

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

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

MDL DOCKET NO. 1203

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

AMERICAN HOME PRODUCTS
CORPORATION

CIVIL ACTION NO. 99-20593

PRETRIAL ORDER NO. 2807

AND NOW, this 26th day of March, 2003, after a hearing to discuss the objections to the Rules for the Audit of Matrix Compensation Claims proposed by the AHP Settlement Trust, it is hereby ORDERED that said Rules, as further revised by the Court and attached as Exhibit A, are APPROVED.

BY THE COURT:

Handwritten signature: James Bartle
J.

**RULES FOR THE AUDIT
OF MATRIX COMPENSATION CLAIMS**

EFFECTIVE DECEMBER 1, 2002

EXHIBIT A

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GENERAL PROVISIONS

These Rules (“Rules”) implement the provisions of the Nationwide Class Action Settlement Agreement with American Home Products Corporation (“Settlement Agreement”) relating to the audit (“Audit”) of Claims for Matrix Compensation Benefits pursuant to Pretrial Order No. 2662 (and any related Pretrial Orders) and Sections VI.E and VI.F of the Settlement Agreement. These Rules shall be interpreted in accordance with the Settlement Agreement and apply to every Claim for Matrix Compensation Benefits first placed into Audit after December 1, 2002.

Rule 1. Definitions. The following terms shall have the meanings as set forth below. Any capitalized terms not specifically defined in these Rules shall have the meanings given to them in the Settlement Agreement, any Court Approved Procedure, or any Pretrial Order issued by the Court.

(a) **“Attestation Form”** means the form that the Auditing Cardiologist completes, attesting that he/she has reviewed the medical information submitted with a Claim and opining whether there was a reasonable medical basis for each GREEN Form Question at Issue.

(b) **“Attesting Physician”** means any physician who completes all or any aspect of Part II of the GREEN Form.

(c) **“Audit File”** means records received or maintained by the Trust that pertain to an Audit of a Claim for Matrix Compensation Benefits, including all documents sent to or from the Auditing Cardiologist, documents sent to the Trust in connection with an Audit, Contest Materials, and/or any other documents upon which the individual’s Claim is based.

(d) **“Audit Notification Letter”** means the letter described in Rule 6.

(e) **“Auditing Cardiologist”** means any independent Board-Certified Cardiologist or Board-Certified Cardiothoracic Surgeon (with the qualifications required under Rule 2 engaged by or through the Trust to audit Claims for Matrix Compensation Benefits).

(f) **“Auditing Cardiologist Worksheet”** means the form that is supplied by the Trust to the Auditing Cardiologist with the Electronic Audit Application, on which the Auditing Cardiologist records specific findings from his/her evaluation of an Echocardiogram.

(g) **“Claim”** means the submission of the form(s) through which a Claimant seeks Matrix Compensation Benefits, along with all other material, including correspondence, documents, and videotapes or disks of Echocardiograms submitted with such form(s) or in support of such a Claim.

(h) **“Claimant”** means any person who submitted a Claim under the Settlement Agreement.

(i) **“Contest Materials”** means the materials described in Rule 18(b).

(j) **“Court” or “Trial Court”** means the United States District Court for the Eastern District of Pennsylvania presiding over MDL Docket No. 1203, which has original and exclusive jurisdiction over all provisions of the Settlement Agreement.

(k) **“Echocardiogram”** means the Echocardiogram tape or disk relating to a Claim for Matrix Compensation Benefits.

(l) **“Electronic Audit Application”** means the method by which the Auditing Cardiologist records and reports Audit findings.

(m) **“Final Post-Audit Determination”** has the meaning given such term in Rule 18(c).

- (n) **“GREEN Form Question at Issue”** means each answer of the Attesting Physician described in Rule 5.
- (o) **“Matrix Compensation Benefits”** means the monetary amount associated with a Claimant's medical condition, based upon the severity of his/her medical condition, his/her age at diagnosis, and the corresponding placement on the payment matrices, as defined in Section IV.B. *et seq.* of the Settlement Agreement.
- (p) **“Medical Records CAP”** means the Court Approved Procedure governing the Medical Records Relating to Matrix Claims.
- (q) **“Medical Status Letter”** means a written communication from the Trust to a Claimant in Audit pursuant to Rule 9.
- (r) **“Post-Audit Determination”** means the Trust’s determination, based on finding(s) at Audit, regarding the Claimant’s eligibility for Matrix Compensation Benefits.
- (s) **“Settlement Agreement”** means the Nationwide Class Action Settlement Agreement with American Home Products Corporation dated November 18, 1999, as amended.
- (t) **“Supplemental Matrix Claim”** means a Claim submitted by a Claimant for a higher level of Matrix Compensation Benefits because of the worsening of any condition that originally qualified the Claimant for Matrix Compensation Benefits, as provided in Section IV.C.3 of the Settlement Agreement.
- (u) **“Trust”** means the AHP Settlement Trust as defined in Section I.57 of the Settlement Agreement.
- (v) **“Wyeth”** means Wyeth, formerly known as American Home Products Corporation.

Rule 2. *Qualifications of Auditing Cardiologists.* The Trust shall maintain a pool of qualified Auditing Cardiologists for reviewing Claims in Audit. Each Auditing Cardiologist shall be an independent Board-Certified Cardiologist, or Board-Certified Cardiothoracic Surgeon, with Level 3 training in Echocardiography. When necessary to sustain the optimal number of Auditing Cardiologists, the Trust may engage Board-Certified Cardiologists and Board-Certified Cardiothoracic Surgeons who have been certified by the National Board of Echocardiography in Transthoracic Echocardiography and have completed Level 2 training in Echocardiography. Absent Court approval, no person shall serve as an Auditing Cardiologist if that person is a Trustee of the Trust, has served as an Attesting Physician in more than ten Claims, or would be disqualified from serving as a Trustee under the provisions of Section VI.A.4.b of the Settlement Agreement. If an Auditing Cardiologist has been an Attesting Physician on a Claim, he/she may not review that Claim in Audit.

AUDIT PROCESS

Rule 3. *Claims in Audit.* The Trust shall refer to Audit all Claims that have been completed in accordance with the terms of Section VI.C of the Settlement Agreement and any Court Approved Procedures concerning completeness criteria that, from the face of the GREEN Form submitted, allege a medical condition for which the Claimant may be entitled to Matrix Compensation Benefits.

Rule 4. *Procedures to Initiate Audit of Claims.* As soon as reasonably practicable after the Trust determines under Rule 3 that a Claim should be referred to Audit under Rule 3, the Trust shall forward each Claim to an Auditing Cardiologist. The Trust shall submit to the Auditing Cardiologist the Electronic Audit Application and the documentation specified in Section VI.E.6 of the Settlement Agreement.

Rule 5. *Review of Claims in Audit.* The Auditing Cardiologist shall review a Claim in accordance with these Rules to determine whether there was a reasonable medical basis for each answer in Part II of the GREEN Form that differs from the Auditing Cardiologist's finding on that specific issue ("GREEN Form Question at Issue"). The Trust shall review a Claim to determine whether there were any intentional material misrepresentations made in connection with the Claim. The Trust may consider information from other Claims in Audit to determine the existence of facts or a pattern of misrepresentations implicating intentional misconduct by an attorney and/or physician that may warrant relief pursuant to Section VI.E.8 of the Settlement Agreement.

Rule 6. *Notification to Claimant of Audit.* No later than five days after a Claim has been forwarded to an Auditing Cardiologist, the Trust shall send a letter to the Claimant informing him/her that the Claim is in Audit ("Audit Notification Letter"), along with a copy of these Rules.

Rule 7. *Review by Auditing Cardiologist.* In conducting the Audit of a Claim, the Auditing Cardiologist shall:

(a) Thoroughly review the materials forwarded pursuant to Section VI.E.6 of the Settlement Agreement, that is the videotapes or disks of Echocardiograms, medical reports and other information submitted by a claimant in support of a claim, together with a copy of the claimant's medical records, and Echocardiogram videotapes or disks obtained by the Trust. The Auditing Cardiologist shall not be instructed on the order in which the materials shall be reviewed. If the Auditing Cardiologist cannot evaluate an Echocardiogram or a condition or factor on the Echocardiogram to a reasonable degree of medical certainty, pursuant to the

applicable Pretrial Order, the Auditing Cardiologist shall answer "Not Evaluable" on the Auditing Cardiologist Worksheet as to that Echocardiogram or to that condition or factor.

(b) Enter answers in response to questions generated by the Electronic Audit Application with respect to the Claim.

(c) Except where the Auditing Cardiologist has determined the Echocardiogram or certain factors on the Echocardiogram to be Not Evaluable, state on the Attestation Form whether there was a reasonable medical basis for each GREEN Form Question at Issue and provide the underlying explanation for this determination. The Auditing Cardiologist shall confirm these findings before final submission of the Electronic Audit Application to the Trust.

(d) No later than thirty days after receipt of a Claim from the Trust, return to the Trust the secure Electronic Audit Application, by regular mail, together with any Echocardiogram(s) and other documentation sent by the Trust to the Auditing Cardiologist in connection with the Audit.

Rule 8. *Trust's Review of Auditing Cardiologist Findings.* No later than twenty-one days after the Trust's receipt of the Electronic Audit Application from the Auditing Cardiologist, the Trust shall review the Electronic Audit Application to evaluate whether the Auditing Cardiologist has determined the Echocardiogram to be Not Evaluable, has identified certain factors as Not Evaluable, or has identified missing documentation. Where the Auditing Cardiologist has identified Not Evaluable factors or missing documentation, the Trust shall determine whether the Not Evaluable or missing information is material to a determination of eligibility for Matrix Compensation Benefits. If the factor(s) and/or missing information are not material to a determination of eligibility for Matrix Compensation Benefits, the Trust shall

determine the Matrix Compensation Benefits, if any, for which the Claimant is eligible.

Rule 9. *Medical Status Letter.* If the Auditing Cardiologist has determined an Echocardiogram to be Not Evaluable, or if the Trust determines that Not Evaluable factor(s) and/or missing documentation are material to a determination of eligibility for Matrix Compensation Benefits, within fourteen days after the completion of the Trust's review under Rule 8, the Trust shall mail to the Claimant a Medical Status Letter in accordance with any Pretrial Order governing technical deficiencies in Echocardiograms.

Rule 10. *Suspension of Audit After Medical Status Letter.* If the Trust sends a Medical Status Letter to a Claimant, the Trust shall suspend the Audit of that Claim until the Claimant has completed or failed to complete the Claim as requested.

Rule 11. *Response to Medical Status Letter.* If the Claimant fails to complete the Claim as requested in a Medical Status Letter, the Trust shall proceed with a determination on the Claim under Rule 12. If the Claimant timely submits materials to the Trust in response to a Medical Status Letter, the Trust promptly shall forward the materials, if appropriate, to the same Auditing Cardiologist who reviewed the Claim previously and the Auditing Cardiologist shall review the Claim in accordance with Rule 7. After the Auditing Cardiologist completes this review, the Audit shall be completed and the Trust shall make a determination on the Claim pursuant to Rules 12 and 13.

<p style="text-align: center;">DETERMINATIONS OF ELIGIBILITY FOR MATRIX COMPENSATION BENEFITS</p>
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Rule 12. *Determinations of Matrix Eligibility.* No later than thirty days after the Audit has been completed under Rule 8 or Rule 11, the Trust shall determine the Matrix Compensation Benefits, if any, to which the Claimant is entitled, based upon the findings of the Auditing Cardiologist in Audit and all information regarding the Claim necessary to determine

eligibility for Matrix Compensation Benefits under the Settlement Agreement. If the Trust determines that the Claim is payable on Matrix B, the Trust shall issue a Post-Audit Determination that the Claim will be paid on Matrix B, at the appropriate Matrix Level. If the Trust determines that the Claim is not payable, the Trust shall issue a Post-Audit Determination denying the Claim.

Rule 13. *Claims Potentially Payable on Matrix A.* If the Trust determines after Audit that the Claim is potentially payable on Matrix A, no later than thirty days after the Audit has been completed under Rule 8 or Rule 11, the Trust shall determine whether the Claimant has complied with the Medical Records Court Approved Procedure ("CAP"). If the Claimant has not complied with the Medical Records CAP, no later than fourteen days after the Trust has made this determination, the Trust shall mail notice informing the Claimant of the actions required for the continued processing of the Claim. If the Claimant complies with the Medical Records CAP, the Trust shall issue a Post-Audit Determination under Rule 15. If the Claimant fails to comply with the Medical Records CAP, the Trust shall issue a Post-Audit Determination that the Claim will be paid on Matrix B at the appropriate Matrix Level.

Rule 14. *Receipt and Review of the Claimant's Submission.* If the Claimant submits General Medical Records in response to the Trust's notification under Rule 13, the Trust shall send those records to a Trust Cardiologist, an Auditing Cardiologist, or a qualified Trust representative to determine if the information is relevant to whether the Claim is payable on Matrix A. The Trust shall complete its review of these General Medical Records no later than ninety days after their receipt by the Trust. If the Claimant submits a Verification in response to the Trust's notification under Rule 13, the Trust shall review the Verification to ensure that it complies with the Medical Records CAP. The Trust shall complete its review of the Verification

no later than thirty days after the Trust's receipt of such Verification.

Rule 15. *Post-Audit Determination Following Review of Materials.* If the Trust's review of General Medical Records or a Verification submitted in support of a Claim does not reveal any factor that places the Claim on Matrix B, and if the Trust otherwise determines that the Claim is eligible for payment on Matrix A, the Trust shall issue a Post-Audit Determination that the Claim will be paid on Matrix A, at the Matrix Level supported by the Auditing Cardiologist's findings. If the Trust's review of the General Medical Records or the Verification reveals a factor that places the Claim on Matrix B, the Trust shall issue a Post-Audit Determination that the Claim will be paid on Matrix B, at the appropriate Matrix Level. If the Claimant has submitted a signed agreement to be paid on Matrix B, the Trust shall pay the Claim at the agreed Matrix Level on Matrix B.

Rule 16. *Timing of Post-Audit Determinations.* The Trust shall issue Post-Audit Determinations no later than fourteen days after the Trust makes its determination under Rules 12, 13, or 15 regarding the Matrix Compensation Benefits, if any, for which the Claimant is eligible.

Rule 17. *Content of Post-Audit Determination.* A Post-Audit Determination shall inform the Claimant of: (a) the results of the Audit, including the name of the Auditing Cardiologist and the explanation provided by the Auditing Cardiologist pursuant to Rule 7(c); (b) the Matrix Compensation Benefits, if any, for which the Claimant is entitled; and (c) the Claimant's right to accept or contest the Trust's Post-Audit Determination.

Rule 18. *Procedures After a Post-Audit Determination.*

(a) Claimant Acceptance. The Claimant shall be deemed to have accepted the

Trust's Post-Audit Determination either by affirmative written communication to the Trust or by failure to deliver to the Trust a written contest of the Post-Audit Determination postmarked no later than sixty days after the date of the Post-Audit Determination.

(b) Contest. To contest the Post-Audit Determination, the Claimant shall send a written communication to the Trust postmarked no later than sixty days after the date of the Post-Audit Determination, stating that the Claimant contests the Post-Audit Determination. In contesting any aspect of the Post-Audit Determination based on any finding(s) of the Auditing Cardiologist, the Claimant shall state the factual reasons for the contest and identify any alleged errors made by the Auditing Cardiologist. With this written communication, the Claimant may submit certain materials (the written communication and any such materials shall be the "Contest Materials") to the Trust. These Contest Materials: (1) shall not include materials previously submitted with the Claim; (2) shall not be cumulative of materials previously submitted with the Claim; (3) shall be limited to the specific issue(s) relating to the Post-Audit Determination; and (4) may include a verified statement of a medical expert. After the expiration of this sixty-day deadline, the Trust shall not accept any Contest Materials or other documentation from the Claimant unless the Trust grants a timely request for an extension of this deadline upon good cause shown.

(c) Procedures After Contest. If the Claimant timely contests the Trust's Post-Audit Determination, the Trust shall review any Contest Materials, and no later than thirty days after the Trust's receipt of the Contest Materials, issue a Final Post-Audit Determination on the Claim. The Final Post-Audit Determination shall include an explanation of the Trust's assessment of the Claim and may also include or describe:

- (1) arguments or explanations refuting the Claimant's Contest Materials;
- (2) a verified expert opinion;

- (3) any evidence that refutes the Claimant's position that a reasonable medical basis exists to support a GREEN Form Question at Issue; and/or
- (4) any evidence that refutes the Claimant's position that all statement of material fact made in connection with the Claim are true.

If the Claimant disputes the Final Post-Audit Determination, the Claimant, no later than thirty days after the date of the Final Post-Audit Determination, shall postmark and mail a written communication to the Trust stating that the Claimant disputes the Trust's Final Post-Audit Determination, after which the Claim shall proceed through the Show Cause process under these Rules. The Show Cause process shall be limited to those issues and evidence presented by the Claimant in any submitted Contest Materials and by the Trust in its Final Post-Audit Determination, unless, after good cause shown, the Special Master allows a party to present additional issues and/or evidence.

(d) If the Trust has determined in a Final Post-Audit Determination that a Claim is payable on Matrix B and the Claimant timely disputes this Final Post-Audit Determination and seeks payment on Matrix A in the Show Cause process, the Trust shall pay Matrix Compensation Benefits to the Claimant on Matrix B, pursuant to the Trust's procedures for the payment of Matrix Compensation Benefits to eligible Claimant, and the Claimant may receive such payment without prejudice to the Claimant's position in the Show Cause process.

(e) **Other Contests.** On Claims in Audit, any Claimant's attorney's contest regarding fees or costs, any Derivative Claimant's contest regarding the allocation of payments, any subrogee's contest regarding recovery on any subrogation claim, any contest over proof of Diet Drug use or duration of use, and any dispute over any issue that affects eligibility for and/or the amount of Matrix Compensation Benefits payable on a Claim other than the issue of the correctness of medical findings made in an Audit, shall be heard pursuant to an appeal and

arbitration under Section VI.C.4 of the Settlement Agreement, and not through the Show Cause process. In addition, all Claims for Matrix Compensation Benefits denied by the Trust without Audit, including without limitation those denied as incomplete or on the ground that the Green Form as completed does not establish a Matrix-Level condition, shall be heard pursuant to an appeal and arbitration under Section VI.C.4 of the Settlement Agreement, and not through the Show Cause process.

SHOW CAUSE PROCESS

Rule 19. *Preparation of Show Cause Application.* No later than fourteen days after the Trust's receipt of notice that the Claimant contests the Trust's Final Post-Audit Determination, the Trust shall prepare and file with the Court an Application for Issuance of an Order to Show Cause ("Application") seeking the relief requested by the Trust. The Trust shall serve a copy of the Application upon the Claimant by certified mail, return receipt requested, or by equivalent means.

Rule 20. *Contents of the Show Cause Application.* An Application shall include the following:

- (a) identity of the Claimant and his/her Claim number;
- (b) a statement that the Trust has determined that, as a result of an Audit, the Claim was denied in whole or in part;
- (c) a prayer for specific relief, including a request that the Court, pursuant to Section VI.E.8 of the Settlement Agreement, grant such relief as may be appropriate, including any of the following:
 - (1) an Order disallowing and denying payment in whole or in part for the Claim;

- (2) an Order imposing penalties including the payment of the Trust's costs and attorneys' fees to the extent permitted by law; and/or
- (3) an Order making a referral to the United States Attorney or other appropriate law enforcement officials for possible criminal prosecution if there is probable cause to believe that the Claim was submitted fraudulently; and
- (4) notice to the Claimant that failure to respond or comply with these Rules could result in an Order granting the relief requested by the Trust.

Rule 21. ***Issuance of Order to Show Cause.*** After receipt of the Trust's Application, the Court shall issue an Order directing the Claimant to show cause why the relief requested by the Trust should not be granted ("Order to Show Cause") and referring the Application to the Special Master for further proceedings.

Rule 22. ***Documentation in Support of Trust's Application for Show Cause.*** The Trust shall serve upon the Special Master documentation to support its Application ("Supporting Documentation"), postmarked or hand-delivered no later than fourteen days after the date of the Order to Show Cause. The Trust's Supporting Documentation shall include: (a) a detailed Statement of the Case, as described more fully in Rule 23; (b) the Attestation Form; (c) the Auditing Cardiologist Worksheet(s); (d) any and all other materials submitted to and/or completed by the Auditing Cardiologist; and (e) the Audit File.

Rule 23. ***Trust's Statement of the Case in Show Cause.***

(a) The Trust's Statement of the Case shall contain a detailed statement of the issues surrounding the Claim and:

- (1) a description of the procedural history of the Claim, including relevant dates, where applicable;
- (2) the grounds for the Trust's Final Post-Audit Determination; and
- (3) the Trust's position on the necessity of the assignment of a Technical Advisor.

(b) If the Application is based, in whole or in part, on the grounds that an Echocardiogram or any factor on an Echocardiogram was Not Evaluable, and/or that no reasonable medical basis exists for a GREEN Form Question at Issue, the Statement of the Case also shall include:

- (1) the specific medical findings of the Auditing Cardiologist on matters to be Not Evaluable and/or on the GREEN Form Questions at Issue;
- (2) a certification by the Auditing Cardiologist of the specific factors (*e.g.*, specific medical records or parts thereof and findings from his/her review of the Echocardiogram) that he or she considered and relied upon in concluding that there was no reasonable medical basis for each GREEN Form Question at Issue;
- (3) the background of the Auditing Cardiologist, which can consist of the Auditing Cardiologist's curriculum vitae; and
- (4) a certification by the Auditing Cardiologist that the steps taken in reviewing the Claim were consistent with Rule 7.

(c) If the Application is based, in whole or in part, on the grounds that an intentional misrepresentation of material fact was made in connection with the Claim, the Statement of the Case also shall include a detailed description of any and all facts the Trust relied on in concluding that there was an intentional material misrepresentation of fact.

Rule 24. *Burden of Proof in Show Cause.* Where the Trust's Final Post-Audit Determination was based, in whole or in part, on the ground that no reasonable medical basis exists for a GREEN Form Question at Issue, the Claimant shall have the burden of proving that there was a reasonable medical basis for the answer(s) of the Attesting Physician. Where the Trust's Final Post-Audit Determination was based, in whole or in part, on the grounds that an intentional misrepresentation of a material fact was made in connection with the Claim, the Claimant shall have the burden of proving that all representations of material fact in connection with the Claim are true.

Rule 25. *Claimant's Response in Show Cause.* After receipt of the Trust's Supporting Documentation, the Special Master shall serve a copy on the Claimant and direct the Claimant to send a Response, if any, to the Special Master. A Claimant's Response shall be postmarked no later than twenty-one days after the date of the Special Master's service of the Supporting Documentation on the Claimant. If the Claimant fails to file a Response within the time prescribed by the Special Master, or if the Claimant requests the Special Master to proceed without a formal Response, the Special Master shall proceed in accordance with these Rules.

Rule 26. *Contents of the Claimant's Response in Show Cause.* The Claimant's Response shall be limited to the issues and evidence identified by the Claimant in the Claimant's Contest Materials the Claimant has submitted to the Trust, unless upon good cause shown the Special Master allows the introduction of additional issues and/or evidence. The Claimant's Response shall state his/her position on the necessity of the assignment of a Technical Advisor. The Special Master shall serve a copy of the Claimant's Response, if any, on the Trust.

Rule 27. *Trust's Reply in Show Cause.* If the Claimant files a Response, the Trust shall be permitted to file a Reply, postmarked no later than fourteen days after the date of the Special Master's service of the Response on the Trust. The Special Master shall serve a copy of the Trust's Reply, if any, on the Claimant. If the Claimant does not file a Response, the Trust may not file a Reply.

Rule 28. *Contents of the Trust's Reply in Show Cause.* The Trust's Reply shall be limited to the issues raised by the Claimant in the Response and to the issues and evidence identified by the Trust in its Final Post-Audit Determination, unless upon good cause shown the Special Master allows the introduction of additional issues and/or evidence.

Rule 29. *No Further Filings Permitted in Show Cause.*

(a) The record before the Special Master (“Special Master Record”) shall be closed no later than fourteen days after:

- (1) the Special Master’s receipt of the Claimant’s indication that no Claimant Response will be filed;
- (2) the expiration of the time for the Claimant to file a Response; or
- (3) the Special Master’s receipt of the Trust’s Reply, where applicable.

(b) No further briefing or documentation shall be permitted except where the Claimant seeks permission, in writing, from the Special Master to file a Sur-Reply. Requests to file a Sur-Reply must be filed no later than fourteen days after the date of the Special Master’s service of the Trust’s Reply on the Claimant and must include a copy of the proposed Sur-Reply. The Special Master will grant permission for the filing of a Sur-Reply only upon good cause shown. The Special Master shall serve a copy of any permitted Sur-Reply on the Trust.

Rule 30. *Appointment and Assignment of Claim in Show Cause to Technical*

Advisor. The Court will appoint one or more qualified persons to serve as Technical Advisor(s). After the Special Master Record is closed, and after consideration of the positions of the Trust and the Claimant regarding the appointment of a Technical Advisor, the Special Master may assign a Technical Advisor to review the Special Master Record and prepare a report to the Court setting forth his/her opinions regarding the issue(s) in dispute in the Audit. The Technical Advisor will be assigned according to his/her expertise and based upon the nature of the medical issue(s) present in the Audit.

Rule 31. *Costs of Technical Advisor.* If the Special Master determines that it is

necessary to assign a Technical Advisor, the Special Master shall require the Claimant, in advance, to submit a cashier’s or certified check to pay the reasonable costs for the review and

report by the Technical Advisor. Further:

(a) the costs of the Technical Advisor shall be established by the Special Master in an amount not to exceed \$1,500;

(b) a Claimant may file a request with the Special Master asking that the costs of the Technical Advisor be waived due to true financial hardship. Any such request must include relevant financial documentation supporting the existence of a true financial hardship. In the event that the Special Master concludes that payment of the Technical Advisor's costs creates a true financial hardship, the Trust shall pay the Technical Advisor's costs; and

(c) if the Trust does not prevail on all aspects of its Application, the Trust shall reimburse the Claimant for the Technical Advisor's costs.

Rule 32. *Qualifications of Technical Advisor.* Each Technical Advisor shall be a Board-Certified Cardiologist or Board-Certified Cardiothoracic Surgeon who has Level 3 training in Echocardiography or a Board-Certified Neurologist or Neurosurgeon or a Board-Certified Pathologist. Absent Court approval, no person shall serve as a Technical Advisor if that person is a Trustee of the Trust, has served as an Attesting Physician, Auditing Cardiologist, or would be disqualified from serving as a Trustee under the provisions of Section VI.A.4.b of the Settlement Agreement.

Rule 33. *Duties of the Technical Advisor.*

(a) If the Special Master refers a Claim to a Technical Advisor, the Technical Advisor shall review the Special Master Record, including a copy of any Echocardiogram. Following that review, the Technical Advisor shall issue a written report ("Technical Advisor's Report") setting forth his or her opinion as to whether:

(1) there was a reasonable medical basis for the Attesting Physician's specific

answer(s) to each GREEN Form Question at Issue; and/or

- (2) material representations of fact made in connection with the Claim are true.

(b) The Technical Advisor shall transmit the Technical Advisor's Report and return the Special Master Record, including a copy of the Echocardiogram, to the Special Master no later than thirty days after receipt of the Special Master Record.

Rule 34. *Service of Technical Advisor's Report.* The Special Master shall serve a copy of the Technical Advisor's Report on the Trust and the Claimant, who each may submit a Response to Technical Advisor's Report, not exceeding five pages in length, to the Special Master. Any such Response shall be postmarked no later than fourteen days after the Special Master's service of the Technical Advisor's Report on the parties. The Response(s) may address only the findings of the Technical Advisor and shall be limited to the evidence already in the Special Master Record.

Rule 35. *Close of Show Cause Record and Referral to Court for Determination.* The Show Cause Record, which shall include all documentation provided in the Show Cause Process, shall be closed by the Special Master upon the: (a) receipt of the Response(s), if any, to the Technical Advisor's Report; (b) expiration of the fourteen day period for filing a Response to the Technical Advisor's Report; or (c) close of the Special Master Record pursuant to Rule 29 where the matter has not been referred to a Technical Advisor. Upon the close of the Show Cause Record, the Special Master shall notify the Court that the record is complete and ready for a determination.

Rule 36. *Discretion to Consolidate Show Cause Proceedings.* The Special Master has the discretion to consolidate Show Cause Proceedings before him, either *sua sponte* or on application, pursuant to the standards applicable to consolidation under Federal Rule of Civil

Procedure 42.

Rule 37. *Show Cause Hearings.* An Application will be decided without a Hearing unless the Court orders otherwise. A Hearing, if permitted, may be in person, by video or by telephone conference.

Rule 38. *Relief in Show Cause.*

(a) If the Court determines that there was no reasonable medical basis to support the Attesting Physician's answer to each GREEN Form Question at Issue, and/or that the Claimant intentionally made a material misrepresentation of fact in connection with the Claim, the Court shall confirm the Post-Audit Determination and may grant such other relief as may be appropriate, including any of the following:

- (1) an Order disallowing the Claim;
- (2) an Order imposing penalties including the payment of the Trust's costs and attorneys' fees to the extent permitted by law; and/or
- (3) an Order making a referral of the matter to the United States Attorney or other appropriate law enforcement officials for possible criminal prosecution if there is probable cause to believe that the Claim was submitted fraudulently.

(b) If the Court determines that there was a reasonable medical basis to support the Attesting Physician's answer to each GREEN Form Question at Issue, and/or that the Claimant did not make an intentional misrepresentation of a material fact in connection with the Claim, the Court shall enter an Order directing the Trust to pay the Claim in accordance with the Settlement Agreement.

MISCELLANEOUS PROVISIONS

Rule 39. *Special Master's Costs.* The costs and fees of the Special Master in connection with these Rules shall be paid by the Trust, unless otherwise ordered by the Court.

Rule 40. *Withdrawals and Closure of Claims.* Any withdrawal of a Claim by the Claimant after the date of a Medical Status Letter, the Trust's Post-Audit Determination, the Claimant's execution of an agreement to be paid on Matrix B, or any final decision by the Trial Court on a Claim in Audit shall close that Claim, with prejudice, as to any condition that has been claimed or could have been claimed as of the date of the Attesting Physician's signature on Part II of the GREEN Form or, where the date of the Attesting Physician's signature is not present, the date the GREEN Form was received by the Trust. After withdrawal of a Claim, a Claimant may submit a GREEN Form only if based on a subsequent Echocardiogram, which the Claimant alleges shows a change in the Claimant's medical condition.

Rule 41. *No Discovery.* Neither the Trust nor the Claimant shall be permitted to conduct any discovery relating to an Application.

Rule 42. *Settlement Agreement Interpretation.* Pursuant to the Court's exclusive and continuing jurisdiction to implement the Settlement Agreement, as retained in Section VIII.B.1 of the Settlement Agreement and Paragraph 11 of Pretrial Order No. 1415, the Court has exclusive jurisdiction to decide any issue requiring interpretation of the Settlement Agreement. As to any issue arising in the Show Cause process that involves Settlement Agreement interpretation, the Court may solicit the views of Class Counsel and Wyeth.

Rule 43. *Participation by Wyeth and Class Counsel.* Wyeth and Class Counsel shall not submit materials in the Show Cause Process unless requested by the Court or Special Master. Pursuant to the terms of Pretrial Order No. 2351, relating to Protective Order Concerning Confidential Information of the AHP Settlement Trust, Wyeth and Class Counsel at their own expense may obtain copies from the Trust of any of the filings related to the Show Cause proceedings.

Rule 44. *Interpretation of Rules.* These Rules shall be interpreted in accordance with the terms of the Settlement Agreement. If a dispute arises regarding the application of the Rules, the Trust or the Claimant may petition the Special Master for an interpretation of the Rules. The Special Master shall decide all disputes regarding the application of the Rules, subject to Court review. The Special Master may implement any procedural requirements necessary to implement these Rules efficiently.

Rule 45. *Confidentiality.* The disclosure of information obtained in Audit is governed by these Rules, the terms of the Settlement Agreement and any other Order governing confidentiality that has or may be entered by the Court.

Rule 46. *No New Claim or Supplemental Matrix Claims.* The Show Cause proceeding shall not be used for the submission of a new Claim or a Supplemental Matrix Claim. Instead, Claimants shall submit any new or Supplemental Matrix Claims to the Trust, to be processed in accordance with the Settlement Agreement.

Rule 47. *Computation of Time.* In computing a period of time prescribed or allowed by these Rules, a day shall mean a calendar day. The day of any act or event after which a designated period of time begins to run shall not be included. The last day of the period shall be included, unless it is a Saturday, Sunday or legal holiday, in which event the period shall run until the end of the next day which is not a Saturday, Sunday or legal holiday. Intermediate Saturdays, Sundays and legal holidays shall be included in the computation, unless the period of time prescribed or allowed is less than eleven days. The Special Master, upon good cause shown, may extend any deadline prescribed in these Rules.