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

IN RE: DIET DRUGS (Phentermine/ : MDL Docket No. 1203
Fenfluramine/Dexfenfluramine) :
PRODUCTS LIABILITY LITIGATION :

THIS DOCUMENT RELATES TO: :
SHEILA BROWN, SHARON GADDIE, : CIVIL ACTION NO. 99-20593
VIVIAN NAUGLE, QUINTIN LAYER, :
and JOBY JACKSON-REID, :
individually and all others similarly situated, :
Plaintiffs, :
v. :
AMERICAN HOME PRODUCTS :
CORPORATION, :
Defendant. :

PRELIMINARY STATEMENT

Faced with the knowledge that this Settlement was inadequately funded from its inception, Wyeth -- along with its allies -- have engaged in a meritless course of slanderous allegations aimed at discrediting the plaintiffs' bar in general and certain plaintiffs' firms in particular, with unsupported allegations of fraud and conspiracy. Wyeth and its allies have sought to convince the Court that Wyeth and the AHP Settlement Trust are faced with a massive conspiracy involving hundreds of lawyers *and physicians* around the country intent on defrauding the Trust and Wyeth of billions of dollars. In so doing, they have irreparably damaged the good names, reputations and, in many cases, the businesses of the physicians and attorneys and even the class members who have been the targets of this smear campaign. See, e.g., Answer and Counter-claims filed by Linda Crouse, M.D. in the Trust's law suit against her, annexed to the Affidavit of Denise A. Rubin dated March 11, 2004 ["Rubin Aff."] at Exhibit "A".

The within is respectfully offered in opposition to two motions filed by defendant Wyeth, the first, seeking a stay in the payment of non-priority Matrix claims, and the second, seeking

implementation of a new Court Approved Procedure (“CAP”) that is ostensibly aimed at further winnowing out so-called illegitimate claims. As will be shown in these papers and in those previously filed by our colleagues in opposition to Wyeth’s motion, the motion is baseless, the allegations are baseless as they have been throughout, and this Court should deny both of the pending motions and do all in its power to move these claims through the process, rather than aid Wyeth in creating a further bottleneck.

COUNTER-STATEMENT OF THE CASE

With no evidence of fraud, the sole support for the repeated allegations of wrongdoing against the class members, their counsel and their physicians has been and remains the disparate number of claims that have been filed under the NATIONAL CLASS ACTION SETTLEMENT AGREEMENT WITH AMERICAN HOME PRODUCTS, INC. (the “Settlement Agreement”), as contrasted with the projections of anticipated claims submitted to this Court at the time of the fairness hearing.

Despite a dearth of evidence to support Wyeth’s contention that the current 100% audit program is unable to eliminate “medically unreasonable” claims, Wyeth proposes a series of drastic steps that will fundamentally change the terms of the contract for which the class members bargained. Wyeth asks this Court to add additional steps and wholly new requirements to support the claimants’ submissions *before they will even be submitted to audit*, much less deemed sufficiently “legitimate” as to be paid. It is difficult to imagine the claim that will be sufficiently unassailable in Wyeth’s estimation as to pass muster.

The genesis of the huge divergence between the projected claims and the actual claims is an essential point, and it is imperative that this Court fully appreciate how, and to what extent, the actual projections proposed by Class Counsel’s expert, Dr. Stephen Goodman, were artificially altered – and significantly reduced -- before submission to this Court. Notably, we do not challenge the epidemiology that formed the basis for this Settlement. In fact, when comparing the projections of Class Counsel’s epidemiology expert with those of our own, the

numbers are substantially the same. However, we can demonstrate that there were significant omissions and errors in the final projections supplied to the Court at the time of the fairness hearing, and that these omissions and exclusions raise serious questions regarding the legitimacy of the Settlement itself.

Although this Settlement was intended to compensate people who had FDA-positive levels of mitral regurgitation, Class Counsel's final projections *removed all FDA-positive mitral regurgitation class members* who used the drugs for more than 60 days from consideration, with no explanation. This was done despite the fact that Class Counsel's epidemiology expert Dr. Goodman projected that there were approximately 210,000 class members who were FDA-positive for mitral regurgitation at the time of the fairness hearing.

Hence, it should come as no surprise that there are many more claims for Level II benefits based on mitral regurgitation than accounted for in the fairness hearings because those class members had been systematically eliminated from the projections.

The parties have been aware of these serious problems from the beginning. Rather than address them directly, however, they have chosen instead to victimize the class members who were the intended beneficiaries of the settlement agreement, their attorneys and their physicians. The accusations of fraud and deceit and the vociferous allegations of collusion and misconduct are Wyeth's, the Trust's and their allies' effort to deflect attention from the fact that their claims projections had no basis in fact or science and that their subsequent administration of this settlement has been abysmal.

While, as noted above, we do not dispute the epidemiological basis of the Settlement, the fact is that -- either knowingly or unknowingly -- there was a vast undercounting of potential claims because those claims based on moderate mitral regurgitation were not even considered. The claims projections presented at the fairness hearing were based on the work of three experts retained by Class Counsel, Epidemiologist Steven N. Goodman, M.D.; Cardiologist Dean G. Karalis, M.D., and Forensic Economist, Samuel J. Kursh, Ph.D.

Dr. Steven N. Goodman

To prepare a projection of the total number of potential Matrix claims, a series of benchmarks had to be established. The first was the total number of Pondimin and/or Redux users in the United States; the second, how many of those users would develop FDA-positive levels of valvular regurgitation; and the third was how many of those with FDA-positive levels of valvular regurgitation would qualify for Matrix benefits.

To fix the potential number of class members, the parties relied on the results of a May 1997 Wyeth marketing study that claimed there were 4 million users of Pondimin and 2 million users of Redux. Based on this stipulation, the population of potential class members was fixed at 6 million.

To determine the number of potential FDA positive class members, Class Counsel relied on Dr. Steven N. Goodman's analysis. Dr. Goodman's declaration and supplemental declaration were submitted to support the settlement at the time of the fairness hearings, and copies of those declarations are annexed to the Rubin Aff. at Exhibit "B".

Dr. Goodman based his projections of potential FDA qualifying class members on a meta-analysis of the available epidemiological studies at the time. While these projections were adequate to determine potential FDA positive class members, they provided no breakdown between the various grades of regurgitation.

The NATIONWIDE CLASS ACTION SETTLEMENT WITH AMERICAN HOME PRODUCTS CORPORATION ("Settlement Agreement") provides benefits based on demonstrated left sided valvular heart disease ("VHD") involving either the mitral or aortic valve. Findings of valvular regurgitation involving either valve may qualify a class member for benefits. Thus it was necessary for Dr. Goodman to determine the rate of disease in the exposed population for **each** valve.

With respect to the aortic valve, Dr. Goodman in declaration found that the baseline risk of base risk of FDA positive aortic regurgitation was 3.1% and increased 1% per month with each month of use of Pondimin and or Redux, with a rate of 14.5% for those who used the drugs for greater than nine months. See Supplemental Declaration of Steven N. Goodman, Rubin Aff., Exhibit “B,” at p. 3, Conclusion ¶¶ 1-2 (*n.b.*: Dr. Goodman’s Supplemental Affidavit is at the end of Exhibit “B”, and page 3 of that Supplemental Affidavit is numbered as “page 29 of 30” of that Exhibit).

A rate of mitral valvular disease must also be calculated. Based upon his analysis Dr. Goodman concluded that the baseline risk of FDA-positive mitral regurgitation in the unexposed population was 2.1% with an **exposed risk of 3.5%**. See Supplemental Declaration of Steven N. Goodman, Rubin Aff., Exhibit “B” at p. 3, Conclusion ¶¶ 5-6 (exhibit page 29 of 30).

Relying on these rates, Dr. Goodman projected the total number of class members who would have FDA-positive valvular regurgitation. Using Dr. Goodman’s findings the following table can be compiled:

PONDIMIN AND REDUX: 6,000,000 TOTAL USERS			
<u>DAYS OF THERAPY</u>	<u>USERS</u>	<u>FDA+AI</u>	<u>FDA+MR</u>
1-30	2,670,000	109,470	93,450
31-60	1,216,000	62,016	42,560
61-90	672,000	40,992	23,520
91-120	442,000	31,381	15,470
121-150	310,000	25,110	10,850
151-180	218,000	19,838	7,630
181-210	164,000	16,564	5,740
211-240	106,000	11,766	3,710
241-270	80,000	9,680	2,800
271+	122,000	17,690	4,270
TOTAL		344,507	210,000

Total FDA+ AI	=	344,507
Total FDA+ MR	=	210,000
Total FDA-positive		554,507

This results in a minimum potential FDA-positive population of 544,507 of which 237,012 would have used the drugs for greater than 60 days, while 307,496 would have used the drugs

for 60 days or less. Included in that total are **210,000 potential claims for Matrix benefits based upon FDA positive mitral regurgitation**. We do not disagree with Dr. Goodman's methodology or findings.

Dr. Dean G. Karalis

From the potential FDA-positive population it was necessary that a calculation be done to determine the number of class members who could potentially qualify for Matrix benefits. The Matrix is based five levels of compensation, ostensibly based on levels of severity of the claimants' illness.

However, as this Court has learned, the vast majority of claims that have been filed to date are for Level II benefits and not for Level I. A claimant qualifies for Level I benefits upon a finding of at least severe aortic or mitral regurgitation. By contrast, a claim for Level II benefits can be based on a finding of moderate mitral regurgitation if it is accompanied by one or more complicating factors as defined in the Settlement Agreement.

To accurately project the number of potential Matrix claims, the number of total potential claims would have to be broken down to determine how many would initially qualify for Level I benefits, Level II benefits, and so on. No such calculation was done, however. Instead, Class Counsel and Wyeth relied solely on Dr. Karalis' unsupported opinions, as set forth in his declaration (a copy of which is annexed to the Rubin Aff. as Exhibit "C"), to determine the number of potential FDA-positive Matrix qualifiers.

Dr. Karalis stated that he expected anywhere from 5%-10% of FDA-positive claimants to eventually progress to Matrix Level I and from there they would progress through the payment Matrix based on the rate of progression for aortic regurgitation. See Declaration of Dean G. Karalis, M.D., Rubin Aff., Exhibit "C" at p.20, § F ¶ 49(a) (*n.b.*: like Dr. Goodman's declaration exhibits at Exhibit "B", this is a lengthy, multi-document exhibit. This reference corresponds to page 20 of 73 in exhibit "C").

Most notably, Dr. Karalis made no attempt to predict how many people would initially qualify for Matrix Level II benefits based on a finding of moderate mitral regurgitation with an accompanying qualifying condition, a critical error.

In an obese population the presence of one or more of the additional qualifying conditions required for Level II benefits is very common. To ignore the fact that studies have found left atrial enlargement in 37% of healthy, normotensive, obese people *who were not exposed to diet drugs* is both inexplicable and indefensible.

Even given Dr. Karalis' flawed analysis, applying his findings should have resulted in anywhere from 11,850 to 23,701 claims for Matrix A benefits and from 15,375-30,750 claims for Matrix B benefits.

Still, the projections submitted at the fairness hearing were even lower.

Dr. Samuel J. Kursh

The final effort to complete the Settlement's claims projection was performed by an economist Dr. Samuel J. Kursh, whose report (a copy of which is annexed to the Rubin Aff., at Exhibit "D") was entered into evidence at the fairness hearing.

Relying in part on the opinions and projections submitted by Dr. Goodman and Dr. Karalis, it is Dr. Kursh who determined that out of the entire population of 6 million users, only 8,345 would ever qualify for Matrix A benefits and 27,227 would qualify for Matrix B benefits. This Court relied upon that projection as the sole basis for its pretrial order 2662 that implemented a 100% audit of all claims for Matrix benefits.

The declaration of Paul N. Hopkins, M.D., MSPH is annexed here as Exhibit "D". In that declaration, Dr. Hopkins provides an analysis of the claims projections and of Dr. Kursh's methodology and projections. Among other things Dr. Hopkins has stated:

Having reviewed all of the material submitted by Class Counsel to support their claims regarding the number of potential class members who could possibly qualify for Fund B benefits, I find major discrepancies between the projections made on behalf of Class Counsel and what may easily be derived from published sources. These discrepancies are of a magnitude that is difficult

to believe they were made without a preconceived effort to minimize the extent of the potential damage caused by fenfluramine and dexfenfluramine.

These criticisms are primarily directed to Dr. Kursh, whose calculations inexplicably excluded class members with mitral regurgitation from consideration. This is best demonstrated by the table that appears on page 4 of his report, reprinted below:

Pondimin		4,000,000		
Days of Therapy	Percentage	Users	% FDA+	# FDA+
61-90	11.9%	476,000	3.0%	14,280
91-120	8.3%	332,000	4.0%	13,280
121-150	6.0%	240,000	5.0%	12,000
151-180	4.3%	172,000	6.0%	10,320
181-210	3.3%	132,000	7.0%	9,240
211-240	2.1%	84,000	8.0%	6,720
241-270	1.6%	64,000	9.0%	5,760
271+	2.4%	96,000	14.5%	13,920
				85,520
Redux		2,000,000		
Days of Therapy	Percentage	Users	% FDA+	# FDA+
61-90	9.8%	196,000	3.0%	5,880
91-120	5.5%	110,000	4.0%	4,400
121-150	3.5%	70,000	5.0%	3,500
151-180	2.3%	46,000	6.0%	2,760
181-210	1.6%	32,000	7.0%	2,240
211-240	1.1%	22,000	8.0%	1,760
241-270	0.8%	16,000	9.0%	1,440
271+	1.3%	26,000	14.5%	3,770
				25,750

In the chart above, the column entitled “Days of Therapy” lists the duration of use. The column entitled “Percentage” indicates the percentage of total users who used the drugs for that period. The column entitled “users” indicates the total number of users. The column entitled “% FDA+” we assume was meant to represent the FDA+ rate in the exposed population, however given Dr. Goodman’s findings, this is clearly incorrect.

From the chart above, it is apparent that Dr. Kursh took only the increased risk of aortic regurgitation alone, and used that as the factor to compute the total number of FDA-positive class members who took the drugs for greater than 60 days. Not only was the background rate of aortic regurgitation deducted but *no calculation was made for those with FDA-positive mitral regurgitation.*

Simply stated, although the Settlement Agreement provides benefits for those with either aortic or mitral regurgitation, only those potential claimants with aortic regurgitation were

considered in these projections. Dr. Kursh's prediction that there would only be 8345 Matrix A claims erroneously addressed only those claims based upon aortic regurgitation.

Conversely, Dr. Kursh does include the baseline risk of MR (2.1%) in his calculations with respect to those who would qualify for Matrix B benefits. There is no explanation given why the background rate was used for one and the other, nor why no calculations were made using the exposed rate of 3.5%.

This egregious omission has served as the basis for each and every effort by Wyeth, Class Counsel and the Trust to limit the payment and processing of claims.

Wyeth Was Also Complicit

Neither Wyeth nor Class Counsel can deny that -- for the purposes of claims projections -- those class members with FDA-positive mitral regurgitation were wholly excluded.

The consequences of this omission are clear. At the fairness hearing Wyeth submitted the expert report of Dr. Mark McClellan (a copy of which is annexed to the Rubin Aff. as Exhibit "E"). At attachment "E" of his report Dr. McClellan indicates that *no cases, (0)*, will ever progress to Level II benefits based upon a diagnosis of moderate MR.

There is no reasonable explanation for that contention, because no one can dispute the fact that the Settlement Agreement was constructed -- at least in part -- to provide benefits for class members who had moderate mitral regurgitation.

Given the magnitude of this Settlement, it is inconceivable that Wyeth didn't know that the projections erroneously excluded FDA-positive mitral regurgitation claimants from the model. Surely, at some point prior to the application for the 100% audit someone would have checked the experts' calculations and the underpinnings of their assumptions.

POINT I.
**THE NUMBER OF CLAIMS FOR LEVEL II BENEFITS
THAT HAVE BEEN FILED IS CONSISTENT WITH THE
EPIDEMIOLOGY RELIED UPON BY THE COURT AT THE
FAIRNESS HEARING**

Over the past several months we have conducted a detailed analysis of the claims projections submitted by Class Counsel at the time of the fairness hearing. As part of our efforts we asked Dr. Paul N. Hopkins, the co-director of Cardiovascular Genetics at the University of Utah School of Medicine to evaluate the claims projections submitted at the fairness hearing. We also asked Dr. Hopkins to perform his own analysis regarding the number of potential Level I and Level II claims. Dr. Hopkins performed a meta-analysis similar to Dr. Goodman's. His analysis, along with the Exhibits he annexed to his Declaration, is annexed here as Exhibit "F".

As part of his analysis, Dr. Hopkins evaluated available epidemiological data to project the number of class members who would qualify for level II benefits based upon FDA-positive mitral regurgitation and the presence of left atrial enlargement. Left atrial enlargement is one of the complicating conditions defined in the Green Form.

From available published sources, there is a study that has documented left atrial enlargement in 37% of the healthy obese population.¹

Other studies that included individuals with conditions such as valvular regurgitation found rates as high as 74.7%.²

Using this one factor alone, Dr. Hopkins was able to project approximately how many class members would qualify for Matrix benefits. A summary of the Settlement's projections and Dr. Hopkins' comparative projections appears in the table below:

¹ Sasson Z, Rasooly Y, Gupta R, Rasooly I. Left atrial enlargement in healthy obese: prevalence and relation to left ventricular mass and diastolic function. *Can J Cardiol* 1996; 12:257-263.

² Gerds E, Oikarinen L, Palmieri V, Otterstad JE, Wachtell K, Boman K, Dahlof B, Devereux RB. Correlates of left atrial size in hypertensive patients with left ventricular hypertrophy: the Losartan Intervention For Endpoint Reduction in Hypertension (LIFE) Study. *Hypertension* 2002; 39:739-743

	Estimate for settlement	Hopkins, 2004
Number exposed	6,000,000	6,000,000
Duration of use distribution	provided by Wyeth	Same
FDA+ AR, number expected		
Used =60 days	237,020	217,610
Used >60 days	111,270	256,084
FDA+ MR, number expected		
Used =60 days	126,000	119,817
Used >60 days	0	79,546
Matrix A, number expected - total	8345	
Level I (severe AR+MR)	7511	21,545
Level II	834	24,350 – 49,161 (moderate MR+LAE only)
Matrix B (use =60 days), number - total	27,227	
Level I (severe AR+MR)	24,504	27,325
Level II	2,723	36,678 – 74,049 (moderate MR+LAE only)

This projection, based on the presence of left atrial enlargement only, compares favorably with number and type of claims that have been filed with the AHP Settlement Trust. By including the other Level II factors, the potential number of qualifying level II claims rises.

Neither this Court nor the parties can responsibly or reasonably continue to rely on the faulty calculations produced at the time of the fairness hearings as a basis to support allegations of fraud and misconduct.

POINT II.
**SERIOUS QUESTIONS HAVE BEEN RAISED
REGARDING THE PROJECTIONS UPON WHICH THIS
SETTLEMENT WERE BASED THAT REQUIRE FURTHER
INQUIRY AND DISCOVERY**

While Wyeth and its allies continue casting dispersions on the plaintiffs' bar they have refused re-examine the projections that formed the basis of this settlement.

According to Dr. Hopkins' declaration, "[t]hese discrepancies are of a magnitude that is difficult to believe they were made without a preconceived effort to minimize the extent of the potential damage caused by fenfluramine and dexfenfluramine."

Certainly Class Counsel and its experts Dr. Karalis and Dr. Kursch have offered no explanation as to why those with FDA-positive mitral regurgitation were excluded from the claims projection.

Particularly in light of the gravity of the charges that have been levied against scores of attorneys, physicians and claimants because of this faulty error-ridden projection, further inquiry is minimally reasonable.

As a first step, a limited number of depositions might be adequate to provide meaningful answers to the questions raised by Dr. Hopkins' findings.

POINT III.
**THERE IS NO BASIS FOR WYETH'S REQUEST FOR A
STAY OF PROCESSING**

Despite Wyeth's baseless allegations they have failed to submitted any evidence of fraud that would require this Court to stay the processing of claims.

Wyeth did not present evidence of *even a single illegitimate claim* that was paid after audit. Instead this Court has been left with outrageous allegations of impropriety against the attorneys and physicians involved in these matters, including, of all things, the fact some claimants were given water before they underwent echocardiograms. There is no basis for the allegation that drinking water will adversely effect the accuracy an echocardiogram.

Unable to substantiate their claims of fraud, Wyeth and their allies now attempt to disqualify thousands of claims, including legitimate claims, based on their fanciful interpretation of the Settlement Agreement's requirements.

New definitions of "diagnosis" and "supervision" are now being sought, both of which will materially alter the definitions of those terms that are widely accepted in the medical community, and that have been so accepted for generations.

POINT IV.

THERE IS NO PRACTICAL NEED FOR A STAY

Wyeth's request for a stay demonstrates that Wyeth will do anything to prevent the Trust paying the remaining legitimate claimants the benefits to which they are entitled.

It is true that the Trust will not have adequate funds to pay all legitimate claimants. That shortfall is not the result of fraud, however, but rather, is a consequence of a gross underestimation of the potential number of claims.

This Court has already implemented adequate safeguards to ensure that only legitimate claims will be paid. Moreover, even those safeguards are being routinely abused by the Trust and its auditors to avoid paying legitimate claims.

This Court's pretrial order 2662 required that the Trust audit each and every claim. Court-approved procedure ("CAP") No. 4 requires each approved claimant to submit additional documentation that a full complete medical history was taken by a cardiologist and that proof of such be filed with the Trust.

Notwithstanding these additional hurdles, it was and is still apparent to Wyeth and its allies that there will be too many legitimate claims for the Trust to pay.

Wyeth encouraged the Trust to adopt a Claims Integrity Program. The result of the Claims Integrity Program is that now nearly half of the claims that remain to be processed are being held in abeyance pending the completion of Trust investigations.

The re-prioritization of the claims has further diminished the pool of available claims that can be sent to audit.

While all of these efforts have been underway to limit the pool of available claims that can be processed, the AHP Settlement Trust has increased its ability to audit claims. Finally having a sufficient number of auditors to process claims in a timely and efficient manner, the Trust is, incredibly, left with no claims to audit. The waste of Trust resources that should rightly be used to compensate injured class members is indefensible.

More to the point, further delays in addressing the claims and further allegations against the plaintiff's bar, the claimants' attesting physicians and the claimants themselves cannot remedy a Settlement Agreement that was based on wholly incorrect and insufficient projections.

This Court should deny both of the Wyeth motions, that seeking a stay of claims processing and that seeking a further court-approved procedure. The motion is little more than a further attempt to hide the inequities of this Settlement Agreement and its irreparably erroneous foundations from the class members, this Court and the public.

CONCLUSION

The new standards Wyeth seeks to impose on the audit and claims administration process, as well as the proposed stay of claims processing, are wholly worthless and unnecessary steps to further burden this already-emasculated settlement agreement and claims process. There is no need for further burdening of the system, further expenses to reduce the assets of the Trust that should be going to the benefit of the injured claimants, and no real benefit to the proposed remedies Wyeth seeks. For all of these reasons, as well as the reasons set forth herein and in the submissions in opposition to Wyeth's motion by Baron & Budd, LLP and by Fleming & Associates, LLP, this Court should deny Wyeth's applications in their entirety.

Dated: Great River, New York
March 15, 2004

Respectfully submitted,

NAPOLI KAISER BERN & ASSOCIATES, LLP
Attorneys for Claimants

By: _____
Denise A. Rubin (DR-5591)

3500 Sunrise Hwy., Suite T207
Great River, NY 11739
(212) 267-3700

HARITON & D'ANGELO, LLP
Attorneys for Claimants

By: _____
Mario D'Angelo
A Member of the Firm

3500 Sunrise Hwy., Suite T207
Great River, NY 11739
(631) 224-1133

On the Brief:
Paul J. Napoli

UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

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IN RE: DIET DRUGS (Phentermine/ Fenfluramine/ Dexfenfluramine) PRODUCTS LIABILITY LITIGATION	:	CIVIL ACTION 99-20593
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THIS DOCUMENT RELATES TO: SHEILA BROWN, SHARON GADDIE, VIVIAN NAUGLE, QUINTIN LAYER, and JOBY JACKSON-REID, Individually and all others similarly situated,	:	Hon. Harvey Bartle
	:	DECLARATION OF SERVICE
Plaintiffs,	:	
-against -	:	
	:	
AMERICAN HOME PRODUCTS CORPORATION,	:	
	:	
Defendants.	:	
-----X	:	

DENISE A. RUBIN, an attorney duly admitted to practice in the State of New York and before the United States Court of Appeals for the Third Circuit, hereby declares that on March 15, 2004, I caused a true copy of the within Amended Supplemental Memorandum in Opposition to Wyeth’s Motion for A Stay in Claims Processing and For Implementation of a Further Court Approved Procedure, with its annexed exhibits, to be served on the following person(s) by email and filed electronically with the Court:

Andrew A. Chirls Esq.
Wolf, Block, Schorr & Solis-Cohen, LLP
1650 Arch Street, 22nd Floor
Philadelphia, PA 19103

Robert D. Rosenbaum
Arnold & Porter
555 Twelfth Street, NW
Washington, DC 20004-1206

Peter L. Zimroth
Arnold & Porter
399 Park Avenue, 34th Floor
New York, New York 10022-4690

Gregory P. Miller, Esq.
Special Master, MDL-1203
Miller Alfano & Raspanti PC
1818 Market Street, Suite 3402
Philadelphia, PA 19103
gmliller@mar-law.com

Michael Fishbein
Levin Fishbein Sedran & Berman
510 Walnut Street, Suite 500
Philadelphia, Pennsylvania 19106

Denise A. Rubin (DR-5591)