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

In Re: Diet Drugs

(Phentermine/Fenfluramine/

Dexfenfluramine) Products Liability

Litigation

MDL NO. 1203

This Document Relates To: Sheila Brown, et. al. v. American Home Products

Corporation

CIVIL ACTION No. 99-20593

ELEVENTH AMENDMENT TO THE NATIONWIDE CLASS ACTION SETTLEMENT AGREEMENT WITH AMERICAN HOME PRODUCTS **CORPORATION**

Dated: June 14, 2023

TABLE OF CONTENTS

		<u>Page</u>
I. D	EFINITIONS USED IN THIS ELEVENTH AMENDMENT	3
Α.	Incorporation of Settlement Agreement Definitions	3
В.	Eleventh Amendment Definitions.	
II. O	PERATIVE TERMS	9
A.	Continuation of Matrix Compensation Benefits Eligibility and Pa	-
В.	Transfer of Administration of the Diet Drug Settlement Programmer Termination of the AHP Settlement Trust	
C.	Nature of the Settlement Fund.	
D .	Appointment of and Service by the Claim Administrator	
E.	Claim Submission.	
F.	Proof of Use and Duration of Use of the Diet Drugs	
G.	Complete Claim Requirements.	
Н.	Threshold Eligibility Review of Claims	
I.	Medical Review of Claims.	
J.	Appeal of Claim Outcomes	
K.	Derivative Claimants.	
L.	Processing of Healthcare Liens.	
M.	Liens and Other Matters Affecting the Payment of Benefits	
N.	Arbitration and Show Cause Provisions	
0.	Enhancements to the Administration of the Settlement Agreement.	
P.	Class Counsel Fees and Costs	
Q.	The Maximum Available Settlement Fund Amount	23
R.	Clarification of Applicable Requirements and Procedures	23
S.	Miscellaneous Terms.	
III. A	APPROVAL AND OTHER TERMS	25
A.	Joint Application for District Court Approval	25
В.	Conditions to Effectiveness of the Eleventh Amendment	
\overline{C}	Fffective Date	27

D.	Retained Jurisdiction	27
E.	Survival of Settlement Agreement Terms	27
F.	Headings	
G.	Counterparts	27
	•	
EXHI	BIT 1: Previous Court Approved and Other Procedures	Ex.1-1
EXHI	BIT 2: Order-Preliminary Approval	Ex.2-1
EXHI	BIT 3: Postcard Notice	Ex.3-1
EXHI	BIT 4: Order-District Court Approval	Ex.4-1

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WHEREAS, on November 18, 1999, American Home Products Corporation and Class Counsel executed the Nationwide Class Action Settlement Agreement with American Home Products Corporation ("Original Settlement Agreement") arising from the marketing, sale, distribution and use of the diet drugs Pondimin® and ReduxTM;

WHEREAS, since the Court entered Pretrial Order ("PTO") No. 1415 on August 28, 2000, approving the Original Settlement Agreement as amended by the first four amendments thereto, the Settlement Agreement has been amended another six times as follows:

- 1. The Fifth Amendment was approved in PTO No. 2677 on December 11, 2002;
- 2. The Sixth Amendment was approved in PTO No. 2778 on March 12, 2003;
- 3. The Seventh Amendment was approved in PTO No. 4567 on March 15, 2005 (following preliminary approval granted in PTO No. 3880 on August 26, 2004);

- 4. The Eighth Amendment was approved in PTO No. 3881 on August 26, 2004;
- 5. The Ninth Amendment was approved in PTO No. 5398 on July 1, 2005; and
- 6. The Tenth Amendment was approved in PTO No. 8506 on July 2, 2010.

WHEREAS, on March 11, 2002, American Home Products Corporation changed its corporate name to "Wyeth;"

WHEREAS, on October 16, 2009, Wyeth became a wholly owned indirect subsidiary of Pfizer Inc., and on November 9, 2009, Wyeth converted its corporate status under Delaware law and changed its name to "Wyeth LLC;"

WHEREAS, all benefits under the Settlement Agreement have been distributed and concluded, other than potential payment of additional, "incremental" Matrix Compensation Benefits to a group of approximately 2,700 Class Members who remain eligible to submit a claim for such additional incremental Matrix Compensation Benefits;

WHEREAS, those Class Members previously received payment of Matrix Compensation Benefits, were not subject to the Seventh Amendment to the Settlement Agreement, and may submit a claim if the severity of their underlying valve disease progresses before they reach age 80, such that they meet the eligibility requirements for payment of Matrix Compensation Benefits at a higher Matrix Level and in a larger amount than they previously received under the terms of the Settlement Agreement;

WHEREAS, during the four-year period of 2019 through 2022, the AHP Settlement Trust has received an average of only four claims for incremental Matrix Compensation Benefits per year;

WHEREAS, such reduced claim activity has caused the extensive structure of the AHP Settlement Trust to be excessive and unnecessary and presents the need for a simpler, streamlined, and more efficient administrative process to implement the Settlement Agreement; and

WHEREAS, Wyeth and Class Counsel (the "Parties") have agreed it is appropriate and mutually beneficial to Wyeth and the affected Class Members to modify certain terms of the Settlement Agreement to adjust for changed circumstances in the manner set forth in this Eleventh Amendment;

NOW THEREFORE, in consideration of the covenants and undertakings expressed in this Eleventh Amendment and subject to Court approval, the Parties agree that the Settlement Agreement is further amended by this Eleventh Amendment as follows.

I. DEFINITIONS USED IN THIS ELEVENTH AMENDMENT

- A. Incorporation of Settlement Agreement Definitions. The capitalized terms used and not specifically defined in this Eleventh Amendment have the meanings given to them in the Settlement Agreement. For convenience, some of those terms are repeated in Section I.B.
- **B.** Eleventh Amendment Definitions. As used in this Eleventh Amendment, these terms have the following meanings:
 - 1. "Appeal" means a proceeding before the Court to review a final outcome issued by the Claim Administrator, as described in Section II.J.
 - 2. "BrownGreer" means BrownGreer PLC (or its corporate successor), a claims administration service provider in Richmond, Virginia.
 - 3. "CEP" means the three-person Consensus Expert Panel originally appointed in Court Approved Procedure No. 11 (Audit of Matrix Claims; approved by PTO No. 6100), consisting of a cardiologist designated by each of the Trust, Class Counsel, and Wyeth, or, if a replacement is needed at any time, such other cardiologist agreed upon and jointly nominated by Wyeth and Class Counsel and appointed by the Court to serve as a member of the CEP.
 - **4.** "CEP Review" means the review of a Claim to determine the medical issues presented by the Claim, pursuant to Section II.I.2.
 - 5. "Claim" means the Green Form (or such other Claim Form in use by the Claim Administrator) submitted to seek Incremental Matrix

Compensation Benefits for a Progression Matrix Level Condition. and all materials and information submitted or created during processing relating to it.

- 6. "Claim Administrator" means BrownGreer, the entity to be nominated by the Parties to be appointed by the Court to perform the functions and obligations of the Claim Administrator. An authorized representative of the Claim Administrator may execute contracts and take such other actions as necessary to perform the role of the Claim Administrator.
- 7. "Claim Administrator Fees and Costs" mean the fees and costs of the Claim Administrator relating to the administration and implementation of the Settlement Agreement, as described in Section II.D.3.
- 8. "Claimant" means the Diet Drug Recipient asserting a Claim or the Representative Claimant asserting a Claim on behalf of a deceased or legally incapacitated Diet Drug Recipient. Where a Claim is asserted by a Representative Claimant on behalf of a Diet Drug Recipient, all references to the medical conditions on which the Claim is based are to the medical conditions of that Diet Drug Recipient.
- **9.** "Class Counsel Fees and Costs" mean the fees and costs awarded by the Court to Class Counsel, as described in Section II.P.
- **10. "Complete Claim"** means a Claim on which the Claimant has submitted or the Claim Administrator has in its possession the information and materials required for a Complete Claim under Section II.G.
- 11. "Court" or "District Court" means the United States District Court for the Eastern District of Pennsylvania.
- **12. "District Court Approval"** means the entry by the Court of an Order approving the Eleventh Amendment, as described in Section III.A.3.
- 13. "Derivative Claimants" are persons who have a legally recognized claim for loss of services, consortium, support, or the like, arising from injury to a Diet Drug Recipient and who properly and timely

- registered for benefits with the Trust by Date 2 (May 3, 2003), pursuant to Sections IV.B.1.c and IV.B.2 of the Settlement Agreement.
- 14. "Effective Date" means 30 days after the date of District Court Approval, unless any party has obtained before then a stay of District Court Approval pending appeal. If a stay of District Court Approval is obtained, the Effective Date will be the date, if any, on which District Court Approval is affirmed on appeal without any material change and any appellate stay has been vacated.
- 15. "Eleventh Amendment Class Members" mean all Diet Drug Recipients (or the Representative Claimants of Diet Drug Recipients) who: (a) are not Category One Class Members or Category Two Class Members under the Seventh Amendment to the Settlement Agreement; and (b) on or before the Effective Date, had been paid Matrix Compensation Benefits by the Trust on any Matrix Level other than Matrix Level V. This definition of Eleventh Amendment Class Members includes the Class Members defined as the "Age 80 Class Members" in the Tenth Amendment to the Settlement Agreement.
- 16. "Fund Depository" means the bank or other financial institution holding the Settlement Fund. The Claim Administrator, with the agreement of the Parties, will select the Fund Depository. The Claim Administrator will issue such instructions as are necessary to accomplish the timely payment from the Settlement Fund of all amounts payable from the Settlement Fund under the Settlement Agreement (including this Eleventh Amendment).
- 17. "General Medical Records" mean the information and materials described in Section II.G.4.
- 18. "Healthcare Lien" means a Medicare Claim and any other claim for reimbursement or Lien by a federal of state agency, healthcare provider, or insurer (that has not released all claims regarding Diet Drug Recipients) asserted to the Claim Administrator or required by applicable law regarding amounts expended for the care and treatment of the Progression Matrix Level Condition on which Incremental Matrix Compensation Benefits have been determined payable to an Eleventh Amendment Class Member.

- 19. "Implementation Costs" mean the Class Counsel Fees and Costs, Claim Administrator Fees and Costs, fees and expenses of the members of the CEP, any charges of the Fund Depository, expenses or fees of any service provider or vendor necessary to implement the Settlement Agreement, tax obligations of the Settlement Fund as a QSF, any other costs of administration incurred by the Settlement Fund.
- 20. "Incremental Matrix Compensation Benefits" mean the incremental dollar amount, if any, by which the Matrix Grid Amount for a higher Matrix Level for a Progression Matrix Level Condition exceeds the Matrix payment previously made to or on behalf of the Eleventh Amendment Class Member, pursuant to Section IV.C.3 of the Settlement Agreement.
- 21. "Lien" means any known or asserted lien, subrogation right, reimbursement right, third-party interest, claim, mortgage, pledge, charge, security interest, or legal encumbrance, of any nature, whether statutory or otherwise, regardless of whether it has the legal status of a lien under applicable law, seeking payment or repayment of any amount out of the Matrix Compensation Benefits payable on a Claim.
- **22.** "MMSEA" means the Medicare, Medicaid, and SCHIP Extension Act of 2007 and its applicable regulations.
- **23.** "MMSEA Query" means the query required by the MMSEA to determine whether a person is Medicare Entitled, as set forth in Section II.L.
- **24.** "MSP" means the Medicare Secondary Payer Act, 42 U.S.C.A. §§ 1395y(b) *et seq.*, and its applicable regulations.
- 25. "Matrix Grid Amount" means the dollar amount payable on Matrix A-1 or Matrix B-1 in the year in which the payment of Incremental Matrix Compensation Benefits is made.
- 26. "Maximum Available Settlement Fund Amount" or "MASFA" has the meaning set forth in Section II.Q.

- 27. "Medical Review" means the processing of a Claim to determine if it is eligible for payment on any Matrix Level that would qualify the Claimant for Incremental Matrix Compensation Benefits, as described in Section II.I.
- 28. "Medicare" means the federal Medicare program and all representatives of that program, including the Centers for Medicare & Medicaid Services and any Coordination of Benefits Contractor or other representative engaged by the Medicare program.
- **29.** "Medicare Claim" means any actual or potential claims by Medicare for reimbursement under the MSP.
- **30.** "Medicare Entitled" means a person who is identified as eligible for Medicare benefits in response to an MMSEA Query.
- **31. "Motion for Approval"** means the joint motion filed by the Parties with the Court seeking approval of the Eleventh Amendment, as described in Section III.A.1.
- 32. "Non-Healthcare Lien" means any Lien asserted by a Lien Claimant other than Healthcare Liens where there is a legal obligation to withhold payment of any Matrix Compensation Benefits payable on a Claim under applicable federal or state law. This definition includes Liens: (a) for attorneys' fees and/or costs for work performed in representing an Eleventh Amendment Class Member individually in the Settlement Program; (b) from a federal or state child support agency for unpaid child support arrears; (c) from a federal, state, or local tax agency for unpaid tax obligations; (d) for debts based on a contract, business, loan, or any other debt enforced in a final judgment entered by a federal or state court; or (e) based on UCC-1 perfected security interests in the proceeds of a claim as evidenced by a UCC-1 filing and a security agreement granting a security interest in general intangibles, payment intangibles, or the proceeds of a litigation claim.
- **33. "Preliminary Approval Order"** means the Order entered by the Court in conformity with Section III.A.2.
- **34.** "Progression Matrix Level Condition" means that the condition of the Diet Drug Recipient which qualified such person for payment of

Matrix Compensation Benefits has progressed to a more severe condition after the Matrix Payment Cut-Off Date that would qualify the Diet Drug Recipient for Matrix Compensation Benefits on a higher Matrix Level, under Sections IV.C.2 and IV.C.3 of the Settlement Agreement.

- **35. "PTO No. 1823 Reserve"** means the separate account maintained by the Trust pursuant to Paragraph 3 of PTO No. 1823, entered on March 21, 2001 (Document 101957).
- **36.** "QSF" means a "qualified settlement fund" for federal tax purposes under Section 468B of the Internal Revenue Code and Treas. Reg. Section 1.468B-1.
- **37.** "QSF Administrator" means the Claim Administrator acting as QSF "administrator" within the meaning of Treasury Regulation 1.468B-2(k)(3).
- **38.** "Reconsideration" means the processing steps to have the Claim Administrator or CEP re-review the determinations made on or regarding a Claim or other matter.
- **39. "Reduction Factors"** mean any of the medical conditions that reduce eligibility from Matrix A-1 to Matrix B-1 under Section IV.B.2.d of the Settlement Agreement.
- **40.** "Representative Claimant" means a person with legal authority to act on behalf of a deceased or legally incapacitated Eleventh Amendment Class Member.
- **41.** "Section" means the sections of this Eleventh Amendment, unless otherwise specified.
- **42.** "Settlement Agreement" means the Original Settlement Agreement, as amended by all its Amendments.
- 43. "Settlement Fund" means the account held at the Fund Depository for the funds deposited by Wyeth to pay benefits under the Settlement Agreement and the costs of administering the Settlement Program, including Implementation Costs.

- 44. "Settlement Program" or "Diet Drug Settlement Program" means the claims process and compensation system created under the Settlement Agreement, which previously has been referred to on the Settlement website as the "AHP Diet Drug Settlement."
- **45. "Technical Advisor"** means 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, appointed by the Court to provide advice to the Court as needed on medical issues presented in Appeals.
- **46. "Technical Advisor Fee"** means a fee of \$1,500 (or such other amount approved by the Court) for the services of a Technical Advisor relating to an Appeal.
- **47. "Threshold Eligibility Requirements"** mean the requirements described in Section II.H.1 for eligibility to submit a Claim and be processed for eligibility for payment of Incremental Matrix Compensation Benefits.
- **48. "Trust"** means the AHP Settlement Trust established under the Settlement Agreement.
- **49. "Trustee"** means the person currently serving as or having the holdover duties and authority of the Trustee of the Trust, referred to in the Ninth Amendment as the "Ninth Amendment Trustee."

II. OPERATIVE TERMS

A. Continuation of Matrix Compensation Benefits Eligibility and Payment Provisions. This Eleventh Amendment does not modify in any respect the Matrix Compensation Benefits payable to eligible Eleventh Amendment Class Members (and the benefits payable to associated eligible Derivative Claimants) under the terms of Section IV.B of the Settlement Agreement, the Seventh Amendment to the Settlement Agreement, and the Court's previous interpretations and applications of the terms of the Settlement Agreement. All provisions of the Settlement Agreement and previous rulings of the Court affecting eligibility to submit a Claim for Incremental Matrix Compensation Benefits and for payment of such benefits, the amount of such payment, the Matrices and Matrix payment

amounts, qualification on Matrix A-1 or Matrix B-1, the circumstances determining whether Matrix A-1 or Matrix B-1 is applicable to a Claim, the benefits payable to Derivative Claimants, the annual increase in Matrix payment amounts under Section IV.C.1 of the Settlement Agreement, Pfizer's guarantee of Wyeth's financial obligations under the Settlement Agreement, including this Eleventh Amendment, and other terms regarding eligibility and payment of Matrix Compensation Benefits remain in full force and effect.

B. Transfer of Administration of the Diet Drug Settlement Program and Termination of the AHP Settlement Trust.

- 1. Transfer of Administration on the Effective Date: As of the Effective Date of this Eleventh Amendment, all responsibility for the implementation of the Settlement Agreement is transferred from the Trust to the Claim Administrator.
- 2. Effect of Transfer of Administration: At the time of such transfer:

 (a) the Trust and the May 19, 2005 Amended and Restated AHP Settlement Trust Agreement (Ex. A to the Ninth Amendment to the Settlement Agreement) will terminate; (b) references in Section III of the Settlement Agreement to the Trust and its structure, governance, responsibilities, and operations will be deemed to apply to the Claim Administrator, except as modified by this Eleventh Amendment; (c) the Claim Administrator will have all the rights and responsibilities of the Trust and the Trustee under the Settlement Agreement and will exercise the functions that were to be exercised by the Trust under the Settlement Agreement, subject to the terms of this Eleventh Amendment; and (d) the Claim Administrator will succeed to all the rights and responsibilities of the Trust and Trustees under all contracts to which the Trust is a party.
- Actions to Cause the Transfer of Administration: The Trustee will have the authority and obligation to take all steps necessary for the complete and prompt transition of all such contracts to the Claim Administrator to the extent required by any such contract and to assign and transfer to the Claim Administrator all electronic data and information in the possession or control of the Trust, hard copy books and records of the Trust, licenses, servers and hardware, website URL, toll-free number, P.O. Box, and other materials used in the operation of the Trust. After the Effective Date, the Trustee will be considered

to have hold-over authority, if necessary, solely for the purpose of effectuating the transfers and assignments required under this Eleventh Amendment.

C. Nature of the Settlement Fund.

- 1. QSF Status of the Settlement Fund: On the Effective Date, the Settlement Fund of the Trust will continue as a QSF administered by the Claim Administrator, with the Claim Administrator serving as the QSF Administrator. To perform its duties in implementing the Settlement Agreement, the QSF Administrator will have access to and authority over the Settlement Fund at the Fund Depository.
- 2. QSF Compliance: The QSF Administrator will: (a) comply with all requirements applicable to a QSF, including all tax filing, payment and reporting requirements imposed by Treasury Regulations issued under Section 468B of the Internal Revenue Code, any successor provisions, any comparable provisions of state or local tax laws, or otherwise, except to the extent that there has been a final determination, binding on the applicable taxing authority, the QSF Administrator, and Wyeth to the effect that other requirements apply to the QSF Administrator in lieu of the QSF requirements; (b) take any action necessary to create and maintain the status of the Settlement Fund as a QSF; (c) timely file such income tax and other returns and statements as are required to comply with applicable provisions of the Internal Revenue Code and of any state law and the regulations; and (d) timely pay taxes and any other obligations or liabilities which at any time are lawfully levied, assessed upon or become payable in respect of the Settlement Fund or the QSF. The QSF Administrator will not take any action that will adversely affect the qualification of the Settlement Fund as a qualified settlement fund.
- 3. Deposits into the Settlement Fund: No Administrative Reserve or other minimum balance will be required in the Settlement Fund, other than any minimum required by the Fund Depository to maintain an open account. All amounts in the Settlement Fund may be used to pay Incremental Matrix Compensation Benefits, Implementation Costs, and any other obligation and expense of the Settlement Program, including payments made pursuant to any Court-approved program involving the future compromise of any potential rights of Eleventh

Amendment Class Members under the Settlement Agreement. If at any time the amounts in the Settlement Fund are insufficient to pay such obligations, the Claim Administrator will notify Wyeth on a monthly basis of the deposit required to pay such obligations and Wyeth will deposit such required funds into the Settlement Fund within 15 days after such request. Any objection by Wyeth to a requested amount must be resolved with Class Counsel or the matter presented to the Court within that 15-day period.

- 4. Discontinuance of QSF Status: At any time, Wyeth may elect to discontinue the treatment of the Settlement Fund as a QSF and instead have all payments of Incremental Matrix Compensation Benefits, Implementation Costs, and any other obligation and/or expense of the Settlement Fund made directly by Wyeth. Wyeth will notify the Claim Administrator and Class Counsel of such election not less than 30 days prior to it becoming effective. In the event of such an election, the 15-day period of Section II.C.3 will apply to payments to be made directly by Wyeth as requested by the Claim Administrator.
- D. Appointment of and Service by the Claim Administrator.
- 1. Appointment and Term: The effectiveness of this Eleventh Amendment and the Parties' respective obligations under it are conditional upon the appointment of BrownGreer as the Claim Administrator and the withdrawal of as BrownGreer as counsel to Wyeth on or before the Effective Date.
- 2. Contractual Arrangement: The Claim Administrator will serve under the terms of a contract among Class Counsel, Wyeth, and the Claims Administrator, as approved by the Court.
- 3. Claim Administrator Fees and Costs: No later than January 31 of each year, the Claim Administrator will submit to the Parties and the Court a projected annual budget for its fees and costs of administering and implementing the Settlement Agreement for that calendar year. On a monthly basis the Claim Administrator will report to the Parties the fees it has incurred and the costs it has expended in connection with the administration of the Settlement Agreement in the previous month and will be paid monthly from the Settlement Fund based on such reports to the extent that either party does not object to such

payments within five days after receiving the Claim Administrator's monthly report of fees and costs. If not resolved by the Claim Administrator and the Parties, any such objection will be determined by the Court.

- 4. Support Functions of the Claim Administrator: The Claim Administrator will provide the technology, hardware, software applications, communications, processing functions and operations, system and data security, website, online applications, and any staff necessary to perform the duties of the Claim Administrator in implementing the Settlement Agreement. Class Counsel will have complete access to all Claims, reports, and any other information of the Claim Administrator relating to its performance.
- E. Claim Submission. An Eleventh Amendment Class Member must submit a Claim for Incremental Matrix Compensation Benefits no later than four years from the date on which the Eleventh Amendment Class Member was first diagnosed as having the Progression Matrix Level Condition upon which the Claim is based. This provision incorporates into the Settlement Agreement the directive in Court Approved Procedure No. 16 (Payment and Claim Filing Deadlines; approved by PTO No. 8559 and by the Court of Appeals in In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Products Liab. Litig., 763 F. App'x 237 (3d Cir. 2019)). All Claims must be submitted to the Claim Administrator in hard copy or using an online process provided by the Claim Administrator.
- F. Proof of Use and Duration of Use of the Diet Drugs. Section VI.C.2.d of the Settlement Agreement governs the documentary proof of the period of time for which the Diet Drugs were prescribed and dispensed to the Diet Drug Recipient who is the subject of a Claim.
- G. Complete Claim Requirements. Under Sections IV.B.2.c(3) through (5) and VI.C.4a(1) through (8) of the Settlement Agreement and Court-Approved Procedure 4 (Medical Records Relating to Matrix Claims; approved by PTO 2805), a Claim must contain the following to be considered a Complete Claim to be processed for payment eligibility and submitted with a Claim, unless already in the possession of the Trust or Claim Administrator or in any particular instance the Claim Administrator determines that the material is not necessary to determine the proper outcome on the Claim:

- 1. Green Form: Green Form Parts I, II, and, if the Claimant is represented by counsel, Part III, properly completed and signed (or such other form for this purpose adopted by the Claim Administrator, with the approval of Class Counsel).
- 2. Echocardiogram(s): If not previously submitted in a readable form:

 (a) copy of the videotape, disc, or other usable digital format (using DICOM standards and viewable using a DICOM reader, or compatible with other currently available technology) of the Echocardiogram of the Diet Drug Recipient upon whose condition the Claim is based, meeting the Echocardiogram criteria of the Settlement Agreement and supporting the condition which qualifies the Diet Drug Recipient for a particular Matrix Compensation Benefit; and (b) the Gray Form or written report of such Echocardiogram(s). The Claim Administrator may convert videotape recordings into Audio Video Interleave (AVI) multimedia container format or such other format to render them readable under currently available technology.
- 3. Medical Records: The records and documents necessary to support a reasonable degree of medical certainty: (a) that the Diet Drug Recipient has a Progression Matrix Level Condition which qualifies for Incremental Matrix Compensation Benefits; and (b) if the Claim seeks payment on Matrix A, the presence or absence of all the conditions for eligibility on Matrix A rather than Matrix B under Section IV.B.2.d of the Settlement Agreement.
- 4. General Medical Records and Medical History for Claims on Matrix A: If the Claim seeks payment on Matrix A and if the Claim Administrator or the CEP determines they are relevant to the conditions asserted as the basis of the Claim and are needed to evaluate the Claim, (particularly the Reduction Factors that may be applicable to the Claim), General Medical Records regarding the Diet Drug Recipient, including, for the period beginning five years preceding the Diet Drug Recipient's Diet Drug use and continuing through the submission of the Claim, the 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 condition forms the basis of the Claim. If a Claimant seeks payment on Matrix A, the Claimant may elect to (a) submit all the Claimant's General Medical Records (in legible and usable form) to the Claim Administrator; (b) submit a Physician Verification Form and DDR Acknowledgment (substantially in conformance with the form attached to Court Approved Procedure 4 and as provided by the Claim Administrator) regarding the review and reporting of the Diet Drug Recipient's medical history, in lieu of submitted General Medical Records; or (c) agree to be paid Matrix Compensation Benefits on Matrix B in full satisfaction of the Claim being processed.

5. Lien and Attorney Documents: The information on subrogation claims or liens and, if the Claimant is represented by counsel, the documents and information regarding the fee agreement and costs incurred, as required by Section VI.C.4.c of the Settlement Agreement, if applicable to the Claim.

H. Threshold Eligibility Review of Claims.

- 1. Threshold Eligibility Requirements: A Claim will be processed by the Claim Administrator to determine whether the Claimant qualifies for payment of Incremental Matrix Compensation Benefits if it satisfies each of these Threshold Eligibility Requirements:
 - (a) The Claimant is an Eleventh Amendment Class Member eligible to seek and receive Incremental Matrix Compensation Benefits;
 - (b) The Claim was timely submitted to the Claim Administrator or was timely submitted to the Trust before the Effective Date;
 - (c) The Claim states a Progression Matrix Level Condition that would qualify the Claimant for Incremental Matrix Compensation Benefits;
 - (d) The Claimant was diagnosed with the Progression Matrix Level Condition upon which the Claim is based before the Claimant reached the age of 80 years old;

- (e) The Claim is not a duplicate of a previously paid or denied Claim;
- (f) The Claim seeks payment on a Matrix Level that, if eligible, would result in payment of Incremental Matrix Compensation Benefits to the Claimant; and
- (g) The Claim is a Complete Claim.
- 2. Notice of Additional Information or Documents Needed: Within 10 days after submission of any elements of a Claim, the Claim Administrator will review the Claim to assess its completeness and whether the Claim satisfies the Threshold Eligibility Requirements. If the Claim Administrator determines that the Claim does not satisfy the Threshold Eligibility Requirements, it will provide the Claimant with notice of any deficiency and afford the Claimant a reasonable time (no fewer than 30 days) to explain any questions regarding Threshold Eligibility and to submit any missing information or documents required to make the Claim a Complete Claim.
- 3. Outcome of Threshold Eligibility Review: Within 10 days after the completion of the steps in Section II.H.1, the Claim Administrator will determine whether the Claimant and the Claim satisfy the Threshold Eligibility requirements and will move the Claim to Medical Review or notify the Claimant of a denial of a Claim on any Threshold Eligibility ground(s) no later than 15 days after the completion of the steps in Section II.H.2.
- 4. Reconsideration by the Claim Administrator and Final Determination: A notice of denial based on a failure to meet Threshold Eligibility Requirements will afford the Claimant a reasonable time (no fewer than 20 days) to have the Claim Administrator reconsider the denial and to provide any information or documents the Claimant would like the Claim Administrator to consider. If the Claimant does not timely request Reconsideration, the denial will become final. If the Claimant does timely request Reconsideration, within 10 days after the request, the Claim Administrator will re-review the Claim, determine whether the Claimant has satisfied the Threshold Eligibility Requirements for the

Claim and either move the Claim to Medical Review or notify the Claimant of a final denial on Threshold Eligibility Requirements.

5. Appeal: A Claimant receiving a notice of final denial of a Claim on Threshold Eligibility Requirements under Section II.H.4 may file an Appeal of that determination to the Court under Section II.J. No Appeal may be filed unless the Claimant had requested Reconsideration by the Claim Administrator and the Claim Administrator has issued a notice of outcome after Reconsideration.

I. Medical Review of Claims.

- 1. Matrix Eligibility Determination by the Claim Administrator: Within 10 days after a determination that a Claim meets the Threshold Eligibility Requirements, the Claim Administrator may determine without the need for CEP Review whether there is a reasonable medical basis for Green Form Part II answers (or equivalent answers in the Claim Form in use at the time by the Claim Administrator) material to the Claim and whether the Claim is eligible for payment on any Matrix Level that would qualify the Claimant for Incremental Matrix Compensation Benefits, and, if so, the amount of such benefits. If the Claim Administrator makes such a determination, the Claim Administrator will notify the Claimant that the Claim is payable and the amount of Incremental Matrix Compensation Benefits payable on the Claim.
- 2. CEP Review: A Claim not found payable under Section II.I.1 will be presented to the CEP for review within 10 days after a determination that a Claim establishes the Threshold Eligibility Requirements, provided, however, that the Claim Administrator may determine that a Claim is payable pursuant to Section II.I.1 at any time before the CEP takes final action in its review of the medical basis for the Claim. The CEP may require the Eleventh Amendment Class Member to submit additional materials or information if the CEP deems them necessary for the proper assessment of the Claim. Within 20 days after presentation of the Claim to the CEP together with the additional materials or information required by the CEP, if any, the CEP will review the Claim and determine whether there is a reasonable medical basis for Green Form Part II answers (or equivalent answers in the Claim Form in use by the Claim Administrator) material to the Claim

(including answers regarding Reduction Factors) and whether the Claim is eligible for payment on any Matrix Level that would qualify the Claimant for Incremental Matrix Compensation Benefits. Within five days after a determination by the CEP, the Claim Administrator will notify the Claimant of that determination and the amount, if any, of Incremental Matrix Compensation Benefits payable on the Claim.

- **3. CEP Adjudication**: The CEP will attempt to achieve consensus on all its determinations, but where consensus cannot be reached will act by majority vote.
- 4. **Reconsideration by the CEP and Final Determination:** The Claim Administrator will afford the Claimant a reasonable time (no fewer than 20 days) to have the CEP reconsider any determination that is adverse to the Claimant and to provide any information or documents the Claimant would like the CEP to consider. If the Claimant does not timely request Reconsideration, the outcome after CEP Review in Section II.I.2 will become final. If the Claimant does timely request Reconsideration by the CEP, within five days the Claim Administrator will present the Claim to the CEP. Within 20 days after such presentation, the CEP will re-review the Claim to make the determination required by Section II.I.2. Within five days after a determination by the CEP, the Claim Administrator will notify the Claimant of that determination after Reconsideration and the amount, if any, of Incremental Matrix Compensation Benefits payable on the Claim.
- **5. Appeal:** A Claimant receiving a notice after Reconsideration by the CEP may file an Appeal to the Court under Section II.J. No Appeal may be filed unless the Claimant had requested Reconsideration by the CEP and the Claim Administrator has issued a notice of outcome after Reconsideration.
- J. Appeal of Claim Outcomes.
- 1. Time for Appeal: Any Claimant who, after seeking Reconsideration as provided above, receives a notice that the Claim was denied, in whole or in part, for failure to meet Threshold Eligibility Requirements under Section II.H or on Medical Review grounds under Section II.I may, within 60 days after the date of such notice,

file an Appeal to the Court seeking review of the outcome on the Claim by filing with the Court a notice of Appeal and a supporting memorandum of law.

- 2. Record on Appeal: The record before the Court on an Appeal will be limited to the record before the Claim Administrator (and the CEP, as applicable) at the time of the outcome subject to the Appeal, unless the Court directs the submission of additional information or materials. If requested by the Court: (1) the Claim Administrator may provide information regarding the processing of the Claim and the outcome being reviewed; (2) Class Counsel and Wyeth each may file a response to the Appeal; and (3) a Technical Advisor may assist the Court on any medical issues presented by the Appeal.
- 3. **Technical Advisor Fee:** If requested by the Court, the Technical Advisor will review the Appeal record and prepare a Technical Advisor Report to the Court setting forth the Technical Advisor's opinions regarding the medical issue(s) in dispute. If the Court requires review by a Technical Advisor, the Appeal will not proceed until the Claimant advances to the Claim Administrator the Technical Advisor Fee and the Appeal will be dismissed if such Technical Advisor Fee is not timely paid. An Eleventh Amendment Class Member may request that the Court waive the Technical Advisor Fee due to true financial hardship. Any such request must include relevant financial documentation supporting the existence of a true financial hardship. If the Court concludes that payment of the Technical Advisor's costs creates a true financial hardship for an Eleventh Amendment Class Member in an Appeal, the Settlement Fund will pay the Technical Advisor Fee for that Appeal.
- 4. Standard of Review on Appeal: The Claimant will have the burden of proving on Appeal that any material factual or medical determination on the Claim by the Claim Administrator or the CEP was clearly erroneous. The Court will review *do novo* any questions of law, including those regarding the interpretation of language in the Settlement Agreement.
- 5. Claim Found Payable on Appeal: If the Court (or the Court of Appeals for the Third Circuit) rules on an Appeal that the Claim is payable in an amount greater than found by the Claim Administrator

on the Claim (other than because of the annual 2% increase in the Matrix Grid Amounts under the Settlement Agreement) the Claim Administrator will, within 15 days after the Court's determination, pay the Eleventh Amendment Class Member Incremental Matrix Benefits in accordance with the Court's determination and the amount of any Technical Advisor Fee paid by the Claimant in connection with the Appeal.

K. Derivative Claimants.

- 1. Notice of Outcome: A notice from the Claim Administrator to a Claimant regarding payable Incremental Matrix Compensation Benefits will include information on any benefits payable to Derivative Claimants of the Claimant under Sections IV.B.1.c and IV.B.2 of the Settlement Agreement, if applicable, as determined by the Claim Administrator.
- 2. **Reconsideration:** Such notice will afford the Derivative Claimant(s) a reasonable time (no fewer than 20 days) to have the Claim Administrator reconsider the Derivative Claimant determinations and to provide any information or documents the Claimant would like the Claim Administrator to consider. If a Derivative Claimant does not request Reconsideration, the Claim Administrator's determination of the Derivative Claimant's entitlement to benefits as stated in the Claim Administrator's notice will become final. If the Derivative Claimant does timely request Reconsideration, within 10 days after the request, the Claim Administrator will re-review the Claim, determine the appropriate result under the terms of the Settlement Agreement, and notify the Derivative Claimant of that determination.
- Appeal: A Derivative Claimant who continues to object to the Claim Administrator's benefit determination as to that Derivative Claimant after seeking Reconsideration may file an Appeal to the Court under Section II.J. No Appeal may be filed unless the Derivative Claimant had requested Reconsideration by the Claim Administrator and the Claim Administrator has issued a notice of outcome after Reconsideration. The provisions of Section II.J on the Appeal process will apply as relevant to any Appeal by a Derivative Claimant.

L. Processing of Healthcare Liens. The Claim Administrator will conduct an MMSEA Query as to the Diet Drug Recipient subject to a Claim found eligible for payment of Incremental Matrix Compensation Benefits. When the MMSEA Query results in a report that the Diet Drug Recipient at issue is Medicare Entitled, then the Claim Administrator will coordinate with the Eleventh Amendment Class Member to resolve any Medicare Claim concerning the Incremental Matrix Compensation Benefits payment and may employ outside consultants to assist in that resolution process. The Claim Administrator will recognize and process legitimate Healthcare Liens on the Incremental Matrix Compensation Benefits payment amount in accordance with applicable law. No Healthcare Lien will be recognized in favor of any insurer or third-party payor that previously has waived or released all such claims relating to Diet Drug Recipients.

M. Liens and Other Matters Affecting the Payment of Benefits.

- 1. Notice of Outcome: A notice from the Claim Administrator to a Claimant regarding payable Incremental Matrix Compensation Benefits will include information on the amounts necessary to satisfy any Healthcare Lien, Non-Healthcare Lien, any Derivative Claimant's entitlement, and (after the Claimant has submitted the information and materials necessary to make the determination) any fees or costs allocated to the Eleventh Amendment Class Member's individual counsel out of the Incremental Matrix Compensation Benefits payment. Such notice also will be provided to any Lien claimant (other than as to Medicare Claims or any other federal or state agency with a Healthcare Lien resolved by the Claim Administrator with that agency) or counsel affected by the notice.
- 2. Reconsideration: Such notice will allow the Eleventh Amendment Class Member and others subject to the determinations in the notice a reasonable time (no fewer than 20 days) to have the Claim Administrator reconsider the determinations and to provide any information or documents for the Claim Administrator to consider. The outcome in the notice will become final as to any determination not subject to a timely request for Reconsideration. If there is a timely request for Reconsideration, within 10 days after the request, the Claim Administrator will re-review the issue, determine the appropriate result under the terms of the Settlement Agreement and applicable law, and notify the requesting party of that determination.

- **3. Appeal:** A party objecting to that determination may file an Appeal under Section II.J. No Appeal may be filed unless the party had requested Reconsideration by the Claim Administrator and the Claim Administrator has issued a notice of outcome after Reconsideration. The provisions of Section II.J on the Appeal process will apply as relevant to any Appeal under this Section II.M.3.
- N. Arbitration and Show Cause Provisions. The provisions of Section VI.C.4 of the Settlement Agreement regarding arbitration and those of Section VI.E of the Settlement Agreement regarding show cause proceedings are removed from the Settlement Agreement as no longer necessary, in light of the terms of this Eleventh Amendment, to secure the fair and accurate administration of the Settlement Agreement for the benefit of Eleventh Amendment Class Members.
- O. Enhancements to the Administration of the Settlement Agreement. The Claim Administrator may alter any of the functions, procedures, systems, processes, operations, notices and other communications, and forms or other materials previously used by the Trust as necessary to facilitate the prompt and effective implementation of the Settlement Agreement in the best interests of the Eleventh Amendment Class Members, provided that no such changes or procedures may impair the substantive rights of any Eleventh Amendment Class Members to Incremental Matrix Compensation Benefits.

P. Class Counsel Fees and Costs.

Right to Class Counsel Fees and Costs: Class Counsel will have the 1. right to receive reimbursement of all costs reasonably incurred by them and reasonable attorneys' fees not to exceed the hourly value of the professional time expended for the following professional activities: (a) the development, negotiation, presentation, implementation and administration of this Eleventh Amendment (including discussions and analysis of changes to the administration of the Settlement Agreement that led to this Eleventh Amendment); (b) responding to requests directed to them by the Claim Administrator as set forth in Section II.S.3 of this Eleventh Amendment; and (c) providing assistance to unrepresented Class Members as set forth in Section II.S.3 of this Eleventh Amendment. Such fees and cost reimbursements shall be determined and awarded by the Court and,

- upon such Court determination and award shall be paid by the Settlement Fund as further provided herein.
- 2. Motion for Court Approval. Applications for an award of attorneys' fees and cost reimbursements may be submitted to the Court on a quarterly schedule (or on such other schedule as agreed upon by the Parties or directed by the Court). The first such motion will include any time incurred by Class Counsel for which compensation is requested in the development and Court approval of this Eleventh Amendment (including discussions and analysis of changes to the administration of the Settlement Agreement that led to this Eleventh Amendment). The fee adjudication procedures established in PTO 16, PTO 1164, paragraph 3 of PTO 5400 and paragraph 7 of PTO 7763A will not apply to the preparation and presentation of such fee petitions.
- 3. Pre-Filing Meet and Confer: No later than 20 days before filing a motion under Section II.P.2, Class Counsel will provide Wyeth a copy of the motion and its supporting materials. The Parties will meet and confer to review the request and any objections by Wyeth. If the Parties are unable to resolve any such objections, Wyeth may respond to the motion and present its position to the Court for resolution.
- 4. Payment by the Settlement Fund: Amounts awarded by the Court as Class Counsel Fees and Costs will be paid by the Settlement Fund not later than 30 days after the date of the Court's award of such fees and costs.
- Q. The Maximum Available Settlement Fund Amount. The Maximum Available Fund B Amount (which, after the Fifth Amendment and the merger of Fund A and Fund B into one Settlement Fund, is the result of the Adjusted Maximum Fund B Amount under Section I.1 of the Settlement Agreement) is renamed the Maximum Available Settlement Fund Amount (or "MASFA"). Each deposit by Wyeth into the Settlement Fund (or payment directly by Wyeth if the QSF has been discontinued) under Section II.C.3 or Section II.C.4 will reduce MASFA as of the time it is made or paid. The Claim Administrator will maintain an accurate accounting of the MAFSA.
- R. Clarification of Applicable Requirements and Procedures. The Settlement Agreement, including this Eleventh Amendment, sets forth the terms and requirements for payment of Incremental Matrix Compensation Benefits and

the essential procedures for the implementation of the Settlement Agreement. The Parties agree that the agreed and other processing procedures, as well as the Court Approved Procedures, identified in the attached Exhibit 1 are moot or no longer necessary and jointly will request the Court to vacate any orders approving them.

S. Miscellaneous Terms.

- 1. Financial Records of the Claim Administrator: The Claim Administrator will maintain complete and current records of the assets and expenses of the Settlement Fund. The Claim Administrator is not required to perform an annual external audit of its financial statements or to issue an external audit report.
- 2. Report to the Court and the Parties: No less frequently than every six months, the Claim Administrator will provide a report to the Court and the Parties on the implementation of the Settlement Agreement, including information on the following during the reporting period and cumulatively as of the date of the report (unless otherwise specified below):
 - (a) Implementation Costs, showing the amount of CEP Fees and Costs, Class Counsel Fees and Costs, Claim Administrator Fees and Costs, tax payments, and other payments for obligations of the Settlement Program other than as to Claims payments;
 - (b) Claims submitted, by Claimant age and Matrix Level asserted;
 - (c) Claims denied at any stage in the process, by Claimant age and Matrix Level asserted;
 - (d) Claims paid Incremental Matrix Compensation Benefits, by Claimant age and Matrix Level;
 - (e) Payments to Derivative Claimants;
 - (f) Payments made on Liens of any kind;
 - (g) The number and age distribution of Eleventh Amendment Class Members remaining eligible to seek Incremental Matrix Compensation Benefits as of the date of the report; and

- (h) The MASFA as of the date of the report.
- **3**. Assistance to **Unrepresented Eleventh Amendment Class** Members and to the Claim Administrator: Class Counsel may assist unrepresented Eleventh Amendment Class Members as requested on any matter concerning their rights under the Settlement Agreement and the submission, completion and adjudication of any Claim for Incremental Matrix Compensation Benefits, including any Appeal by an unrepresented Eleventh Amendment Class Member. In addition, at any time the Claim Administrator may request input from Class Counsel on an issue of Settlement Agreement interpretation or application, or any issue affecting the administration of the Settlement Agreement. Class Counsel may request and the Court may award compensation as Class Counsel Fees and Costs for time reasonably incurred for assisting unrepresented Class Members and assisting the Claim Administrator in this manner, in accordance with Section II.P.2.
- 4. Contact Information for Eleventh Amendment Class Members:
 Each Eleventh Amendment Class Member must keep the Claim
 Administrator apprised of current information on the Eleventh
 Amendment Class Member's name and contact information, including
 counsel information.
- 5. Notices on Claim Outcomes: Notices of outcome issued by the Claim Administrator to an Eleventh Amendment Class Member who currently is represented by individual counsel will be sent to that counsel and not directly to the Eleventh Amendment Class Member. Notices issued by the Claim Administrator to an Eleventh Amendment Class Member who is not represented by individual counsel will be sent directly to the Eleventh Amendment Class Member.

III. APPROVAL AND OTHER TERMS

- A. Joint Application for District Court Approval.
- 1. Joint Motion for Approval: Within five days after the full execution of this Eleventh Amendment, the Parties will move jointly for the

Court to enter orders: (a) granting Preliminary Approval of the Eleventh Amendment and (b) granting District Court Approval of the Eleventh Amendment. The Motions will be filed electronically and served upon all persons who have registered for electronic filing or who are otherwise entitled to receive copies of electronically filed documents in MDL 1203 and Civil Action No. 99-20593. *See In re Diet Drugs*, 93 Fed.Appx. 338, 344 (3rd Cir. Feb. 23, 2004). *See also* Memorandum in Support of PTO No. 8506 July 2, 2010) (approval of 10th Amendment) at 13, citing *In re: The Prudential Ins. Co. of America Sales Practices Litig.*, 962 F. Supp. 450, n.10 (D.N.J. 1997), aff'd 148 F.3d 283 (3rd Cir. 1998). The Trust will post a copy of the Motion for Approval and supporting materials on its website. The Parties also may post them to a website created by the Claim Administrator for such purpose.

- **2. Preliminary Approval Order:** The Motion for Preliminary Approval will include a request to the Court to enter an order substantially in the form attached as Exhibit 2:
 - (a) Granting Preliminary Approval of the Eleventh Amendment;
 - (b) Directing that the Eleventh Amendment Class Members are not required to file any response to the Motion for Approval but establishing a period of no more than 30 days from the date of the order for any Eleventh Amendment Class Member who wishes to do so; and
 - (c) Approving a postcard notice (substantially in the form attached as Exhibit 3) and directing the Parties to mail such notice to the Eleventh Amendment Class Members and their counsel at the last known address available for them in the Trust's database, as updated through national database research.
- **3. District Court Approval Order:** The Motion for Approval will include a request to the Court to enter an order substantially in the form attached as Exhibit 4:
 - (a) Granting District Court Approval of the Eleventh Amendment in its entirety under the standard which would be applicable under Fed.R.Civ.P. 23(e) as fair, reasonable, adequate, and non-

- collusive, and requiring compliance with the terms of the Eleventh Amendment;
- (b) Appointing BrownGreer as the Claim Administrator;
- (c) Vacating PTO No. 1823 and considering the amount in the PTO No. 1823 Reserve as funds available in the Settlement Fund;
- (d) Vacating the Orders relating to Court Approved Procedures identified in Section A of the attached Exhibit 1.
- **B.** Conditions to Effectiveness of the Eleventh Amendment. The effectiveness of the Eleventh Amendment and the Parties' respective obligations under it are subject to: (1) entry of the Preliminary Approval Order; (2) entry of the District Court Approval Order; and (3) the absence of a stay pending appeal from any District Court Approval Order within 31 days from the date of that order or the entry of an order vacating such a stay if it is entered.
- C. *Effective Date*. The provisions of this Eleventh Amendment regarding implementation of the Settlement Agreement will become effective and applicable as of the Effective Date.
- **D.** Retained Jurisdiction. The Court retains original and exclusive jurisdiction over the interpretation and enforcement of this Eleventh Amendment incident to its exclusive, retained jurisdiction under Section VIII.B.1 of the Settlement Agreement and Paragraph 11 of PTO No. 1415 entered by the Court on August 28, 2000.
- E. Survival of Settlement Agreement Terms. Except as expressly modified in this Eleventh Amendment and as necessary to permit the complete implementation of this Eleventh Amendment, all terms and provisions of the Settlement Agreement remain in full force and effect.
- **F.** *Headings.* The headings of the Sections of this Eleventh Amendment are included for convenience only and will not be deemed to constitute part of this Amendment or affect its construction.
- **G.** *Counterparts.* This Eleventh Amendment may be executed in counterparts by facsimile signature. Each counterpart will be effective as part of a fully executed original Eleventh Amendment.

IN WITNESS WHEREOF, the Parties have duly executed this Eleventh Amendment to the Settlement Agreement by their respective counsel, as set forth below, as of the Effective Date.

*****SIGNATURES APPEAR ON FOLLOWING PAGE****

WYETH LLC

By: Veffrey N. Myers	
Position: Vice President	
Date: June 13, 2023	
CLASS COUNSEL By:	By:
Arnold Levin, Esquire Laurence S. Berman, Esquire LEVIN, SEDRAN & BERMAN 510 Walnut Street, Suite 500 Philadelphia, PA 19106	Michael D. Fishbein, Esquire 1706 Rittenhouse Sq. No. 1201 Philadelphia, PA 19103
Date:	Date:

WYETH LLC

By:	_
Position: Vice President	
Date:	

CLASS COUNSEL

By: A nold Levin, Esquire

Laurence S. Berman, Esquire LEVIN, SEDRAN & BERMAN 510 Walnut Street, Suite 500 Philadelphia, PA 19106

By: 9

Michael D. Fishbein, Esquire 1706 Rittenhouse Sq. No. 1201

Philadelphia, PA 19103

Date: June 13, 2023

EXHIBIT 1

Previous Court Approved and Other Procedures

PREVIOUS COURT APPROVED AND OTHER PROCEDURES

A. Previous Court Approved Procedures:

- CAP 1 (PTO No. 1718) Establishing Procedures to Resolve Non-Federal Subrogation Claims
- CAP 2 (No PTO number) -- Governs Claims of or on Behalf of Minors, Incapacitated Persons and Deceased Persons
- CAP 3 (No PTO number) Authorizing Steps to be Taken by AHP Settlement Trust and Class Counsel Regarding Assistance to Pro Se Claimants
- 4. CAP 4 (PTO No. 2805) Medical Records Relating to Matrix Claims
- 5. CAP 5 (PTO No. 2806) Credentials of Auditing Cardiologists
- 6. CAP 6 (No PTO number) Reimbursement for Additional Medical Services
- 7. CAP 7 (No PTO number) Pro Se Claimants Completeness Assistance Program
- 8. CAP 8 (No PTO number) Reporting Requirements of the AHP Settlement Trust
- 9. CAP 9 (PTO No. 5983) Procedure for the Audit of Fund A Claims
- CAP 10 (PTO No. 6085) -- Processing of Claims as to Certain Medicare Eligible Claimants
- 11. CAP 11 (PTO No. 6100) Audit of Matrix Claims
- 12. CAP 12 (PTO 6100) Re-Audit of Certain Claims for Matrix Compensation Benefits
- 13. CAP 13 (PTO No. 6707) Procedure for the Disposition of Pre-Stay Payable PADs and PADLs
- 14. CAP 14 (PTO No. 6999) Procedure for the Audit of Category Two Claims with Conflicting Diagnoses
- CAP 15 (PTO No.) 7688 Procedure for the Resolution of Certain Matrix Claims In Show Cause
- 16. CAP 16 (PTO No. 8559) Payment and Claim Filing Deadline
- 17. CAP 17 (PTO No. 9103) Processing of Medicare Claims

B. Previous Agreed Processing Procedures:

- 1. APP 01-001 Determination of Drug Use and Duration for Certain Fund A Benefits
- 2. APP 01-002 GRAY Form Requirement for Cash/Med Benefits on PINK Form AIO Claims
- 3. APP 01-003 Transesophogeal Echocardiograms and Successive Echocardiograms
- 4. APP 01-004 Relevance of Question 12 in PINK or BLUE Form for Certain Fund A Benefits:
- 5. APP 01-005 Inventory of ORANGE Form #2 and ORANGE Form #3 Forms and the Processing of BLUE Forms by Persons Who Have Also Submitted ORANGE Form #2 or #3
- 6. APP 01-006 Standards for Equating Numeric Indicators with Regurgitation Levels for Fund A AIO Benefits
- 7. APP 01-007 Standards for Interpreting Ambiguous Echo Reports for Fund A AIO Benefits

C. Other Previous Claims Processing Procedures:

- 1. Duration of Use (8/16/2000)
- 2. Subrogation (8/16/2000)
- 3. Record Retrieval Process (8/16/2000)
- 4. Foreign Claimants (8/16/2000)
- 5. Board-Eligible and Board-Certified Physicians (8/16/2000)
- 6. Policy for Processing Multiple Claim Form Submissions (11/9/2000)
- 7. Policy on Quantification of Claims for Purposes of Determining the Number and Extent of Audits of Claims to be Performed (11/16/2000)
- 8. Standards for Providing Echocardiograms for True Financial Hardship or Compassionate and Humanitarian Reasons (11/16/2000)
- 9. Policy on Access to Claims Information by American Home Products Corporation for Audit Purposes (11/16/2000)

- 10. Subrogation Issues and Subrogation Information Form (12/4/2000)
- 11. Filing Appeals of Decisions by the ICA/Trust Regarding Invalid Opt-Outs (12/7/2000)
- 12. PMC Access to Claims Information (1/12/2001)
- 13. Qualifications of Reviewing Cardiologists (1/12/2001)
- 14. AHP Settlement Trust Attorney Fee Policy (1/23/2001)
- 15. Parallel Processing of AIO Claims (5/25/2001)
- 16. Interim Procedures Regarding Intermediate and Back-End Opt-Outs before Final Judicial Approval (5/25/2001)
- 17. Parallel Processing of AIO Claims (Version 2) (7/3/2001)
- 18. Revised Claims Processing Guidelines (5/8/2001)
- 19. Changes to Proof Requirements for AIO Claims (7/3/2001)
- 20. Green Form Questions Requiring Review of Medical Records for Consistency (6/28/2001)
- 21. Agreed Funding Procedure No. 02-01 (3/31/2002)
- 22. Agreed Funding Procedure No. 02-02 (3/31/2002)
- 23. Agreement Regarding Quarterly Funding (11/6/2002)
- 24. Agreed Funding Procedure No. 02-03 (6/6/2005)
- 25. Memorandum of Understanding Regarding the Seventh Amendment (11/15/2004)
- 26. Joint Response to PTO 8549—Policy on Missing Echo Tapes (11/4/2010)

EXHIBIT 2

Order-Preliminary Approval

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

In Re: Diet Drugs (Phentermine/Fenfluramine/ Dexfenfluramine) Products Liability Litigation	MDL NO. 1203
This Document Relates To: Sheila Brown, et. al. v. American Home Products Corporation	CIVIL ACTION No. 99-20593

PRETRIAL	ORDER NO.			

(Preliminary Approval of the Eleventh Amendment and Notice to Affected Class Members)

AND NOW, this ____ day of _______, 2023, upon consideration of the Joint Motion to Approve the Eleventh Amendment to the Settlement Agreement and finding that the terms of the proposed Eleventh Amendment appear to fall within the range of possible approval, permitting a preliminarily determination of fairness, reasonableness, and adequacy of the terms, it is hereby ORDERED that the request for preliminary approval in the Joint Motion is GRANTED. Accordingly, it is further ORDERED as follows:

- 1. *Preliminary Approval*. The Eleventh Amendment is preliminarily approved.
- 2. Approval of Mailed Notice to Eleventh Amendment Class Members.

 The postcard notice proposed by the Parties and in the form attached to this Order, is

approved. Not later than ten (10) days from the date of this order, the Parties will cause such notice to be mailed to the Eleventh Amendment Class Members as defined by the Eleventh Amendment, at the last known address available for them in the database of the AHP Settlement Trust, as refreshed by a query to a national address database. Where the database of the AHP Settlement Trust indicates that an Eleventh Amendment Class Member is represented by one or more counsel, the notice also will be mailed to the last known attorney listed in the database. Where an attorney represents more than one Eleventh Amendment Class Member, it will be sufficient to provide that attorney with a single copy of the notice. The cost of the notice will be paid by the Settlement Fund.

- 3. Responses to the Motion for Approval. Eleventh Amendment Class Members are not required to file any response to the Joint Motion for Approval. However, if any Eleventh Amendment Class Member chooses to do so, any response to the Joint Motion must be filed with the Clerk of this Court no later than thirty (30) days from the date of this Order. A response not timely filed will not be considered.
- **4.** *Posting of this Order.* The Parties are to cause a copy of this Order to be posted on the official website of the AHP Settlement Trust and the website established by the Eleventh Amendment Claim Administrator.

5. Retained Exclusive Jurisdiction. Without affecting the finality of this Order in any way, the Court retains original and exclusive jurisdiction over the interpretation, implementation, and enforcement of this Order and the Protocol, incident to its retained jurisdiction under Section VIII.B.1 of the Settlement Agreement and Paragraph 11 of PTO No. 1415 entered by the Court on August 28, 2000.

BY THE COURT:
Harvey Bartle III. J.

Diet Drugs Settlement P O Box 85006 Richmond, VA 23285

FIRST-CLASS MAIL U.S. POSTAGE PAID PERMIT NO

NOTICE REGARDING THE PONDIMIN® AND

REDUX™ CLASS <u>ACTION</u> SETTLEMENT

Your Notice ID: 123456789



John D. Sample, Jr. 123 Main Street Apt. #6 New York, NY 12345-6789

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

In Re: Diet Drugs (Phentermine/Fenfluramine/ Dexfenfluramine) Products Liability Litigation (MDL No. 1203)

This Document Relates To: Sheila Brown, et. al. v. American Home Products Corporation (Civil Action No. 99-20593)

This Notice is given pursuant to an order issued by the United States District Court for the Eastern District of Pennsylvania (the "Court").

On _______, 2023, Class Counsel and Wyeth filed a joint Motion asking the Court to approve an Eleventh Amendment to the Nationwide Class Action Settlement of the litigation relating to the diet drugs Pondimin® and Redux™. The Memorandum in Support of the Motion explains that the Parties agreed to this Eleventh Amendment and seek its approval by the Court to streamline, expedite, and modernize the processing of any claims submitted for incremental Matrix Compensation Benefits and make the administration structure more in line with the low

level of claim activity over the past several years. The Eleventh Amendment, if approved, will replace the AHP Settlement Trust and its Trustee with BrownGreer PLC as Claim Administrator to process all Claims for incremental Matrix compensation under the Settlement, subject to the supervision of and right of a Class Member to appeal to the Court. The proposed Eleventh Amendment does not change the compensation rights of any Class Member under the terms of the Nationwide Class Action Settlement Agreement.

You may read the Motion, Memorandum in Support, and the Eleventh Amendment and its Exhibits by going to the AHP Settlement Trust website at settlementdietdrugs.com or the website at www.dietdrugsettlementprogram.com. You may also request a copy by writing to Diet Drug Settlement Program, P.O. Box 85006, Richmond, VA 23285.

BY ORDER OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Ex. 2-4

EXHIBIT 3

Postcard Notice

Diet Drugs Settlement P O Box 85006 Richmond, VA 23285

FIRST-CLASS MAIL U.S. POSTAGE PAID PERMIT NO

NOTICE REGARDING THE PONDIMIN® AND

REDUX™ CLASS <u>ACTION</u> SETTLEMENT

Your Notice ID: 123456789



John D. Sample, Jr. 123 Main Street Apt. #6 New York, NY 12345-6789

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

In Re: Diet Drugs (Phentermine/Fenfluramine/ Dexfenfluramine) Products Liability Litigation (MDL No. 1203)

This Document Relates To: Sheila Brown, et. al. v. American Home Products Corporation (Civil Action No. 99-20593)

This Notice is given pursuant to an order issued by the United States District Court for the Eastern District of Pennsylvania (the "Court").

On _______, 2023, Class Counsel and Wyeth filed a joint Motion asking the Court to approve an Eleventh Amendment to the Nationwide Class Action Settlement of the litigation relating to the diet drugs Pondimin® and Redux™. The Memorandum in Support of the Motion explains that the Parties agreed to this Eleventh Amendment and seek its approval by the Court to streamline, expedite, and modernize the processing of any claims submitted for incremental Matrix Compensation Benefits and make the administration structure more in line with the low

level of claim activity over the past several years. The Eleventh Amendment, if approved, will replace the AHP Settlement Trust and its Trustee with BrownGreer PLC as Claim Administrator to process all Claims for incremental Matrix compensation under the Settlement, subject to the supervision of and right of a Class Member to appeal to the Court. The proposed Eleventh Amendment does not change the compensation rights of any Class Member under the terms of the Nationwide Class Action Settlement Agreement.

You may read the Motion, Memorandum in Support, and the Eleventh Amendment and its Exhibits by going to the AHP Settlement Trust website at settlementdietdrugs.com or the website at www.dietdrugsettlementprogram.com. You may also request a copy by writing to Diet Drug Settlement Program, P.O. Box 85006, Richmond, VA 23285.

BY ORDER OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Ex. 3-1

EXHIBIT 4

Order-District Court Approval

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

In Re: Diet Drugs (Phentermine/Fenfluramine/ Dexfenfluramine) Products Liability Litigation	MDL NO. 1203
This Document Relates To: Sheila Brown, et. al. v. American Home Products Corporation	CIVIL ACTION No. 99-20593

(District Court Approval of the Eleventh Amendment to the Settlement Agreement)

AND NOW, this ____ day of _______, 2023, upon consideration of the Joint Motion to Approve Eleventh Amendment to the Settlement Agreement, it is hereby ORDERED that the Joint Motion is GRANTED. Accordingly, it is further ORDERED:

- 1. Approval of the Eleventh Amendment. The Eleventh Amendment is approved in its entirety. The Court finds that the notice provided the Class regarding the Amendment and all proceedings relating to its development and approval comply with the requirements of due process, Fed.R.Civ.P. 23, and applicable law.
- 2. Appointment of the Claim Administrator. Pursuant to the agreement and nomination by the Parties and for good cause shown, BrownGreer PLC is

appointed the Claim Administrator of the Settlement Agreement pursuant to the joint nomination of the Parties. Wyeth has informed Class Counsel and the Court that BrownGreer will withdraw as counsel for Wyeth prior to assuming the duties as Claim Administrator. Its appointment as Claim Administrator will become effective upon the filing of papers on the docket that accomplishes the withdrawal as a matter of record in the case.

- 3. Implementation of the Eleventh Amendment. Class Counsel, Wyeth, the Claim Administrator, and the AHP Settlement Trust are authorized and directed to proceed with the implementation of the Eleventh Amendment in accordance with its terms.
- 4. Termination of Trust. The AHP Settlement Trust is terminated and its Trustee discharged from any further duties under the Settlement Agreement and the Amended and Restated AHP Settlement Trust Agreement (entered into as of May 19, 2005), except as specified in this Order. The former Trustee, Martin Rudolph, is granted qualified judicial immunity and is forever discharged and released from any and all liabilities which may have arisen in connection with his service as Trustee, including activities undertaken in anticipation of appointment as a Trustee for purposes of carrying out the duties of the Trustee, and this Order precludes, at any time hereafter, any action, suit, or demand on the part of any person against him in connection with his service as Trustee. The provisions of

Section 4.09 (Indemnification) of the Amended and Restated AHP Settlement Trust Agreement governing his service as Trustee remain in full force and effect.

- 5. Vacating of PTO No. 1823. PTO No. 1823 is vacated as moot and no longer necessary. Any funds remaining in the PTO No. 1823 Reserve will be considered part of the Settlement Fund and available to pay claims and costs of administration of the Settlement Agreement.
- 6. Vacating of Previous Court Approved Procedures and Orders.

 Court Approved Procedures 1 through 16 and the Orders approving them (Pretrial Order Nos. ("PTO") 1718, 2805, 2806, 5983, 6085, 6100, 6707, 6999, 7688, 8559, and 9103), and PTO 16, PTO 1164, paragraph 3 of PTO 5400, and paragraph 7 of PTO 7763A are vacated as no longer applicable or as superseded by the terms of the Eleventh Amendment.
- 7. **Posting of this Order.** The Parties are to cause a copy of this Order to be posted on the official website of the AHP Settlement Trust and on the website established by the Claim Administrator, www.dietdrugsettlementprogram.com.
- 8. Retained Exclusive Jurisdiction. Without affecting the finality of this Order in any way, the Court retains original and exclusive jurisdiction over the interpretation, implementation, and enforcement of this Order incident to its retained jurisdiction under Section VIII.B.1 of the Settlement Agreement and Paragraph 11 of PTO No. 1415 entered by the Court on August 28, 2000.

BY THE COURT:
Harvey Bartle III, J.
Traivey Dartie III, J.