

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

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

MDL DOCKET NO. 1203

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

CIVIL ACTION NO. 99-20593

AMERICAN HOME PRODUCTS
CORPORATION

COURT-APPROVED PROCEDURE NO. 9
(Procedure for the Audit of Fund A Claims)

AND NOW, on the date set forth in the accompanying Pretrial Order No. 5983, in accordance with the Nationwide Class Action Settlement Agreement with American Home Products Corporation ("Settlement Agreement"), as amended, and the agreement of Class Counsel and Wyeth, it is hereby ORDERED that:

1. ***Incorporation of Settlement Agreement Definitions.*** The capitalized terms used in this Procedure shall have the same meaning as those terms have in the Settlement Agreement, as amended. Additional capitalized terms defined in this Procedure shall have the meanings given to them in this Procedure.

2. ***Applicability.*** This Procedure applies to every Claim for Additional Medical Services or Cash benefits ("CMS Benefits") designated by Wyeth for Audit pursuant to Section VI.F.2 of the Settlement Agreement where the Class Member does not also have a Claim for Matrix Compensation Benefits that is subject to Audit under Pretrial Order No. 2662 and is based on the same echocardiogram underlying the Claim for CMS Benefits. If a Class Member has submitted one echocardiogram that forms the basis for both a Claim for CMS Benefits and a Claim for Matrix Compensation Benefits, and Wyeth has designated the Class Member's Claim for CMS Benefits for Audit, the Class Member's entitlement to CMS Benefits and/or Matrix Compensation Benefits shall be determined based on the results of the Audit of the Claim for Matrix Compensation Benefits conducted under Pretrial Order No. 2662.

3. ***Withdrawal of Certain Audit Designations.*** In its sole discretion, Wyeth may at any time withdraw any Fund A Audit designation on any Claim. If Wyeth withdraws a Fund A Audit designation on a Claim and the Trust determines that the Claim is otherwise eligible for

the CMS Benefit, the Trust shall pay such CMS Benefit within 45 days after the date of Wyeth's withdrawal of the designation.

4. ***Qualifications of Fund A Auditing Cardiologists.*** The Trust shall maintain a pool of qualified Auditing Cardiologists to conduct the Audit of Claims for CMS Benefits ("Fund A Auditing Cardiologists"). Each Fund A Auditing Cardiologist shall be an independent Board-Certified Cardiologist or Board-Certified Cardiothoracic Surgeon with: (i) at least Level 2 training in Echocardiography and/or (ii) certification by the National Board of Echocardiography in Transthoracic Echocardiography. Absent Court approval, no person shall serve as a Fund A Auditing Cardiologist if: (a) that person is or has been a Trustee of the Trust; (b) served as an Attesting Physician on more than ten Claims for Matrix Compensation Benefits; and/or (c) would be disqualified from serving as a Trustee under Section VI.A.4.b of the Settlement Agreement.

5. ***Training of Fund A Auditing Cardiologists.*** The Trust shall provide training to the Fund A Auditing Cardiologists in accordance with the principles reflected in the Audit training module approved by the Court in PTO No. 2825 and the methodology used for training approved in PTO No. 4992, and any other applicable Pretrial Orders.

6. ***Schedule for Fund A Audits.*** The Trust shall re-commence the Audit of CMS Benefit Claims with Fund A Audit designations no later than 90 days after the Effective Date of this Procedure, beginning with the Claims with the earliest Audit designations and continuing through the Claims according to date of designation until all such Claims have been reviewed under the terms of this Procedure. Absent good cause, the Trust shall conduct the Audit of CMS Benefit Claims so that its Fund A Auditing Cardiologists have returned to the Trust the worksheet required under Paragraph 7 of this Procedure on at least 250 CMS Benefit Claims per month until all CMS Benefit Claims designated for Audit have been Audited. If the Audit of a CMS Benefit Claim determines that the affected Class Member had FDA Positive Regurgitation based on an echocardiogram conducted during the Screening Period, and the Class Member meets the other criteria for payment of the CMS Benefit under the Settlement Agreement, the Trust shall pay the CMS Benefit to the Class Member within 45 days after the date on which the Audit was completed.

7. ***Echocardiogram Review.*** The Trust shall forward to an Auditing Cardiologist each Claim for CMS Benefits designated by Wyeth for Audit. A Fund A Auditing Cardiologist shall review the echocardiogram, complete a worksheet reporting on the level of regurgitation, if any, found by the Fund A Auditing Cardiologist on the echocardiogram, and determine if there is a reasonable medical basis for the FDA Positive regurgitation finding by the physician who attested to such condition in the Gray Form or the Green Form submitted to the Trust on the Claim. If not timely disputed by the Class Member, the Fund A Auditing Cardiologist's findings shall determine the level of regurgitation, if any, present on the echocardiogram reviewed for the purpose of determining whether the Class Member is entitled to CMS Benefits.

8. ***Notification of Audit Result.*** No later than 30 days after receipt of the Fund A Auditing Cardiologist's worksheet, the Trust shall issue a CMS Post-Audit Determination informing the Class Member of the results of the Audit and advising the Class Member of the

opportunity to submit a Request for Review under Paragraph 9 of this Procedure. The Trust shall send the Class Member a copy of this Procedure along with the CMS Post-Audit Determination.

9. Request for Review. A Class Member may dispute a CMS Post-Audit Determination by submitting to the Trust a Request for Review (“Request for Review”) no later than 30 days after the date of the CMS Post-Audit Determination.

10. Appointment of Fund A Audit Special Master. The Court shall appoint one or more qualified persons to serve as Special Master under Fed. R. Civ. P. 53 to determine Requests for Review under this Procedure (the “Fund A Audit Special Master”). The Fund A Special Master shall have at least the qualifications of the Technical Advisors approved by the Court in PTO No. 3227, and shall be provided the training module approved by the Court in PTO No. 2825, the Settlement Agreement, the Gray Form, and such other materials as the Court shall deem appropriate. The Court authorizes the Fund A Audit Special Master to develop procedures consistent with this Procedure, as the Fund A Audit Special Master deems necessary.

11. Fund A Audit Special Master Review and Report. No later than 14 days after a request by the Fund A Audit Special Master, the Trust shall submit to the Fund A Audit Special Master the CMS Benefits Claim record on a Claim subject to a Request for Review (“CMS Claim Record”). The CMS Claim Record shall include: (a) the Gray Form or Part II of the Green Form upon which the Claim for CMS Benefits is based; (b) the best available copy of the echocardiogram and any related medical records or reports submitted in support of the Claim; and (c) the worksheet completed by the Auditing Cardiologist pursuant to Paragraph 7 of this Procedure. The Fund A Audit Special Master shall review the CMS Claim Record and prepare a report (“Special Master Report”) setting forth his/her opinion as to whether there is a reasonable medical basis for the FDA Positive regurgitation finding attested to by the physician who completed the Gray Form or Part II of the Green Form submitted to the Trust on the Claim. The findings in the Report of the Fund A Audit Special Master shall be final pursuant to Fed. R. Civ. P. 53(g)(3)(B) without the need for further orders of the Court, and shall determine the Class Member’s regurgitation levels for the purposes of determining whether the Class Member is entitled to CMS Benefits.

12. Review Costs. The Trust shall be responsible for remitting to the Fund A Audit Special Master payment for the fees and expenses of the Fund A Audit Special Master in connection with this Procedure. The Class Member shall pay to the Trust \$250 for the cost of the Fund A Audit Special Master to determine a Request for Review submitted by the Class Member (“Review Costs”). The Trust shall pay any actual fees and expenses of the Fund A Special Master in excess of that amount on a particular Claim. A Class Member submitting a Request for Review shall send to the Trust along with the Class Member’s Request for Review a certified or cashier’s check in the amount of \$250 for the Review Costs. If a Class Member fails to remit such Review Costs to the Trust within 30 days after the date of the CMS Post-Audit Determination, the Fund A Auditing Cardiologist’s findings shall determine the level of regurgitation, if any, present on the echocardiogram reviewed for the purpose of determining whether the Class Member is entitled to CMS Benefits, and there shall be no review by the Fund A Special Master. If the Fund A Audit Special Master determines that there was a reasonable


medical basis for the conclusion that the Class Member had FDA Positive regurgitation, the Trust shall refund the \$250 to the Class Member, without interest.

13. ***Applicability of Procedure to Claims Previously Audited.*** The Trust shall notify all Class Members whose Claims for CMS Benefits were denied based on Audits conducted before the date of this Procedure on Claims covered by Paragraph 2 of this Procedure of the opportunity to submit a Request for Review under Paragraph 9 of this Procedure and shall include a copy of this Procedure along with such notice to the Class Member. Any Class Member who decides to dispute the results of such Audit must submit to the Trust a Request for Review and a certified or cashier's check in the amount of \$250 as the Review Costs no later than 30 days after the date of the Trust's notice. If a Class Member does not submit to the Trust a Request for Review and the Review Costs within 30 days after the date of the Trust's notice, the previous Audit findings shall determine the level of regurgitation, if any, present on the echocardiogram reviewed for the purpose of determining whether the Class Member is entitled to CMS Benefits, and there shall be no review by the Fund A Special Master.

14. ***No Effect on Other Benefit Claims.*** The outcome of the Audit of a Claim for CMS Benefits, including any findings of the Fund A Special Master on a Request for Review, shall apply only to the Class Member's Claim for CMS Benefits, shall not be preclusive as to any issue presented by Claims by the Class Member for other benefits under the Settlement Agreement, and shall not affect the Class Member's eligibility for any other benefits. When transmitting notice of the result of a Fund A Audit to such a Class Member, and when paying any CMS Benefit after a Fund A Audit to such a Class Member, the Trust shall notify the Class Member that: (i) the result and payment apply only to the CMS Benefit and shall not affect the Class Member's eligibility for any other Settlement benefit; and (ii) if the Class Member should at any time submit a Claim for Matrix Compensation Benefits, whether the Class Member has been diagnosed as FDA Positive or as having Mild Mitral Regurgitation during the Screening Period shall be determined in the Matrix Audit on the Class Member's Claim without regard to the result of the Fund A Audit on the Class Member's CMS Benefit Claim.

15. ***Effective Date and Duration of this Procedure.*** This Procedure shall become effective on the date of entry by the Court and shall remain in effect until further order of the Court.

BY THE COURT:


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

AGREED:

CLASS COUNSEL:

Michael D. Fishbein / s/08 with permission

Michael D. Fishbein, Esquire
Levin, Fishbein, Sedran & Berman
510 Walnut Street, Suite 500
Philadelphia, PA 19106

Date: December 23, 2005

WYETH

Orran L. Brown

Orran L. Brown
BrownGreer PLC
115 S. 15th Street, Suite 400
Richmond, Virginia 23219

Date: December 23, 2005