

**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.
Plaintiffs,

v.

**AMERICAN HOME PRODUCTS
CORPORATION,**
Defendant.

Civil Action No. 99-20593

**JOINT ANSWER AND PARTIAL OPPOSITION OF CLASS COUNSEL AND WYETH TO
AHP SETTLEMENT TRUST'S MOTION FOR RENEWED SUSPENSION
OF CERTAIN PROCESSING DEADLINES**

Class Counsel and Wyeth partially oppose the AHP Settlement Trust's (the "Trust") Motion for Renewed Suspension of Certain Processing Deadlines. The majority of the processing deadlines relating to Green Form claims for Matrix benefits have been supplanted by PTO No. 2662 (authorizing the audit of every Matrix claim), PTO No. 2807 (approving the *Rules for the Audit of Matrix Compensation Claims*), PTO No. 3185 (approving the prioritization of certain Matrix claims, approving certain provisions of the Operations Plan, and generally authorizing the entire Operations Plan), and PTO No. 3048 (denying the expedited motion of certain Class Members to suspend the Claims Integrity Program). There is no good cause for a blanket suspension of deadlines relating to Fund A benefits. Claims for Screening Program benefits, prescription refunds, and reimbursement for certain privately-obtained echocardiograms should be processed and concluded now. Deficiency processing for these claims should likewise have been completed. We also oppose any further suspension of processing deadlines relating to "Cash/Med" benefits for Class Members who have not filed claims for Matrix benefits.

I. HISTORY OF THE TRUST'S SUSPENSION OF PROCESSING DEADLINES

This is the fourth occasion for the Court to address the issue of extending the Trust's processing deadlines. On November 18, 2002, the Trust proffered to the Court a pretrial order ordering the suspension of certain processing deadlines. The Court entered PTO No. 2663 on December 3, 2002, with reinstatement of the deadlines to begin on May 1, 2003.¹

On April 8, 2003, the Trust filed a Motion for Renewed Suspension of Certain Processing Deadlines. On April 25, 2003, Class Counsel and Wyeth filed a Joint Answer and Partial Opposition. Because the Trust reported then that the majority of echocardiogram Screening Program benefits and prescription refund benefits were completed, Class Counsel and Wyeth took no position on the further suspension of processing deadlines relating to these benefits. However, we opposed the suspension of certain processing deadlines (§§ VI.C.3.i-j) relating to Class Members seeking Cash/Med, and not Matrix, benefits. The Court approved the Trust's request in full in PTO No. 2881, entered June 3, 2003, with reinstatement of the deadlines to begin on November 1, 2003.

On August 4, 2003, the Trust filed a Motion for Authorization to Proceed in Accordance with its Operations Plan, for Imposition of Certain Reporting Requirements, for Suspension of Certain Deadlines and Time Periods and for Approval of Certain Procedures. The Trust requested the extension of two additional deadlines relating to Screening Program benefits (§§ VI.C.3.g-h). On September 17, 2003, the Trust filed an Amended Proposed Pretrial Order in Connection with its Previous Submission of its Operations Plan. The Court approved the Trust's request and entered PTO No. 3185 on December 22, 2003, with reinstatement of the deadlines to begin on February 29, 2004.

On February 26, 2004, the Trust filed its most recent Motion to extend the same processing deadlines addressed in PTO No. 3185. The Trust requested an eight-month extension to

¹ The Court of Appeals for the Third Circuit affirmed PTO No. 2663 on February 18, 2004. *See In re Diet Drugs*, Nos. 02-4613, 02-4616 and 03-1006, 2004 U.S. App. LEXIS 2617, at *2 (3d Cir. Feb. 18, 2004).

October 1, 2004. Attachment 1 to this Answer is a table setting forth this history and the deadlines currently at issue.

II. ARGUMENT

A. Claim Completeness and Deficiency Review.

The Trust has requested an eight-month extension of the suspension of deadlines relating to the assessment of claim completeness and deficiencies as set forth in §§ VI.C.3.a(2) and (4) of the Settlement Agreement. Sections VI.C.3.a(2) and (4) apply to claims for both Fund A and Matrix benefits. The Trust has been afforded numerous opportunities to meet its obligations after the passage of the August 1, 2002 deadline to register for Echocardiogram screening benefits as well as prescription price and certain echocardiogram cost reimbursements, and the May 3, 2003 registration deadline for Cash/Med benefits. Given the previous extensions of time and the Trust's staffing levels, the Trust should now be able to assess the completeness of claims for Fund A benefits within the thirty days specified in the Settlement Agreement.²

For Green Forms seeking Matrix benefits, the *Rules for the Audit of Matrix Compensation Claims* apply to processing deadlines relating to Matrix eligibility. But §§ VI.C.3.a(2) and (4) apply to processing deadlines relating to Trust's pre-audit responsibilities to assess claims for completeness.³ Class Counsel and Wyeth have suggested procedures to the Trust to expedite its completeness and deficiency procedures, which should be made more efficient. The Trust's pre-audit responsibilities have also become subject to a variety of other Court orders involving the Claims Integrity Program and the Trust's Operation Plan, and therefore it is inappropriate to address these responsibilities in an Order here.

² In PTO No. 3382, the Court recently granted certain Class Members a ninety-day extension to obtain Echocardiograms in the Screening Program. The Fund A processing deadlines as to these Class Members are superseded by the issuance of this PTO.

³ The deadlines were further altered by PTO No. 2662 (authorizing the audit of every Matrix claim), PTO No. 2807 (approving the *Rules for the Audit of Matrix Compensation Claims*), PTO No. 3185 (approving the prioritization of certain Matrix claims, approving certain provisions of the Operations Plan, and generally authorizing the entire

B. Provision of Screening Program Benefits, Prescription Refunds, and Reimbursement for Non-Screening Program Echocardiograms.

Class Counsel and Wyeth oppose any further extension—especially an eight-month extension—of deadlines relating to Screening Program benefits, prescription refunds, and reimbursements for non-Screening Program echocardiograms. The Screening Program concluded on January 3, 2003 (July 3, 2003 for eligible Class Members), so there is no justification for suspending the processing deadlines relating to Screening Program benefits in §§ VI.C.3.g(1) and VI.C.3.h(1). The cut-off date for submission of Brown Forms under which Class Members with short term use could obtain Echocardiogram screening benefits was August 1, 2002, so the deadlines set forth in § VI.C.3.h need not be suspended. As for prescription refunds or reimbursements for non-Screening Program echocardiograms, the steps required to process these benefits are minimal. Because the last chance for Class Members to file for these Fund A benefits passed on May 3, 2003, there should be no need to suspend further the processing deadlines set forth in §§ VI.C.3.k-l (prescription refunds) and VI.C.3.n (reimbursements for non-Screening Program echocardiograms). No new claims have arisen in the ten months since the May 3, 2003 deadline, and no new claims can arrive in the future. With the exception of no more than twenty-two White Forms submitted by Class Members already potentially registered for Settlement benefits, three of which had a previous White Form on file, the Trust's Fund A processing volume since May 3, 2003 has not increased. Therefore, the deadlines set forth in §§ VI.C.3.g-h, VI.C.3.k-l, and VI.C.3.n of the Settlement Agreement should not be suspended. According to PTO No. 3185, these processing deadlines were to be reinstated on February 29, 2004. Because this deadline has already passed, we recommend that the Court order the Trust to process these claims within forty-five days following the Court's Order, which is the original time period specified in the Settlement Agreement for the processing of these benefits.

Operations Plan), and PTO No. 3048 (denying the expedited motion of certain Class Members to suspend the Claims Integrity Program).

C. Payment of Cash/Med Benefits.

Class Counsel and Wyeth continue to oppose the suspension of deadlines relating to claims for Cash/Med benefits made by Class Members who did not also seek Matrix benefits. The Trust has explained that Class Members who file for both Matrix and Fund A benefits will have Fund A benefits contingent on the findings of the Auditing Cardiologists. Because these two benefits should not be separately audited, we do not oppose the suspension of Cash/Med processing deadlines relating to Class Members who file for both benefits, as set forth in §§ VI.C.3.i-j of the Settlement Agreement.

However, the Trust should be capable of timely meeting the needs of the Class Members seeking only Cash/Med benefits. Cash/Med benefits are payable under the Settlement Agreement to Class Members who have timely registered for the benefit upon submission of a Gray Form demonstrating that the Class Member had FDA Positive regurgitation. *See* Settlement Agreement §§ IV.A.1.c, IV.A.2.c. Our review of the Trust's database, as of March 17, 2004, shows that there are approximately 13,400 Diet Drug Recipients who: (1) have Gray Forms documenting FDA Positive levels of regurgitation on file that were completed by a physician not subject to scrutiny in the Claims Integrity Program; (2) have not yet been paid Cash/Med benefits; (3) have been designated by the Trust as having a valid and timely Pink or Blue Form; (4) have not settled their claims outside of the National Settlement; and (5) do not also have a valid Green Form asserting a claim for Matrix benefits. We have not assessed whether these 13,400 Diet Drug Recipients are "registered" pursuant to the Trust's policy on the minimum Pink and Blue Form criteria necessary to register a claim for Settlement benefits. Of these Diet Drug Recipients, we believe that 13,386 may facially meet the criteria necessary for Cash/Med compensation, subject to meeting the Trust's eligibility and registration criteria. We could provide the Trust with a list of these Diet Drug Recipients, if needed. An additional approximately 2,200 similarly-situated Diet Drug Recipients have echocardiogram reports on file that are independent of Gray Forms. These Diet Drug

Recipients may be eligible for Cash/Med compensation if they file the requisite Gray Forms documenting FDA Positive levels of regurgitation, and/or if they meet the Trust's eligibility and registration criteria. We are also prepared to provide the Trust with a list of these Class Members, as well.

The processing deadlines specified in §§ VI.C.3.i-j of the Settlement Agreement should not be suspended as to Class Members seeking only Cash/Med benefits. The provision of these benefits to Class Members has significant health implications. *See In re Diet Drugs*, No. 99-20593, 2000 WL 1222042, at *25 (E.D. Pa, Aug. 28, 2000). Because of this, we have repeatedly pressed the Trust to process and pay these claims. *See, e.g.*, Transcript of Proceedings in MDL 1203 dated May 20, 2003 at pp.13-16. Although the Trust has assured us that these claims were receiving prompt consideration, the fact that so many remain unpaid for months or years is particularly troubling. Hence, there should not be further extensions for Trust compliance with the deadlines applicable to these claims. However, because the February 29, 2004 reinstatement deadline specified in PTO No. 3185 has already passed, we would not oppose a final extension of forty-five days for the Trust to process the Cash/Med benefits of Class Members seeking only Cash/Med benefits, which also is the original time period specified in the Settlement Agreement for the processing of these benefits.

III. CONCLUSION

The Court first suspended the processing deadlines at issue here almost sixteen months ago. Since then, the Trust has not met the extended deadlines specified in PTO No. 2663, PTO No. 2881, and PTO No. 3185. No good cause exists for an open-ended, blanket suspension for the fourth time since 2002. We instead suggest an individualized approach for the imposition of extended deadlines that are appropriate to each processing category.

Given the amount of time that has passed, Class Counsel and Wyeth recommend that the Court deny the Trust's request to further extend the deadline specified in §§ VI.C.3.g-h (furnishing Screening Program benefits and paying/denying requests for reimbursement for certain non-

Screening Program echocardiograms), VI.C.3.k-1 (paying prescription refunds), and VI.C.3.n (paying, if funds allow, those entitled to reimbursement for certain non-Screening Program echocardiograms). We also recommend that the Court deny the Trust's request, as to Class Members with Fund A, and not Matrix claims, to extend further the deadlines specified in Settlement Agreement §§ VI.C.3.a(2) to assess claim completeness and deficiencies; in VI.C.3.a(4) to provide notification of information needed to remedy deficiencies; and VI.C.3.i-j to pay or furnish Cash/Med benefits.

Class Counsel and Wyeth recognize that the 100% audit process produces increased pressures on the Trust. For this reason, although the deadlines specified in PTO No. 3185 tolled on February 29, 2004, we would not oppose a final extension of the deadlines above in a time span equal to what was originally specified in the Settlement Agreement. Attachment 1 summarizes our recommendations to the Court in this regard.

 *by O/B w/ permission*

Dated: March 29, 2004

Respectfully submitted,
"s"/ Caroline A. Flotron

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Brown, C.A. No. 99-20593**

ATTACHMENT 1 - TRUST PROCESSING DEADLINES AT ISSUE

A. PTO 2663 <i>entered 12/3/02, affirmed 2/18/04 deadlines suspended until 5/1/03</i>		B. PTO 2881 6/3/03	C. PTO 3185 12/19/03	D. TRUST	E. CLASS COUNSEL & WYETH
Section	Topic	Extension	Extension	Extension	Extension
1.	§ VI.C.3.a(2) [p.95] Review claim and supporting documentation to determine completeness and identify deficiencies within 30 days of claim receipt.	<i>to 11/1/03</i>	<i>to 2/29/04</i>	<i>to 10/1/04</i>	Fund A claims: 30 days after Court Order. Matrix claims: deadline superseded by Court orders.
2.	§ VI.C.3.a(3) [p.95] Confirm that the physician submitting certification in support of Matrix benefits is Board-Certified within 30 days of claim receipt.	<i>to 11/1/03</i>	<i>to 2/29/04</i>	<i>to 10/1/04</i>	Deadline superseded by Court orders.
3.	§ VI.C.3.a(4) [p.95] Inform Class Member of information needed to remedy deficiencies within 30 days of claim receipt. (The notification of Claimant's unique DDR number, which is assigned pursuant to § VI.C.3.a(1) [p.95], was not suspended.)	<i>to 11/1/03</i>	<i>to 2/29/04</i>	<i>to 10/1/04</i>	(1) Fund A claims: 30 days after Court Order. (2) Matrix claims: deadline superseded by Court orders.
4.	§ VI.C.3.g [pp.98-99] Subclass 1(b) Members: Certify eligibility for, and furnish documentation and information to receive, Screening Program benefits within 45 days of receiving completed claim documenting membership in subclass. § VI.C.3.g(1). Pay or deny the net cost of non-Screening Program echocardiograms within 45 days of receiving completed claim documenting membership in subclass. § VI.C.3.g(2).	None	<i>to 2/29/04</i>	<i>to 10/1/04</i>	(1) Screening Program is over. (2) 45 days from Court Order for net cost of echo.
5.	§ VI.C.3.h [pp.99-100] Subclass 1(a) Members: Transmit Brown Form to Subclass Members requesting Screening Program echocardiogram within 45 days of completed claim receipt. § VI.C.3.h(1). Reject request for Screening Program benefits or provide appropriate documentation to receive Screening Program benefits within 45 days of completed Brown Form receipt. § VI.C.3.h(1). Pay or deny the net cost of non-Screening Program echocardiograms within 45 days of receiving completed claim documenting membership in subclass. § VI.C.3.h(2).	None	<i>to 2/29/04</i>	<i>to 10/1/04</i>	(1) Brown Form program is moot. (2) Screening Program is over. (3) 45 days from Court Order for net cost of echo.
6.	§ VI.C.3.i [p.100] Subclass 1(b) and 2(b) Members: Certify that Diet Drug Recipient is or is not entitled to either \$6,000 in cash or \$10,000 in valve-related medical services, and if entitled, pay or furnish such benefits within 45 days of receiving completed claim documenting membership in subclass.	<i>to 11/1/03</i>	<i>to 2/29/04</i>	<i>to 10/1/04</i>	45 days after Court Order unless valid Matrix claim submitted.
7.	§ VI.C.3.j [pp.100-01] Subclass 1(a) and 2(a) Members: Certify that Diet Drug Recipient is or is not entitled to either \$3,000 in cash or \$5,000 in valve-related medical services, and if entitled, pay or furnish such benefits within 45 days of receiving completed claim documenting membership in subclass.	<i>to 11/1/03</i>	<i>to 2/29/04</i>	<i>to 10/1/04</i>	45 days after Court Order unless valid Matrix claim submitted.
8.	§ VI.C.3.k [p.101] Subclass 1(a) and 2(a) Members: Certify amount of prescription refund, and if entitled, make payment, within 45 days of receiving complete claim documenting duration of Diet Drug use.	<i>to 11/1/03</i>	<i>to 2/29/04</i>	<i>to 10/1/04</i>	45 days after Court Order.
9.	§ VI.C.3.l [pp.101-02] Subclass 1(b) and 2(b) Members: Determine amount of refund within 90 days of May 3, 2003. Pay those with documented membership in subclass within 45 days of making refund determination.	<i>to 11/1/03</i>	<i>to 2/29/04</i>	<i>to 10/1/04</i>	45 days after Court Order.
10.	§ VI.C.3.n [pp.102-03] Determine whether Diet Drug Recipient or Representative Claimant requesting reimbursement for non-Screening program echocardiograms not otherwise reimbursed in the Settlement is entitled to benefit within 90 days after May 3, 2003. Pay, if Fund A possesses sufficient assets, reimbursement within 45 days of determination.	<i>to 11/1/03</i>	<i>to 2/29/04</i>	<i>to 10/1/04</i>	45 days after Court Order.

**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.*

Plaintiffs,

v.

**AMERICAN HOME PRODUCTS
CORPORATION,**

Defendant.

Civil Action No. 99-20593

PRETRIAL ORDER NO.

AND NOW, this ____ day of _____, 2004, upon consideration of the AHP Settlement Trust's Motion for Renewed Suspension of Certain Processing Deadlines, the Joint Answer and Partial Opposition of Class Counsel and Wyeth to AHP Settlement Trust's Motion for Renewed Suspension of Certain Processing Deadlines, and responses thereto, it is hereby ORDERED that the Motion is denied with the exception of the deadlines specified in paragraph 1.

(1) The deadlines and time periods of the Nationwide Class Action Settlement Agreement ("Settlement Agreement"), as amended, with the American Home Products Corporation (now known as Wyeth) are suspended as follows:

- (a) The Trust's responsibility for processing Cash/Med benefits, pursuant to of §§ VI.C.3.i-j of the Settlement Agreement, for Class Members with valid Matrix claims currently on file with the Trust, are suspended until such date as the Trust issues a Preliminary Audit Determination Letter with respect to the Matrix claim of each such Class Member; and
- (b) The Trust's responsibility for determining claim completeness and assessing any claim deficiencies, pursuant to §§ VI.C.3.a(2) and (4) of the Settlement Agreement, for Class Members with valid Matrix claims currently on file with the Trust, are superseded by PTO No. 2807 (approving the *Rules for the Audit of Matrix Compensation Claims*), PTO No. 3185 (approving

the prioritization of certain Matrix claims, approving certain provisions of the Operations Plan, and generally authorizing the entire Operations Plan), and PTO No. 3048 (denying the expedited motion of certain Class Members to suspend the Claims Integrity Program).

- (2) The Trust will meet the following processing deadlines as specified:
 - (a) The Trust shall complete its determination of claim completeness and its assessment of any claim deficiencies within 30 days for Fund A claims after receipt by the Trust, pursuant to §§ VI.C.3.a(2) and (4) of the Settlement Agreement;
 - (b) The Trust shall process claims for reimbursement of the net cost of non-Screening Program echocardiograms within 45 days after receiving a completed claim documenting membership in the appropriate subclasses, as provided in §§ VI.C.3.g(2) and VI.C.3.h(2) of the Settlement Agreement;
 - (c) The Trust shall process claims for prescription refunds within 45 days after receiving a completed claim documenting duration of drug use as provided in §§ VI.C.3.k-1 of the Settlement Agreement; and
 - (d) The Trust shall process claims for reimbursement of the net cost of certain non-Screening Program echocardiograms within 45 days after the determination that the fund possesses sufficient assets pursuant to § VI.C.3.n of the Settlement Agreement.
- (3) Nothing in this Order shall be construed to relieve the Trust of its obligation to:
 - (a) Meet the deadlines set forth in §§ VI.C.3.a(1) and VI.C.4.e-n of the Settlement Agreement;
 - (b) Provide Wyeth with access to completed Matrix claims pursuant to § VI.F.1 of the Settlement Agreement within five days of determining that a claim for Matrix Level benefits is complete within the meaning of §§ VI.C.3 and VI.C.4 of the Settlement Agreement and to make tentative determinations of such claims within the time periods otherwise applicable under the Settlement Agreement upon determination that a Claim for Matrix Level Benefits is complete; and
 - (c) Inform the Class Member, in writing, of the unique identifying number assigned to the Class Member's claim pursuant to § VI.C.3.a(4).

(4) This Order supercedes Pretrial Order Nos. 2663, 2881, and 3185, which shall have no further force or effect. This Order shall have no effect on the Trust's obligation to provide specific quarterly and annual reports called for in the Settlement. In addition, the Trust shall report monthly to the Court, Class Counsel and Wyeth in an agreed upon format that covers at least the following:

- (a) Total of all Matrix claims in priority categories received by Trust;
- (b) Processing status of all such Matrix claims;
- (c) Claims remaining to be processed in priority categories;
- (d) Changes in the processing status of such Matrix claims since the prior report;
- (e) Items (b) and (d) above for all claims for Fund A benefits.

BY THE COURT:

Harvey Bartle III, U.S.D.J.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the Joint Answer and Partial Opposition of Class Counsel and Wyeth to AHP Settlement Trust's Motion for Renewed Suspension of Certain Processing Deadlines in the *Sheila Brown* action was filed electronically this 29th day of March 2004 and is available for viewing and downloading from the ECF System of the United States District Court for the Eastern District of Pennsylvania.

The undersigned further certifies that a true and correct copy of the foregoing document will be served on the 30th day of March 2004 by facsimile and U.S. first-class mail, postage prepaid, upon plaintiffs' counsel in the civil actions identified above, and by U.S. first-class mail, postage prepaid, upon all other counsel of record in this action and upon all other counsel required to be served by Pretrial Order No. 19.

s/ Melissa A. Graff
Melissa A. Graff

Date: March 29, 2004