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

PRETRIAL ORDER NO. 2805

AND NOW, this 26th day of March, 2003, after a hearing to discuss objections to the proposed Court Approved Procedure concerning Medical Records Relating to Matrix Claims, it is hereby ORDERED that said Court Approved Procedure, as further revised by the Court and attached as Exhibit A, is APPROVED as Court Approved Procedure No. 4.

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
SHEILA BROWN, SHARON GADDIE, VIVIAN NAUGLE, QUINTIN LAYER, and JOBY JACKSON-REID Individually and all others similarly situated, Plaintiffs, v. AMERICAN HOME PRODUCTS CORPORATION, Defendant.	Civil Action No. 99-20593

COURT APPROVED PROCEDURE NO. 4

(Medical Records Relating to Matrix Claims)

AND NOW, on the date set forth in the accompanying Pretrial Order No. 2805, in accordance with the Nationwide Class Action Settlement Agreement (the "Settlement Agreement"), it is hereby ORDERED as follows:

1. ***Definitions.*** All capitalized terms not otherwise defined in this Procedure shall have the meanings given them in the Settlement Agreement.

2. ***Scope of this Procedure.*** This Procedure applies to medical records and documents relating to all claims for Matrix Compensation Benefits. All Class Members seeking Matrix Compensation Benefits must submit to the Trust the records and documents required by Sections VI.C.4.a(1) through (8) of the Settlement Agreement. If any record or document required by Sections VI.C.4.a(1) through (8) has not been submitted to the Trust and is material to the determination of eligibility for Matrix Compensation Benefits on the claim, the Trust shall consider the claim to be incomplete until the Class Member has satisfied those provisions.

EXHIBIT A

3. ***Records and Documents Expressly Required by the Settlement Agreement for Eligibility on Matrix Levels III, IV, and V.*** A Class Member seeking Matrix Compensation Benefits on Matrix Levels III, IV, or V must submit to the Trust (in addition to the materials referred to in Paragraph 2 above) all other records and documents specified in Sections IV.B.2.c(3) through (5) of the Settlement Agreement (describing the conditions for eligibility for Matrix Compensation Benefits on Matrix Levels III, IV, or V). The Trust shall consider such a claim incomplete unless the Class Member provides such records and documents.

4. ***Medical Records and Documents other than those Described in Paragraphs 2 and 3.*** For purposes of this Court Approved Procedure, "General Medical Records" consist of all records and documents necessary to support a reasonable degree of medical certainty that: (i) the Diet Drug Recipient has the condition which qualifies for a particular Matrix Compensation Benefit; (ii) such condition was not present before Diet Drug use; and (iii) all the conditions for eligibility on Matrix A or B under Sections IV.B.2.d(2) of the Settlement Agreement either are present or are not present. General Medical Records shall include, at a minimum: (a) the tapes/disks of any Echocardiogram at any time of the Diet Drug Recipient upon whose condition the claim is based; and (b) beginning five years preceding the Diet Drug Recipient's Diet Drug use and continuing through the submission of the claim to the Trust, all records and documents of the general care providers (general practitioners, family physicians, primary care providers, and internists) and all subspecialty care providers (including without limitation subspecialists in internal medicine, cardiovascular and neurological surgeons, neurologists, cardiologists, rheumatologists, pathologists, emergency care providers, obstetricians, and gynecologists), who rendered any medical care to and/or were consulted by the Diet Drug Recipient whose claim forms the basis of the claim subject to Audit. The Trust has discretion to specify additional records and documents to be included in the definition of General Medical Records as the Trust deems appropriate in the processing of all claims for Matrix Compensation Benefits, for certain groups of claims, or for individual claims.

5. ***Processing of Claims in the Absence of General Medical Records.*** The Trust shall not treat claims for Matrix Compensation Benefits as incomplete because of the absence of General Medical Records, but instead shall process such claims to eligibility determinations on the basis of the Class Member's submissions, including the processing of claims in audit ("Audit") under Sections VI.E and VI.F of the Settlement Agreement and Pretrial Order No. 2662 and any other applicable Pretrial Order and Court Approved Procedure.

6. ***Additional Steps Regarding Claims Included in Paragraph 5.*** For all claims included in Paragraph 5 above that proceed through Audit and are determined payable on Matrix B, the Trust shall not require the Class Member to provide additional General Medical Records, unless and until the Class Member at any time thereafter seeks benefits on Matrix A. For all claims included in Paragraph 5 above that proceed through Audit and are determined payable on Matrix A, the Trust shall notify the Class Member that the Class Member must elect among three options for the continued processing of the claim:

> **(a)** the Class Member shall submit all the Class Member's General Medical Records (in legible form) to the Trust, by a deadline set by the Trust; or

(b) the Class Member shall submit to the Trust, by a deadline set by the Trust, a Verification in the Form appended to this Court Approved Procedure; or

(c) the Class Member shall agree in writing to be paid Matrix Compensation Benefits on Matrix B in full satisfaction of the claim being processed.

The Trust shall not pay any Matrix Compensation Benefits to the Class Member on the claim being processed unless and until the provisions of this Paragraph 6 are satisfied.

7. ***The Trust's Authority to Require Records and Other Claims Administration Procedures Before the Audit of Claims.*** When the Trust has reasonable grounds that a claim or group of claims for Matrix Compensation Benefits has not been submitted in accordance with the Settlement Agreement, reflects any of the practices determined inappropriate by the Court in Pretrial Order No. 2640 or any Order of the Court, contains misrepresentations of material fact, or suffers from any other circumstance questioning the legitimacy of the claim(s), before the claim(s) are sent to an Auditing Cardiologist, the Trust may require the Class Member to submit all (or some specified portion) of the General Medical Records relating to the claim, and the Verification described in Paragraph 6(b) above, and such other relevant documents or information within the Class Member's custody, possession, or control as may reasonably be requested by the Trust.

8. ***Review of General Medical Records.*** In any instance in which a Class Member has submitted any General Medical Records to the Trust, the Trust shall have such materials reviewed by a Trust Cardiologist, the Auditing Cardiologist, or other qualified Trust representative, to determine the information from such materials relevant to the processing of a claim for Matrix Compensation Benefits.

9. ***Duration of this Procedure.*** This Procedure shall apply to all claims for Matrix Compensation Benefits processed after the date of the approval of this Procedure by the Trial Court and shall remain in place until further order of the Court.

PHYSICIAN VERIFICATION AND DDR ACKNOWLEDGEMENT

This Form must be completed by a Board-Certified Cardiologist, or a Board-Certified Cardiothoracic Surgeon, with at least Level 2 training in Echocardiography. Print or type all information in black ink.

I. DIET DRUG RECIPIENT

Name:	First	Middle	Last
Claim Number		Date of Birth ____/____/____ (Month) (Day) (Year)	Social Security Number _____-_____-_____

II. ATTESTING PHYSICIAN REVIEW OF MEDICAL HISTORY AND RECORDS

I certify that:

1. ☐ I am a Board-Certified Cardiologist, or Board-Certified Cardiothoracic Surgeon, with at least Level 2 training in Echocardiography as specified in A.S. Pearlman *et al.*, *Guidelines for Optimal Physician Training in Echocardiography: Recommendation of the American Society of Echocardiography Committee on Physician Training in Echocardiography*, 60 Am J. Cardiology 158-163 (1987).

2. ☐ I completed and signed on _____(insert date) the GREEN Form previously submitted to the Settlement Trust by this Diet Drug Recipient.
   OR
   ☐ I completed and signed Part II.E of the GREEN Form attached to this Form.

3. ☐ I met with the Diet Drug Recipient in person in my offices (or in a hospital or other health care facility) on _____(insert date) for _____ (state length of session) and took a complete medical history of the Diet Drug Recipient, in conformity with accepted medical standards regarding obtaining a medical history for purposes of diagnosis and treatment of a patient with or suspected of having valvular heart disease. I asked the questions and follow-up questions necessary to provide complete and accurate answers to the questions in Part II.E of the GREEN Form. Where the Diet Drug Recipient was unable to answer a question with certainty, I obtained and reviewed the medical records necessary to provide the requested information. There were no agents and/or representatives of any law firm present during my meeting with this Diet Drug Recipient. **Note:** You must attach your written transcription of this medical history to this Form. Lack of information cannot be the basis for a negative answer to any Green Form question.
   OR

4. ☐ I met with the Diet Drug Recipient in person in a _____ (state type of location, i.e., hotel, clinic, mobile unit, etc.) located at _____ (state specific address) on_____(insert date) for _____ (state length of session) and took a complete medical history of the Diet Drug Recipient, in conformity with accepted medical standards regarding obtaining a medical history for purposes of diagnosis and treatment of a patient with or suspected of having valvular heart disease. I asked the questions and follow-up questions necessary to provide complete and accurate answers to the questions in Part II.E of the GREEN Form. Where the Diet Drug Recipient was unable to answer a question with certainty, I obtained and reviewed the medical records necessary to provide the requested information. This meeting did not take place in an office associated with any law firm and there were no agents and/or representatives of any law firm present during my meeting with this Diet Drug Recipient. **Note:** You must attach your written transcription of this medical history to this Form. Lack of information cannot be the basis for a negative answer to any Green Form question.
   OR

5. ☐ After reasonable inquiry regarding the existence and completeness of such records, I personally reviewed medical records of the Diet Drug Recipient beginning at least five years preceding the Diet Drug Recipient's Diet Drug use and continuing through the submission of the claim to the Trust, including all records and documents of the general care providers (general practitioners, family physicians, primary care providers, and internists) and all subspecialty care providers (including without limitation subspecialists in internal medicine, cardiovascular and neurological surgeons, neurologists, cardiologists, rheumatologists, pathologists, emergency care providers, obstetricians, and gynecologists), who rendered any medical care to and/or were consulted by the Diet Drug Recipient, and satisfied myself that based on that review I could accurately answer the questions in the GREEN Form or in the attached GREEN Form Part II.E.

NOTE: To complete this Form you must answer Questions 1 and 2. You must also answer Question 3, 4 or 5. If you are *not* the physician who attested to the GREEN Form on file, you must complete, sign, and attach Part II.E of a GREEN Form.

III. PHYSICIAN INFORMATION

Name:	First	Middle	Last	
Address:	Street	City	State	Zip code
Telephone: (_____) _____		Fax: (_____)_____	Email:	

NOTE: This Form is an official Court document sanctioned by the Court presiding over the Diet Drug Settlement. Submitting it to the AHP Settlement Trust is equivalent to filing it with a Court. I declare under penalty of perjury that the information I have provided in this Form is correct to the best of my knowledge and information.

Signature: _____ Date:_____/_____/_____
(Month) (Day) (Year)

IV. DIET DRUG RECIPIENT ACKNOWLEDGMENT

NOTE: You must complete Question 1 or Question 2, and sign and date this Form.

I certify that:

1. ***Answer this Question if the physician answered Question 3 or 4 in Section II of this Form:***

☐ I met in person on _____ (insert date) with the physician who completed Sections II and III of this Form. I answered all of his/her questions honestly and completely. I reviewed the physician's answers to the questions on my GREEN Form and affirm that the answers are correct to the best of my knowledge and information.

2. ***Answer this Question if the physician answered Question 5 in Section II of this Form:***

☐ I produced to the physician who completed Sections II and II of this Form, or authorized production to such physician, of my medical records beginning at least five years preceding my Diet Drug use and continuing through the submission of my claim to the Trust, including all records and documents of the general care providers (general practitioners, family physicians, primary care providers, and internists) and all subspecialty care providers (including without limitation subspecialists in internal medicine, cardiovascular and neurological surgeons, neurologists, cardiologists, rheumatologists, pathologists, emergency care providers, obstetricians, and gynecologists), who rendered any medical care to and/or were consulted by me during that period.

NOTE: This Form is an official Court document sanctioned by the Court presiding over the Diet Drug Settlement. Submitting it to the AHP Settlement Trust is equivalent to filing it with a Court. I declare under penalty of perjury that the information provided in this Form is correct to the best of my knowledge and information.

Signature: _____ Date:_____/_____/_____
(Month) (Day) (Year)