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

IN RE: DIET DRUGS (PHENTERMINE, FENFLURAMINE, DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 1203
THIS DOCUMENT RELATES TO:	:	
SHEILA BROWN, et al.	:	
v.	:	
AMERICAN HOME PRODUCTS CORPORATION	:	CIVIL ACTION NO. 99-20593

PRETRIAL ORDER NO. 2662

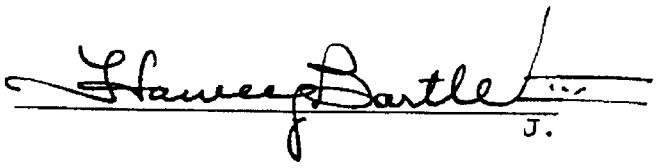
AND NOW, this 26th day of November, 2002, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that:

(1) the AHP Settlement Trust (the "Trust") shall audit every claim for matrix level benefits from Fund B that has not as of the date of this order been paid; and

(2) before referring Fund B claims to audit in accordance with this order, the Trust shall hereinafter delete all references to the attesting cardiologist that are contained within the Green Form, the echocardiogram report and other documentation to be submitted to the auditing cardiologist. To the extent that any reference to the attesting cardiologist is contained on an echocardiogram videotape or digital disk and is

not otherwise easily removable, the Trust shall be under no obligation to do so.

BY THE COURT:



J.

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MEMORANDUM AND PRETRIAL ORDER NO. 2662

Bartle, J.

November 26, 2002

Class Counsel and Wyeth (formerly American Home Products Corp. or AHP) have jointly moved for a modification of the procedures by which the AHP Settlement Trust (the "Trust") currently audits claims for matrix benefits from Fund B. The moving parties contend they have good cause to obtain an order pursuant to the terms of the nationwide class action Settlement Agreement to subject each and every claim for Fund B benefits to an audit by the Trust before the Trust would be required to make any payment. At present, the Settlement Agreement limits the number of audits to fifteen percent of claims filed. See Settlement Agreement §§ VI.E.1 and VI.F.2.

I.

The class action settlement of this massive tort litigation provides benefits to those who took one of two

prescription drugs for weight loss sold in the United States under the brand names Pondimin (fenfluramine) and Redux (dexfenfluramine) ("diet drugs"). If a claimant qualifies for benefits under the Settlement Agreement, he or she will be compensated out of Fund A and/or Fund B. Among other things, Fund A provides three primary benefits: (1) echocardiogram screening; (2) an option between receiving valve-related medical services up to $10,000 in value or $6,000 in cash; and (3) reimbursement for the cost of diet drug prescriptions. See id. at § IV.A. In accordance with the Settlement Agreement, Wyeth deposited $1 billion into Fund A. The monies in Fund B, on the other hand, provide compensatory damages to claimants who have been diagnosed with certain levels of valvular heart disease including, among other things, moderate or more severe mitral or aortic regurgitation.[1] Pretrial Order No. 1415 at 62; see Settlement Agreement § IV.B.2.c. Under the Settlement Agreement, Wyeth agreed to deposit $2.55 billion into Fund B. As of October 31, 2002, the Trust had paid Fund B claims worth more than $900 million. The moving parties seek relief only with respect to claims for Fund B benefits.

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1. Mitral regurgitation occurs as the heart's left ventricle contracts and expels blood into the aorta and the rest of the body. During this process, blood leaks backward, or regurgitates through a defective mitral valve and into the left atrium. As a result of this reverse flow, the heart must work harder to pump the needed blood throughout the heart and into the body. Aortic regurgitation is a similar phenomenon that occurs when blood flows backward from the aorta into the left ventricle through the aortic valve.

In support of their motion, Wyeth and Class Counsel agreed to limit their evidence to information related to the increased number of claims that the Trust has received above what was projected at the date of the Fairness Hearing in 2000 before Judge Louis Bechtle and to the problems that the Trust has experienced in processing claims received to date. The court permitted the parties to engage in limited discovery.

The hearing on the motion scheduled for October 22, 2002 did not go forward as planned. During their preparation, the objecting parties sought production of the Trust's database under Rule 1006 of the Federal Rules of Evidence.[2] The objectors wanted to examine what they maintained to be the source data for statistical summaries on which the moving parties intended to rely at the hearing. After a phone conference with counsel on October 18, 2002 the court postponed the October 22 hearing until October 24, 2002 and scheduled in its place a second status conference to resolve the discovery dispute and other matters that had arisen during the intervening week.

At the October 22 conference, the court provided the objectors with ample opportunity to identify the type of

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2. Rule 1006 states:

> The contents of voluminous writings, recordings, or photographs which cannot conveniently be examined in court may be presented in the form of a chart, summary, or calculation. The originals, or duplicates, shall be made available for examination or copying, or both, by other parties at reasonable time and place. The court may order that they be produced in court.

information that they hoped to glean from the Trust's database if given access. However, at no point did the objectors point to anything specific that they expected to obtain beyond what the moving parties agreed to produce. Nor did the objectors indicate any desire to review the underlying documents that formed the basis of the statistical summaries. Convinced that they were seeking to conduct what would amount to a fishing expedition that would bog down unnecessarily the resolution of the issues before it, the court denied their request. The hearing went forward on October 24, 2002 and lasted two days.

II.

As noted above, monies in Fund B are designed to compensate claimants who suffer from certain levels of valvular heart disease. Claimants who qualify for benefits under Fund B will receive either a full or reduced payment based on the application of several factors including age, duration of diet drug use, the severity of the disease from which they suffer and whether the disease was caused by something other than diet drugs. See Settlement Agreement § IV.B. Full payment on what is known as Matrix A is approximately five times as great as a reduced payment on what is known as Matrix B although payment on Matrix B also is substantial. The average current payment for Fund B claims regardless of matrix level is approximately $400,000.

An individual seeking payment for matrix level injuries from Fund B must follow the protocol outlined in the Settlement

Agreement. First, the claimant must undergo an echocardiogram, or ultrasound of the heart, to determine whether he or she has a qualifying level of valvular heart disease. Second, the claimant must submit to the Trust a Green Form, in which the actual claim for benefits is made. In addition, a board-certified cardiologist or cardio-thoracic surgeon must provide a sworn certification that the claimant either does or does not have a level of valvular heart disease which qualifies the claimant for benefits. Pretrial Order No. 1415 at 52. Along with the Green Form, a videotape or digital disk of the echocardiogram, proof of diet drug use and relevant medical records must be supplied.

As a protective measure, the Settlement Agreement provides for audits of up to fifteen percent of all claims submitted to the Trust without further order of the court. The Trust may designate for audit up to five percent of the claims filed each quarter. Settlement Agreement § VI.E.1. In addition, Wyeth may select for audit up to ten percent of the claims filed each quarter. See id. at § VI.F.2. When a claim is selected for audit, the Trust forwards relevant documentation, including the claimant's medical history and echocardiogram, to an independent board-certified cardiologist. After analyzing the information provided, the auditing cardiologist makes a determination as to whether there was "a reasonable medical basis for the representations made by any physician in support of the [c]laim." Id. at § VI.E.6. If the auditing cardiologist answers this question in the negative, the Trust may not pay the claim and

must apply for a show cause order with the court as to why the claim should be paid. Id. at § VI.E.7. If the auditing cardiologist finds in favor of the claimant, he or she is paid without any further appeal. Id.

During the Fairness Hearing in 2000 prior to Final Judicial Approval of the Settlement Agreement, evidence was presented concerning the anticipated level of demand for Fund B benefits given that six million people nationwide were estimated to have taken one or both of the diet drugs. Expert witnesses analyzed the number of potential class members, the expected participation rate in the settlement, the proportion of participants who will be diagnosed with FDA Positive levels of blood flow regurgitation, the level of regurgitation necessary to qualify for Fund B benefits, and the proportion of claimants entitled to Fund B payments who would be recovering from Matrix B rather than Matrix A. Pretrial Order No. 1415 at 63-64. Based in part on "conservative assumptions likely to overstate the demands on [both] Fund A and Fund B," the expert testimony demonstrated that a maximum of 8,345 people would qualify for the larger Matrix A payments from Fund B and that no more than 27,227 people would qualify for reduced payments on Matrix B. Id. at 64-65; see Report of Samuel J. Kursh, D.B.A., Fairness Hearing Ex. P-94 at 4-5. Matrix B claims would, therefore, outpace Matrix A claims at a three to one rate. In addition, from the statistics presented at the Fairness Hearing it was estimated that the ratio of diet-drug induced aortic regurgitation to diet-

drug induced mitral regurgitation would be five to one. See Supp. Declaration of Steven N. Goodman, M.D., M.H.S., Ph.D., Fairness Hearing Ex. P-90 at 3. A strong body of epidemiological studies supported all these calculations.

After considering the testimony of the experts and the other supporting evidence, Judge Bechtle determined that the $2.55 billion in Fund B would be "sufficient to provide all likely benefits under the Settlement Agreement." Pretrial Order No. 1415 at 66. No evidence was offered to the contrary. See id.

III.

The moving parties contend that the volume and types of Fund B claims received by the Trust as of August 12, 2002 differ materially from the epidemiological projections on which approval of the Settlement Agreement was predicated.[3] They presented as a witness Dr. Thomas Florence, a consultant who works closely with the Trust on claims processing issues. He offered statistics concerning the claims submitted to the Trust as of that date.[4]

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3. Because the Trust was experiencing a significant backlog in opening the mail and entering the information into its computer system, the Trust could only provide data as of August 12, 2002. The Trust experienced a large influx of mail around August 1, 2002, the deadline under the Settlement Agreement for, among other things, registering for the echocardiogram screening program and filing claims for reimbursement of prescription drug costs.

4. Dr. Florence has considerable experience with claims facilities established through mass tort litigations. His company, Analysis Research and Planning Corporation, has worked with the Trust to create a plan to process all claims internally, rather than through an outside facility. He also has assisted (continued...)

Based on Dr. Florence's testimony, we find that as of August 12, 2002, the Trust had received a total of 42,244 Green Forms. Because some claimants filed duplicate forms, this total represents approximately 35,000 claimants, each of whom asserts entitlement to payment for a matrix level condition from Fund B. The Trust received 888 claims per week for the six weeks prior to September 17, 2002. From September 17, 2002 to October 1, 2002 the Trust received 1,400 claims per week. If the trend of 888 per week continues, the Trust will receive a total of 59,994 Green Forms by the end of 2002 and 75,525 by May 3, 2003, the final date on which claimants can register with the Trust for matrix level benefits. This avalanche of filings contrasts sharply with the 35,000 filings which were anticipated from the evidence at the Fairness Hearing before Judge Bechtle.

The information contained in the Green Form also demonstrates a pattern of filings up to this point that departs dramatically from the type of claims that was expected at the time of Fairness Hearing. By August 12, 2002, the Trust had received far more claims seeking benefits for alleged mitral regurgitation than it had for aortic regurgitation. Of the claimants asserting damage either to their mitral or aortic valve, 7,876 sought benefits for qualifying levels of mitral

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4.(...continued)
the Trust on various planning issues, including staffing and computer system requirements and design of a claims tracking system. He is familiar with the Trust's procedures for handling Green Form submissions as well as the database used for tracking those claims.

regurgitation and only 2,712 for qualifying levels of aortic regurgitation.[5] As noted above, the anticipated ratio of diet drug induced aortic regurgitation to mitral regurgitation was five to one. Furthermore, 6,535 of these claims fall on the full payment Matrix A and only 1,519 on the reduced payment Matrix B.[6] Of all the claimants who indicated that they believed they were entitled to payment on either Matrix A or Matrix B, nearly eighty percent have identified Matrix A, which provides the more generous benefits. These numbers are vastly out of proportion with the expected ratio of three Matrix B claims to one Matrix A claim.

IV.

Relying on the claims experience encountered through August 12, 2002, the moving parties contend that the fifteen percent audit cap currently in place under the Settlement Agreement is inadequate to ensure that claims being submitted to the Trust are legitimate. As of now, 85% of the claims must be paid without any real check on their legitimacy. Accordingly, Wyeth and Class Counsel request the court to authorize audits of all claims for matrix benefits from Fund B.

The Settlement Agreement permits this court to order additional audits and adopt additional claims administration

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5. An additional 2,995 claimants were seeking benefits for damage to both their aortic and mitral valves.

6. These statistics are based on assertions made by the claimant in the Green Form. More than 2,500 additional claims did not include an indication of whether the claimant believed he or she was entitled to Matrix A or Matrix B payment.

procedures for "good cause shown." The moving parties assert that this standard has been met. Specifically, the Settlement Agreement states:

> [f]or good cause shown, including without limitation the results of audits conducted on any one or more Claims, groups of Claims, and/or requests for Credits made by [Wyeth], the Court at any time, upon its own motion after notice to [Wyeth] and Class Counsel, or upon motion by any party and after such notice and hearing as the Court may direct, may order the Trustees and/or Claims Administrators to perform such additional audits and/or adopt such additional claims administration procedures as the Court deems appropriate.

Id. at § VI.E.

The Settlement Agreement does not define "good cause." Furthermore, our Court of Appeals has not provided specific guidance on what constitutes good cause in the context of a class action settlement agreement. Generally, however, good cause is a fluid concept, the meaning of which will depend on the circumstances of the individual case. One court has commented that the term is "difficult to [define] in the abstract apart from the moorings of a given case." In re Maxwell Newspapers, Inc., 981 F.2d 85, 90 (2d Cir. 1992).

Under Pretrial Order No. 1415, this court retained "exclusive jurisdiction over this action and each of the Parties, including [Wyeth] and the class members, to administer, supervise, interpret and enforce this Settlement in accordance with its terms ... and to enter such other and further orders as are needed to effectuate the terms of the Settlement." Pretrial

Order No. 1415 at ¶ 11. This court is responsible for overseeing the settlement of this massive class action, particularly to make sure that the Settlement Agreement, as approved by this court, is properly enforced. See In re Prudential Ins. Co. of Am. Sales Practice Litig., 261 F.3d 355, 367-68 (3d Cir. 2001).

Absent any other explanation for the discrepancy in claims filed from the number and types of claims forecast, the moving parties maintain that the system is "being scammed." They point to the September, 2002 hearing involving medically unreasonable echocardiograms submitted by two New York law firms, Hariton & D'Angelo, LLP and Napoli, Kaiser, Bern & Associates, LLP. They urge us to consider the evidence presented there in support of the good cause necessary to grant the relief requested in the matter before us. See Memorandum and Pretrial Order No. 2640 (Nov. 14, 2002). The court found that two cardiologists had acted in a medically unreasonable manner in certifying seventy-eight claims at issue. This led the court, based on good cause, to authorize audits of all claims certified by these two cardiologists and all claims submitted to the Trust by the two law firms that had engaged the two cardiologists.

We agree that the evidence presented at that earlier hearing is relevant and would support a finding of good cause here. However, we believe it is unnecessary to turn to that record. Even without that evidence, the undisputed statistics offered by the moving parties here reflect an obvious increase in the number and value of claims totally at odds with impressive

and undisputed epidemiological evidence presented at the Fairness Hearing. The claims simply do not mesh with the legitimate expectations of the court and the parties. Common sense compels the conclusion that something may be seriously amiss. While it is always possible that the epidemiologists were wrong, it is also quite possible that they were right and that the huge influx of claims is not legitimate. The only way we can ever find out which answer is correct is through 100% audits. Good cause clearly exists to implement this remedy.

This serious situation we face must be addressed, particularly when the sufficiency of Fund B to pay legitimate claims may be at stake. If payments are made to non-qualifying claimants, Fund B, although large, could be at serious risk because of the volume and size of the claims. No one has suggested any viable solution other than the one being adopted by the court. Even the objectors concede that something must be done in light of the statistics before us. Their expert, Dr. Mark Peterson, explained that the disparity in claims received from claims projected is "an event that ... need[s] to [be] consider[ed] and address[ed]."[7] Furthermore, Dr. Peterson did not dispute that additional audits could help the Trust ensure

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7. Dr. Mark Peterson is a member of the research staff at RAND Corporation. He has extensive experience with empirical and public policy research on mass tort issues. He has specifically written reports on claims facilities, like the Trust, which pay out claims for mass torts. He has also served as an expert consultant in mass tort litigations, primarily in the area of helping to set up trusts, but also with respect to issues involving audits of claims.

that claims being paid are legitimate. In response to a question as to how to determine whether there is impropriety or not in the claims filing process, he testified that "[a]n audit is a way to do it."

In sum, we find that good cause exists under the Settlement Agreement to modify the Trust's procedures to order it to designate all Fund B claims for audit. If all the claims are legitimate, no one is really hurt by the 100% audit requirement. Any resulting delay will be minimized by the Trust's plan to retain many more auditing cardiologists. If the Trust is receiving illegitimate claims, they must not be paid. Audits in every case are a much needed palliative.

The motion of Wyeth and Class Counsel for 100% audit of claims for matrix benefits from Fund B will be granted in accordance with the following order.