraph 2 of this Order, AHP or any other Released Party may file a

motion to compel the production of medical evidence in accordance with this Order. The Court may in its discretion refer such motion to the Special Master pursuant to Pretrial Orders Nos. 26 and 36.

5. In the event that AHP or any Released Party challenges a Class Member's diagnosis of PPH, AHP or any Released Party shall use their best efforts to file and serve a motion to enforce Paragraph 7 of PTO 1415 within sixty (60) days of receipt of a complete set of medical evidence from a Class Member.

6. In any motion to enforce Paragraph 7 of PTO 1415, the moving party shall specify, based upon the Class Member's medical records or other information, the criteria of Sections I.46 that the moving party contends have not been satisfied. The motion to enforce also shall include a statement of the reasons supporting the moving party's position, together with any medical evidence demonstrating that the Class Member has not been diagnosed with PPH as defined by Section I.46 of the Settlement Agreement. Such motion shall be signed by counsel for the moving party under the terms of Rule 11 of the Federal Rules of Civil Procedure.

7. If the Class Member disagrees with the moving party's contentions, the Class Member shall file and serve a response within fourteen (14) days setting forth the reasons the Class Member contends that the criteria of Section I.46 are met. Such response shall be signed by counsel subject to the terms of Rule 11 of the Federal Rules of Civil Procedure. The moving party may file and serve a reply within seven (7) days thereafter.

8. If AHP or any other Released Party files a motion to enforce Paragraph 7 of PTO 1415 against any Class Member asserting a claim allegedly based on PPH, the Court may in its discretion refer such motion to the Special Master.

9. In the event that a motion to enforce PTO 1415 is referred to the Special Master by the Court, the Special Master, upon consideration of the parties' motions and any medical evidence submitted by the parties, shall file and serve a Report and Recommendation. That Report and Recommendation shall be based on the specific requirements of Sections I.46 and I.53 and the checklist attached to this Order as Appendix B and shall include the Special Master's findings of fact as to whether the claim being asserted by the Class Member is a Settled Claim under the terms of the Settlement Agreement. In addition to recommending whether or not a Class Member has the right to proceed with an action, the Special Master may consider recommending additional remedies that, in appropriate cases, may include the imposition of sanctions against any party or a party's counsel in the form of fees and costs, including, but not limited to, the fees and costs incurred by opposing counsel and the Special Master in connection with the motion.

10. Any party may file an appeal of the Special Master's Report and Recommendation to the Court, together with a supporting brief, within eleven (11) days after the Report and Recommendation is filed. In any appeal, the appellant shall specify which findings of fact of the Special Master are challenged. In the event that the appellant does not dispute any of the Special Master's findings of fact, said findings of fact shall be deemed uncontested.

11. Any other party may file and serve a responsive brief to an appeal within fourteen (14) days thereafter. Any reply briefs shall be filed and served within seven (7) days after the filing of any responsive brief(s).

12. In most if not all instances, the resolution of disputes under this Order will require only a comparison of the medical records with the attached checklist and will not be unduly time consuming. Accordingly, referral to the Special Master under this Order will not operate to stay the underlying action pending resolution. The Court may, upon application, enjoin any underlying action where necessary to enforce PTO 1415.

13. If a motion to enforce PTO 1415 is granted, the Class Member shall be barred from asserting the claims in question. Granting of the motion, however, shall not preclude the Class Member from subsequently asserting a PPH claim based on a subsequent change in circumstances that meets the criteria of Sections I.46 and I.53 of the Settlement Agreement. The denial of a motion to enforce PTO 1415 pursuant to this Order shall not have any preclusive effect and shall not be admissible in the litigation of such claims. Similarly, such denial shall not preclude AHP or any other Released Party from challenging, in this Court or in the underlying action, the existence of facts that purportedly qualify the Class Member to assert a claim based on PPH.

14. A ruling on a motion to enforce PTO 1415 shall not be deemed an adjudication on the merits of any element of the Class Member's claims against AHP or any other Released Party. Further, nothing in this Order shall affect the right of AHP or any Released Party to conduct discovery relating to a Class Member's claim of PPH or otherwise, as permitted by applicable law.

BY THE COURT:

HARVEY BARTLE III, U.S.D.J.

DATED: February 26, 2002

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46. "Primary Pulmonary Hypertension" ("PPH") is defined as either or both of the following:

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

(1) (a) Mean pulmonary artery pressure by cardiac catheterization of $\geq$ 25 mm Hg at rest or $\geq$ 30 mm Hg with exercise with a normal pulmonary artery wedge pressure $\leq$ 15 mm Hg[9]; or

(b) A peak systolic pulmonary artery pressure of $\geq$ 60 mm Hg at rest measured by Doppler echocardiogram utilizing standard procedures; or

(c) 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

(2) Medical records which demonstrate that the following conditions have been excluded by the following results[10]:

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[9] *See* L. J. Rubin & S. Rich, 99 *Primary Pulmonary Hypertension* (1997) [hereinafter "Rubin & Rich"].

[10] *See* Eugene Braunwald, *Essential Atlas of Heart Diseases*, Current Med. For Atty's 10-9 (1997) [hereinafter "Braunwald II"].

(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

(3) Conditions known to cause pulmonary hypertension[11,12,13] 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.

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[11] *See* Rubin & Rich, *supra* note 9.

[12] *See* Braunwald I, *supra* note 1 at 796-798.

[13] Stuart Rich, *Executive Summary from the Symposium on Primary Pulmonary Hypertension, Evian, France, co-sponsored by the World Health Organization, September 6-10, 1998.*<http://www.who.int/ncd/cvd/pph.html.>

-OR-

b. For a diagnosis made after the individual's death:

(1) 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

(2) Medical records which show no evidence of alternative causes as described above for living persons.

This definition of PPH ("the PPH Definition") is intended solely for the purpose of describing claims excluded from the definition of Settled Claims and for purposes of Section VII.B.4 and 5, below. The Parties agree that the PPH Definition includes but is broader than the rare and serious medical condition suffered by the individuals described in L. Abenhaim, *et al., Appetite-Suppressant Drugs and the Risk of Primary Pulmonary Hypertension, International Primary Pulmonary Hypertension Study Group,* 335(9), New England Journal of Medicine, 609-16 (1996) (the "IPPHS study"). The subjects in that study exhibited significantly elevated pulmonary artery pressures with an average systolic pulmonary artery pressure of 88 mm Hg and average mean pulmonary artery pressure of 57 mm Hg. Two-thirds of the IPPHS patients demonstrated NYHA Class III or IV symptoms. While the IPPHS subjects would fall within the PPH Definition, the definition also includes persons with a milder, less serious medical condition.

53. "Settled Claims" shall mean any and all claims, including assigned claims, whether known or unknown, asserted or unasserted, regardless of the legal theory, existing now or arising in the future by any or all members of the Settlement Class arising out of or relating to the purchase, use, manufacture, sale, dispensing, distribution, promotion, marketing, clinical investigation, administration, regulatory approval, prescription, ingestion, and labeling of Pondimin® and/or Redux™, alone or in combination with any other substance, including, without limitation, any other drug, dietary supplement, herb, or botanical. These "Settled Claims" include, without

limitation and by way of example, all claims for damages or remedies of whatever kind or character, known or unknown, that are now recognized by law or that may be created or recognized in the future by statute, regulation, judicial decision, or in any other manner, for:

a. personal injury and/or bodily injury, damage, death, fear of disease or injury, mental or physical pain or suffering, emotional or mental harm, or loss of enjoyment of life;

b. compensatory damages, punitive, exemplary, statutory and other multiple damages or penalties of any kind;

c. loss of wages, income, earnings, and earning capacity, medical expenses, doctor, hospital, nursing, and drug bills;

d. loss of support, services, consortium, companionship, society or affection, or damage to familial relations, by spouses, parents, children, other relatives or "significant others" of Settlement Class Members;

e. consumer fraud, refunds, unfair business practices, deceptive trade practices, Unfair and Deceptive Acts and Practices ("UDAP"), and other similar claims whether arising under statute, regulation, or judicial decision;

f. wrongful death and survival actions;

g. medical screening and monitoring, injunctive and declaratory relief;

h. economic or business losses or disgorgement of profits arising out of personal injury; and

i. prejudgment or post-judgment interest.

Notwithstanding the foregoing, Settled Claims do not include claims based on PPH, including claims for compensatory, punitive, exemplary or multiple damages based on PPH; provided, however, that if a Class Member receives settlement benefits from Fund B, he/she may not bring a lawsuit based upon a claim for PPH, unless the Class Member was diagnosed with PPH before the Class Member had left-sided heart valve abnormalities (other than those which produce trivial, clinically insignificant left-sided regurgitation) or Endocardial Fibrosis. In addition, notwithstanding the foregoing, Settled Claims do not include claims arising from the exposure of unborn children, *in utero*, to Pondimin® or Redux™, and persons alleging exposure *in utero* to Pondimin® or Redux™ shall not be considered Diet Drug Recipients eligible for benefits under this Agreement.

B

APPENDIX B

PRIMARY PULMONARY HYPERTENSION CHECKLIST

FOR A DIAGNOSIS BASED ON EXAMINATIONS AND CLINICAL FINDINGS PRIOR TO DEATH

PPH DEFINITION IN NATIONAL SETTLEMENT	YES	NO
Part (1): One or more of the following:		
(a) (i) Mean pulmonary artery pressure by cardiac catheterization of $\geq$ 25 mm Hg at rest or $\geq$ 30 mm Hg with exercise; and		
(ii) A normal pulmonary artery wedge pressure $\leq$ 15 mm Hg; or		
(b) A peak systolic pulmonary artery pressure of $\geq$ 60 mm Hg at rest measured by Doppler echocardiogram utilizing standard procedures; or		
(c) 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		
Have the criteria of Part (1) been satisfied?		

PPH DEFINITION IN NATIONAL SETTLEMENT	YES	NO
Part (2): Are there medical records which demonstrate that the following conditions have been excluded by the following results? **(A "NO" with respect to subparts (a) through (d) and, if appropriate, subpart (e) means that the condition has not been excluded, so the claimant does not meet the Settlement definition of PPH)**		
(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 left ventricular ejection fraction (LVEF) < 40% defined by MultiGated Blood-pool Imaging (MUGA), Echocardiogram or cardiac catheterization; and		
(c) Pulmonary function tests demonstrating the absence of obstructive lung disease (forced expiratory volume (FEV)/ forced vital capacity (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		
Have the criteria of Part (2) been satisfied?		

PPH DEFINITION IN NATIONAL SETTLEMENT	YES	NO
Part (3): Have conditions known to cause pulmonary hypertension been ruled out by a Board-Certified Cardiologist or Board-Certified Pulmonologist as the cause of the person's pulmonary hypertension? **("NO" with respect to any of the following conditions means the condition has not been excluded, so the Settlement Definition of PPH has not been met)**		
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		
Familial causes		
Other conditions known to cause pulmonary hypertension		
Have the criteria of Part (3) been satisfied?		
HAVE THE CRITERIA OF PARTS (1), (2), AND (3) BEEN SATISFIED?		