

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. : CIVIL ACTION  
: NO. 99-20593  
v. :  
: :  
AMERICAN HOME PRODUCTS CORPORATION :  
: :  
\_\_\_\_\_ :

**PRETRIAL ORDER NO. 5093**

AND NOW, this 23<sup>rd</sup> day of April, 2005, the court having reviewed the attached procedures for the Eighth Amendment Mediation Program ("Mediation Procedures"), and being satisfied that the Mediation Procedures address to the satisfaction of the parties all comments filed with the court, it is hereby ORDERED that the Mediation Procedures are approved.

BY THE COURT:

\_\_\_\_\_  
HARVEY BARTLE III, J.

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

**EIGHTH AMENDMENT MEDIATION PROGRAM**

A. INTRODUCTION

The Eighth Amendment to the Nationwide Class Action Settlement Agreement with American Home Products Corporation ("Settlement Agreement"), approved by the Court in Pretrial Order ("PTO") No. 3881, allows the Trust, Wyeth, and claimants (collectively referred to herein as "the parties"), to resolve disputed Matrix claims in the show cause process through mediation. See PTO No. 3881 (Aug. 26, 2004). This document sets forth the rules and procedures for the Mediation Program for Claims at Issue in the Show Cause Process ("Mediation Program").

B. BACKGROUND

Generally, the Settlement Agreement provides for the payment of monetary benefits to claimants who are diagnosed with serious Valvular Heart Disease ("VHD"). To seek these benefits, which are known as Matrix Compensation Benefits, a claimant submits a completed, multi-part Green Form to the AHP Settlement Trust ("Trust"). In Part II of the Green Form, a Board-Certified

Cardiologist or Cardiothoracic Surgeon answers a series of questions about the severity of the claimant's VHD.

Generally, all claims for Matrix Compensation Benefits ("Matrix claims") are subject to audit by the Trust. Based upon the audit results and other information necessary to determine a claimant's eligibility, the Trust determines whether the claimant is entitled to any Matrix Compensation Benefits under the Settlement Agreement. If, after this determination, a dispute remains between the Trust and the claimant as to the appropriate level of benefits due, the Trust must apply to the Court for an order directing the claimant to show cause why the Trust's determination is incorrect. Upon entry of an Order, the claim is referred to the show cause process for further proceedings. The Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Procedures") govern claims placed in Audit on or before December 1, 2002. See PTO No. 2457 (May 31, 2002). The Rules for the Audit of Matrix Compensation Claims ("Audit Rules") govern Claims placed in Audit after December 1, 2002. See PTO No. 2807 (Mar. 26, 2003).

C. PURPOSE OF MEDIATION

The purpose of the Mediation Program is to provide the parties with an opportunity to reach a mutually acceptable resolution of

Matrix claims in the show cause process without the need for further litigation. The Mediation Program is a voluntary, non-binding process and is not meant to replace the show cause process. Rather, the Mediation Program provides an alternative method of resolution.

D. ELIGIBILITY

All claims in the show cause process are eligible for the Mediation Program. The Special Master, within his judgment and discretion, will identify claims appropriate for the Mediation Program. The Special Master also will consider for mediation any claim where the Trust, claimant, and/or Wyeth request mediation. A party may not request mediation until the Trust has filed its Statement of the Case and the claimant has filed a Response (or failed to file a timely Response to the Trust's Statement of the Case). For a claim to be referred officially to mediation, the Trust, claimant, and Wyeth must agree to participate in the Mediation Program.

Finally, the Special Master will consider requests to consolidate eligible claims in the show cause process for a single mediation. All requests for mediation, of either a single claim or a group of claims, must be in writing, and all parties to the claim, including Wyeth, must receive a copy of the request.

E. MEDIATION OPTIONS

Once a party to a claim has requested mediation, or the Special Master has identified a claim for referral to the Mediation Program, all parties to the claim will be notified. Each party will then have thirty (30) days to select one of the following options: (1) submit a signed Agreement to Participate in Mediation ("Agreement"), attached hereto as Exhibit A; (2) submit a signed request to defer a decision to participate in formal mediation for sixty (60) days ("Deferral Request"), attached hereto as Exhibit B, in order to participate in the Special Master mediation process described in Section G of these Procedures; or (3) submit a signed Declination Notice, attached hereto as Exhibit C. All correspondence must be sent to the Special Master and all parties to the claim must receive a copy.

Any party may request an extension of time to submit a signed Agreement, Deferral Request, or Declination Notice, by submitting a written request to the Special Master, copying all other parties to the claim, that is received or postmarked before the expiration of the original deadline. If, after thirty (30) days or any applicable extension, all parties have not agreed to participate in the Mediation Program by submitting a signed Agreement or Deferral Request, the stay will be lifted and the claim will proceed in the show cause process. In the event that less than all parties agree

to participate in a particular mediation option, the Special Master will contact the parties and attempt to reach a consensus.

F. IMPACT OF MEDIATION ON SHOW CAUSE PROCESS

All proceedings in the show cause process will be stayed following either a request for mediation or selection by the Special Master for referral to the Mediation Program. For those claims that previously were briefed fully under either the Audit Procedures or Audit Rules, the stay of proceedings will occur prior to the referral of the claim to the Court or a Technical Advisor. The stay shall remain in effect until it is determined that: (1) the Trust, claimant, or Wyeth does not agree that a claim should be mediated; or (2) the attempted mediation of a claim was unsuccessful.

G. SPECIAL MASTER MEDIATION PROCESS

As stated in Section E, parties to a claim may request to defer a decision to participate in formal mediation for a period of sixty (60) days. If Wyeth and a claimant each submit a Deferral Request, Wyeth may communicate directly with claimant's counsel in an attempt to reach a resolution. In the event that Wyeth and counsel for a claimant agree on a resolution of a claim, Wyeth must submit a signed Notice of Agreement ("Notice"), attached hereto as

Exhibit D, to the Special Master. All parties to the claim, including the Trust, must receive a copy of the Notice. All information contained in a Notice shall be treated as Confidential Information under PTO No. 2683 (Dec. 12, 2002), or any subsequent Order of the Court relating to Confidential Information. The Special Master will thereafter contact all parties, including the Trust, to discuss the proposed resolution and facilitate an agreement among all the parties.

An extension of the sixty (60) day period may be granted by the Special Master if, in his discretion, it is determined that additional time will facilitate a resolution. If after the sixty (60) day period, or applicable extension, a resolution cannot be reached among all parties, the parties may choose to enter the formal Mediation Program by submitting a signed Agreement within fourteen (14) days from the expiration of the deferral period. If after fourteen (14) days all parties have not agreed to continue in the Mediation Program, the stay will be lifted and the claim will proceed in the show cause process.

#### H. THE MEDIATORS

The Court will appoint several individuals to serve as mediators in the Mediation Program. The Special Master, as necessary, will provide the mediators with information and training

regarding the terms of the Settlement Agreement.

After receiving a signed Agreement from all parties, the Special Master will send each party a list of those individuals appointed by the Court to serve as mediators, along with information about each mediator's qualifications and potential conflicts. Each party will have ten (10) days in which to strike the name of any mediator from this list. Thereafter, the Special Master will assign the claim to one of the mediators whose name was not stricken by any of the parties. If a party does not return the list within the specified period of time, all mediators shall be deemed acceptable for that party.

I. MEDIATION PROCESS

Once the Special Master has assigned a claim to a mediator, the parties will receive a mediation session notification. The notification will contain the date, time, and location of the mediation session. In addition, the notification will include a deadline by which the parties must submit to the Special Master a confidential summary of their positions, including key factors relating to payment of the Matrix claim under the Settlement Agreement (the "Position Statement"). This Position Statement may be in the form of a letter but may not exceed two (2) pages in length. The Position Statement is not to be served on the opposing

party. Further, the Position Statements are not to be filed with the Court and shall not become part of the show cause record in the event that mediation is unsuccessful. Upon receiving the Position Statements from the parties, the Special Master will forward a copy of all documents filed in the show cause process including any supporting documentation, such as echocardiogram tapes or CD's, and the Position Statements (the "Mediation Record"), to the assigned mediator.

The role of the mediator is that of a neutral intermediary and, at no time, will the mediator be acting as an advocate or attorney or providing legal advice to any party.

J. CONFIDENTIALITY

All offers, promises, conduct and/or statements, whether oral or written, made during the course of the mediation session by any party or their agent shall remain confidential. Such offers, promises, conduct and/or statements shall not be disclosed to third parties and are privileged and inadmissible for any purpose, including impeachment, under Rule 408 of the Federal Rules of Evidence and any applicable federal or state statute, rule or common law provisions. Evidence, however, that is otherwise admissible or discoverable is not rendered inadmissible or not discoverable as a result of its use in the mediation.

K. DISQUALIFICATION OF MEDIATOR AND EXCLUSIONS OF LIABILITY

The mediators shall not be called as witnesses or as experts in any pending or subsequent litigation or arbitration involving the parties and relating in any way to the disputes which are the subject of the mediations. Additionally, the mediators are disqualified as witnesses or as experts in any pending or subsequent proceedings relating to the disputes which are the subject of the mediations. The Trust, with the cooperation of the claimant, shall defend the mediators from any subpoenas from outside parties arising out of the mediations. The mediators are not necessary or indispensable parties in any arbitral or judicial proceedings relating to the mediations or to the subject matter of the mediations. Finally, the mediators are not liable to any party for any act or omission in connection with any mediation conducted in the Mediation Program.

L. MEDIATION SESSION

The Special Master will notify the parties of the date, time and place of the mediation session. It is expected that mediations will be held in person, although with agreement between the parties the mediation may proceed telephonically.

To be effective, each party shall candidly disclose to the mediator, subject to the confidentiality provisions of the

Mediation Program, the facts, theories and opinions that concern the claim at issue. During the mediation session, the mediator may have joint and separate meetings with the parties and their counsel. Information disclosed during separate meetings will not be disclosed to the absent party without prior authorization. A representative of each party with full settlement authority either must be present or immediately available by phone.

M. COSTS OF MEDIATION

The mediators' compensation will be determined by the Special Master. The costs associated with mediations will be advanced by the Trust.

N. POST-MEDIATION PROCESS

Wyeth, in its sole discretion, shall approve any payments to be made on claims in mediation. If a claim is resolved during the Special Master mediation process, or a formal mediation session, the Trust is authorized to pay such amounts as approved by Wyeth. The Trust will confirm the settlement terms, in writing, to the Special Master, the parties, and Class Counsel, within five (5) days of the conclusion of either the Special Master mediation process or formal mediation session. The Special Master will then submit the terms of the settlement to the Court, under seal, for

judicial approval. If the claim is not resolved through mediation, the stay of the show cause process will be lifted and the claim ultimately will be resolved by the Court.

O. NECESSARY TERMS OF MEDIATED RESOLUTION

The resolution of any claim through mediation shall include specific terms relating to: (1) the amount to be paid by the Trust to the claimant in connection with the Matrix claim that was subject to the show cause proceedings that led to the mediation; (2) the treatment to be afforded by the Trust to any other Matrix claim and/or Green Form that has been filed by the claimant with the Trust as of the date of the mediation; and (3) the treatment to be afforded by the Trust to any future claim for Matrix benefits that may be made by the claimant.

P. DISTRIBUTION OF AGREED UPON PAYMENT AMOUNTS

Any payment of Matrix Compensation Benefits made by the Trust to a claimant under these Mediation Procedures shall be considered to be payment of Matrix Compensation Benefits under the Settlement Agreement. The Trust shall distribute the gross amount of compensation agreed upon in mediation in accordance with the requirements of Sections VI.C.4.e-n. of the Settlement Agreement relating to the payment of amounts due to subrogees and other third

parties and the distribution of expense reimbursements and counsel fees, including appropriate deductions for payment of Common Benefit fees.

Q. MODIFICATION OF THESE RULES

The Special Master may modify these rules as necessary for the effective implementation of the Mediation Program.

R. INCORPORATION OF THE SETTLEMENT AGREEMENT

All the terms of the Settlement Agreement, up to and including the Eighth Amendment, are incorporated into the terms of the Mediation Program.

**EXHIBIT A**

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 CLAIMANT:  
MATRIX CLAIM NUMBER:

**AGREEMENT TO PARTICIPATE IN MEDIATION**

I acknowledge receipt of the procedures for the Eighth Amendment Mediation Program ("Mediation Procedures"). I agree to voluntarily participate in the Mediation Program and agree with the Mediation Procedures. I further agree to participate in good faith in this mediation. I acknowledge that all offers, promises, conduct and/or statements, whether oral or written, made during the course of the mediation session by any party or their agent shall remain confidential. I understand that by agreeing to participate in the Mediation Program, I am not waiving any rights I may have in the show cause process should mediation prove unsuccessful. In addition, I agree to abide by the terms of the Settlement Agreement, including the Eighth Amendment to the Settlement Agreement.

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COUNSEL FOR TRUST

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CLAIMANT'S COUNSEL

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COUNSEL FOR WYETH

**EXHIBIT B**

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

IN RE: DIET DRUGS (PHENTERMINE/ :  
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PRODUCTS LIABILITY LITIGATION : MDL DOCKET NO. 1203

THIS DOCUMENT RELATES TO CLAIMANT:  
MATRIX CLAIM NUMBER:

**DEFERRAL REQUEST**

I acknowledge receipt of the procedures for the Eighth Amendment Mediation Program ("Mediation Procedures"). I hereby request to defer a decision to participate in formal mediation pursuant to § G of the Mediation Procedures. I agree to participate in the Special Master mediation process in a good faith attempt to resolve the above-referenced Matrix claim. I understand that I am not waiving my right to participate in the formal mediation process should the Special Master mediation process fail to resolve this claim. I further understand that I am not waiving any rights I may have in the show cause process should mediation prove unsuccessful. Finally, I agree to abide by the terms of the Settlement Agreement, including the Eighth Amendment to the Settlement Agreement.

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COUNSEL FOR TRUST

\_\_\_\_\_  
CLAIMANT'S COUNSEL

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COUNSEL FOR WYETH

**EXHIBIT C**

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

IN RE: DIET DRUGS (PHENTERMINE/ :  
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PRODUCTS LIABILITY LITIGATION : MDL DOCKET NO. 1203

THIS DOCUMENT RELATES TO CLAIMANT:  
MATRIX CLAIM NUMBER:

**DECLINATION NOTICE**

I acknowledge receipt of the procedures for the Eighth Amendment Mediation Program ("Mediation Procedures"). I do not wish to participate in the Mediation Program in regard to the above-referenced Matrix claim. I understand that by declining to participate in the Mediation Program, the stay of the show cause process will be lifted and the claim ultimately will be resolved by the Court.

\_\_\_\_\_  
COUNSEL FOR TRUST

\_\_\_\_\_  
CLAIMANT'S COUNSEL

\_\_\_\_\_  
COUNSEL FOR WYETH

**EXHIBIT D**

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 CLAIMANT:  
MATRIX CLAIM NUMBER:

**NOTICE OF AGREEMENT**

Pursuant to § G of the procedures for the Eighth Amendment Mediation Program ("Mediation Procedures"), Wyeth hereby gives notice that the following confidential agreement has been reached regarding the above-referenced Matrix claim(s):

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I understand that all parties to this claim, or group of claims, must agree before the above-described agreement is finalized. If an agreement is reached among the parties, the claim, or group of claims, will be resolved pursuant to § N of the Mediation Procedures.

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COUNSEL FOR WYETH