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

MEMORANDUM AND PRETRIAL ORDER NO. 2677

Bartle, J. December 10, 2002

Class Counsel and Wyeth (formerly American Home Products Corporation) have jointly moved for approval and implementation of the Fifth Amendment to the court approved Nationwide Class Action Settlement involving the diet drugs commonly known as fen-phen.[1] Movants assert that this amendment represents a material improvement in the settlement terms for the class members.

1. The Movants filed their joint motion for approval of the Fifth Amendment on September 23, 2002. At oral argument on November 21, 2002, the Movants informed the court that the parties had agreed to and executed a revised version of the proposed Fifth Amendment that addresses certain concerns raised by a number of objectors. It is this revised version of the Amendment that is now before us. We will refer to it throughout as the "Fifth Amendment."

I.

On November 18, 1999, American Home Products entered into a nationwide class action settlement agreement that resolved most of the claims arising from the use of two prescription diet drugs, Pondimin (fenfluramine) and Redux (dexfenfluramine), that it had marketed and sold. The parties thereafter agreed to four separate amendments. Following notice to class members and an extensive fairness hearing, my predecessor Judge Louis Bechtle entered Pretrial Order No. 1415, which approved the Settlement Agreement with the four amendments and ordered its implementation. See Pretrial Order No. 1415 (Aug. 28, 2000). Certain groups appealed that order. By January 3, 2002, all of the appeals were resolved, and the settlement agreement achieved the imprimatur of final judicial approval.

The Settlement Agreement with its four amendments makes available several potential benefits to those who took or were prescribed fen-phen and meet certain criteria. These benefits are paid from what are denominated Fund A and/or Fund B. Fund A provides three primary benefits to claimants: (1) free echocardiogram screening, primarily for class members who ingested the diet drugs for sixty-one or more days;[2] (2) an option to receive either valve-related medical services up to $10,000 in value or $6,000 in cash (the "cash/med services benefit"); and (3) reimbursement for the cost of diet drug

2. The Screening Period established under the Settlement Agreement ends on January 3, 2003. See Settlement Agreement § IV.A.1.a.

prescriptions. Settlement Agreement § IV.A. In accordance with the Settlement Agreement, Wyeth met its Fund A obligation by depositing $1 billion with the AHP Settlement Trust (the "Trust"), the entity responsible for administering payment of benefits. Because the amount in Fund A is fixed, the Settlement Agreement establishes a priority among class members for the payment of certain Fund A benefits. For example, the Trust is directed not to pay prescription cost refunds to the members of subclasses who used the diet drugs for sixty-one or more days or to provide certain echocardiogram cost reimbursements to class members unless the Trust determines the Fund A balance is sufficient to pay those benefits after paying or creating a reserve to pay all other Fund A benefits and costs of administration. Id. at §§ IV.A.1.d and IV.A.3.d. Such a decision cannot realistically be made until sometime after May 3, 2003, which is known as Date Two under the Settlement Agreement. Date Two is the final date by which claimants can register for the cash/med services benefit. When the Trustees conclude that the purposes of Fund A have been satisfied, any balance remaining in Fund A is to be transferred to Fund B. See id. at § III.B.4.

The monies in Fund B provide what are known as Matrix level benefits, or compensatory damages, to claimants who have been diagnosed with certain levels of valvular heart disease. Pretrial Order No. 1415 at 49, 62; see Settlement Agreement § IV.B.2.c. Under the Settlement Agreement, Wyeth agreed to make $2.55 billion available for Fund B payments. The Trust may

direct Wyeth to make quarterly deposits as are necessary to pay qualifying Matrix claims and to maintain an administrative reserve of $50 million up to the $2.55 billion cap. To the extent that the Trust does not draw upon the entire $2.55 billion in any one quarter, the remaining balance accrues interest at a rate of one and one-half percent per quarter or six percent per year. All interest accruing carries forward to increase the amount in Fund B. See Pretrial Order No. 1415 at 62-63. Wyeth's Fund B obligations are secured by a perfected security interest in cash-equivalent securities and commercial paper having a value of $370 million (the "Security Fund"). Settlement Agreement § III.E.2.

Class members who have or develop a condition entitling them to compensation under the Settlement Agreement are not bound to accept the benefits offered. Depending on the circumstances, some class members may choose to exercise an intermediate or back-end opt-out and sue Wyeth in the tort system with certain limitations. See Settlement Agreement §§ IV.D.3 and IV.D.4. For example, punitive damages are prohibited. See id. For qualified class members who timely and properly exercise an initial or back-end opt-out right, Wyeth is permitted under the Settlement Agreement to offset its $2.55 billion funding obligation by a percentage of the amount the claimant would have been paid had he

or she not opted-out.[3] See id. at § VII.A.4. This offset is known as a Credit.

II.

The Fifth Amendment would make five significant and numerous technical changes to the Settlement Agreement. The significant changes are outlined below.

First, the Amendment would merge Funds A and B to create one overarching Settlement Fund from which all benefit payments would be made. The merger provisions seek to modify the benefit payment procedures in several important respects. The amount formerly in Fund A automatically would be available to pay Matrix Compensation Benefits that are currently paid through Fund B.[4] Any payments made, however, would not reduce Wyeth's $1 billion Fund A or $2.55 billion Fund B obligations. The provisions also would expedite the payment of certain Fund A benefits. The Trust would be required to pay prescription drug and echocardiogram screening cost refunds without first waiting to determine if the Fund A balance is sufficient to meet the

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3. Specifically, Wyeth is entitled to the lesser of the amount of the payment the class member actually receives or ninety-one percent of the value which the class member would have been paid had he or she not exercised the opt-out. See Settlement Agreement § VII.A.4. The amount that Wyeth is entitled to offset with respect to initial opt-outs is capped at $300 million. See id. at § VII.A.2.a.

4. The Fund A amount would be available to fund Matrix benefits until the balance of the merged Settlement Fund reaches the Administrative Reserve of $50 million that is set forth in the Settlement Agreement as amended. At that point, the Trust would resume funding the payment of Matrix benefits on a quarterly basis or more frequently as agreed to by the parties.

demand for benefits. As noted above, because of the limited amount in Fund A, the Settlement Agreement currently prohibits the Trust from paying benefits to certain class members until it concludes that Fund A can satisfy all potential claims against it. See id. at §§ IV.A.1.d and IV.A.3.d. Under this framework, the Trust cannot realistically meet this requirement for at least another six months. The merger provisions would instead permit all class members to receive these Fund A benefits without that added delay.

The merger provisions also would impose new conditional funding obligations on Wyeth. To the extent that the amount necessary to pay all cash/med services benefits would exceed Wyeth's $1 billion Fund A obligation, these provisions would require Wyeth to pay the excess. It is important to emphasize that the maximum amount in Fund B will not be reduced to compensate for any excess payment Wyeth must make to pay these benefits. Finally, the merger proposal would augment the security interest of the Class. Wyeth would increase the amount of assets on deposit in the Settlement's Security Fund up to eighty percent of the amount transferred from Fund A to the merged Fund.

Second, the Fifth Amendment would alter the process by which Wyeth may seek Credits when class members properly exercise back-end opt-out rights. Wyeth is permitted under the Settlement Agreement to request Credits once it has made payment to a back-

end opt-out claimant.[5] See id. at VII.A.3. The Fifth Amendment would prohibit Wyeth from seeking any back-end opt-out Credits until at least January 3, 2007, five years after the date on which the Settlement Agreement achieved Final Judicial Approval. Accordingly, interest would be earned on an amount in the Settlement Fund that, at least temporarily, could not be reduced by Credits. In addition, accretions also would continue to accrue on the unpaid Fund B amounts which cannot be offset until at least this late date. To help the parties anticipate the impact of future Credits on the Settlement Fund, Wyeth would be required to issue quarterly reports on the amount of Credits that it believes will accrue by virtue of payments during the preceding quarter.

Third, the Fifth Amendment would change the by-laws of the Medical Research Foundation established under the Settlement Agreement. The Foundation, which is to receive up to $25 million from Settlement proceeds, is intended to provide for general medical research and educational efforts on diseases caused by the diet drugs. See id. at IV.A.3. In order to help the Foundation maintain neutrality, the by-laws disqualified any person from performing research if he or she had ever been associated as a witness or expert in any lawsuit involving the use of diet drugs. See id., Ex. 4.

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5. Initial opt-out Credits are already deferred under the Settlement Agreement. See Settlement Agreement § VII.A.2.b.

Based on input from the medical community, the Amendment would obligate the Foundation to concentrate its efforts on the treatment and cure of primary pulmonary hypertension (PPH), a nearly always fatal disease that has been associated with diet drug use. Since there are relatively few physicians who specialize in the diagnosis and treatment of PPH, many of whom have been involved to some degree with this class action litigation, the Amendment eliminates the restrictions on research participation that the by-laws impose. Under the proposal, a researcher would not be disqualified even if he or she had a prior role as a witness in a diet drug case. To ensure neutrality, a body of three Trustees, consisting of Class Counsel, Wyeth's counsel and a neutral third party, would be appointed to establish a protocol of suggested research.

The Fifth Amendment, if approved, will also modify the provisions of the Settlement Agreement that address subrogation claims. When a class member applies for Matrix benefits, he or she must identify any third party, including an insurer or government entity, who has paid or provided healthcare benefits related to the conditions for which they are seeking compensation. See Pretrial Order No. 1415 at 150. The Settlement Agreement and Court Approved Procedure No. 1 sets forth a process for determining the extent and adjudication of any subrogation claim that may exist. See Settlement Agreement § VII.D; Pretrial Order No. 1718. Certain subrogees, however, are not subject to this process because they have released claims

against claimants, Wyeth and the Trust. Accordingly, the net Matrix payment to these class members increased. To offset any advantage this gave to these class members, the class members were required to repay a certain amount, which was deducted from their Matrix benefit and deposited into Fund B. The Fifth amendment would eliminate this repayment provision and would refund all previously made repayments.

Finally, the Fifth Amendment would extend the echocardiogram screening period, which is scheduled to terminate on January 3, 2003. As noted above, to qualify for the Screening Program, class members were required to register with the Trust by August 1, 2002. The Trust has received tens of thousands more registrations than reasonably anticipated. It cannot ensure that all class members who timely requested and qualify for a free echocardiogram will receive one by the January 3, 2003 cut-off date. In fact, given the significant volume of claims awaiting processing by the Trust, class members may not receive the echocardiogram until months after this deadline.

To address this problem, the Fifth Amendment would permit qualifying claimants who timely registered for the Screening Program to receive an echocardiogram after the January deadline provided that it is conducted no later than July 3, 2003.[6] However, the deadline is subject to further extension for

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6. The Settlement Agreement currently allows the court to extend the Screening Program deadline only once, for six months upon a showing of good cause. See Settlement Agreement § IV.A.1.a. It does not provide any mechanism to allow class members who cannot (continued...)

any individual class member as long as he or she can demonstrate good cause and due diligence. Furthermore, for class members who would receive an echocardiogram after the January date, the May 3, 2003 deadline for registering for cash/med benefits and matrix benefits would be extended accordingly. In addition, the decision to exercise an intermediate opt-out would also be extended.

III.

The moving parties contend that the changes embodied in the Fifth Amendment are designed to advance the underlying purposes of the Settlement Agreement in light of the current circumstances of the class and the experience with the administration of that Settlement. The Movants argue that these changes represent material improvements in the Settlement for class members and should be approved.

Our Court of Appeals has not provided specific guidance on the standard to apply when evaluating an amendment to a finally approved class action settlement under circumstances similar to those existing here. However, the standard for analyzing the fairness of a settlement under Rule 23(e) of the Federal Rules of Civil Procedure is clear and we believe relevant to a resolution of the pending motion. The Third Circuit has explained that a court may "approve a proposed class action settlement ... if it is 'fair, adequate, and reasonable' to class

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6.(...continued)
obtain an echocardiogram by the end of those six months to seek redress.

members." Harris v. Reeves, 761 F. Supp 382, 394 (E.D. Pa. 1991) (citing Walsh v. Great Atlantic & Pacific Tea Co., Inc., 726 F.2d 956, 965 (3d Cir. 1983); Girsh v. Jepson, 521 F.2d 153, 156 (3d Cir. 1975)). As the court has noted, fairness is determined in part by the application and analysis of nine factors. These factors are:

> (1) the complexity, expense and likely duration of the litigation ...; (2) the reaction of the class to the settlement ...; (3) the stage of the proceedings and the amount of discovery completed ...; (4) the risks of establishing liability ...; (5) the risks of establishing damages ...; (6) the risks of maintaining the class through the trial ...; (7) the ability of the defendants to withstand a greater judgment ...; (8) the range of reasonableness of the settlement fund in light of the best possible recovery ...; (9) the range of reasonableness of the settlement fund to a possible recovery in light of all the attendant risks of litigation ....

See id. (citing Girsh, 521 F.2d at 157). Ultimately, the decision to approve a settlement is within the sound discretion of the trial court. See id.

Applying the relevant factors of this nine-part analysis to the Fifth Amendment, we find that the proposed revisions are fair, adequate and reasonable. Each of the individual changes will confer an additional benefit on the class members. By merging Funds A and B, the amendment will help decrease administrative costs. Furthermore, the provisions of the Fifth Amendment will expedite the delivery of certain benefits to class members, impose new potential funding requirements on Wyeth, provide greater security for Wyeth's

obligation to the class and improve the value and scope of medical research. All of these changes are consistent with the purposes of the Settlement Agreement and do not impair any rights of class members. There are no pending objections that any of these changes are not "fair, adequate, or reasonable" to the members of the class.

Only the proposed extension of the Screening Program deadline continues to encounter opposition and only because it does not go far enough in the view of several objectors. They have filed a cross motion requesting that the deadline for submitting echocardiograms should also be extended for class members who either have not registered for Screening Program benefits or are not entitled, because they were short terms users of the diet drugs, to participate in the Screening Program under the terms of the Settlement Agreement. None of these objectors contends, however, that the change set forth in the Fifth Amendment is disadvantageous to members of the class. In fact, these objectors have joined the moving parties' request that the Screening Program deadline be extended.

We agree that the proposed modification to extend the Screening Program deadline is fair, adequate and reasonable. Given the large volume of registrations and claims that the Trust received in excess of what they could have reasonably anticipated, many claimants will not receive a Screening Program echocardiogram by the January 3, 2003 deadline. Only with the extension can we ensure that these class members will receive the

echocardiogram that they elected and that they will have an opportunity to qualify for additional benefits as provided for in the Settlement Agreement. At this late date, these class members cannot realistically be expected to seek out private echocardiograms by January 3, 2003 in lieu of their participation in the Screening Program. We believe extending the Screening Program via the Fifth Amendment is preferable to seeking an extension for good cause shown as provided under the current terms of the Settlement Agreement.

We are not persuaded by the objectors' cross-motion that the deadline be extended for those who did not elect Screening Program benefits or who are not eligible for such benefits. By January 3, 2003 class members who chose not to register for Screening Program benefits will have had five years to obtain an echocardiogram. There has been an unprecedented amount of notice associated with the fen-phen class action settlement such that these class members cannot legitimately assert that they were unaware of the dangers that the diet drugs posed. Furthermore, the Fifth Amendment does not alter the distinctions between short-term and long-term users that are already embodied in the Settlement Agreement. The Settlement Agreement provides limited situations under which short term users would qualify for the Screening Program under the Settlement Agreement. To the extent that these class members qualified and timely registered for Screening Program benefits

and did not receive them by January 3, 2003, the extension in the Fifth Amendment would apply to them as well.

IV.

The objectors also contend that the Fifth Amendment should be rejected because notice of the Amendment was not given to the entire class. Rule 23(e) provides that "[a] class action shall not be dismissed or compromised without the approval of the court, and notice of the proposed dismissal or compromise shall be given to all members of the class in such manner as the court directs." Fed. R. Civ. P. 23(e). The trial court has discretion to determine the extent and manner of notice.

Here, the parties arranged for service of the Fifth Amendment on counsel for all represented Matrix Claimants, as reflected in the claims database maintained by the Trust, and on counsel for plaintiffs with active cases in Multi-District Litigation (MDL) 1203. In addition, the Fifth Amendment was posted on the official MDL-1203 Internet website and the Internet website maintained by the Trust.

We believe that the notice provided was sufficient under the circumstances to inform class members of the nature of the proposed changes and of the opportunity to object. Courts have acknowledged that notice to class members is required only when it is consistent with the purpose of Rule 23(e) to protect absent class members. See Austin v. Pennsylvania Dep't of Corrs., 876 F. Supp. 1437, 1455 (E.D. Pa. 1995). As noted above, each of the proposed changes conforms to the purposes of the

underlying Settlement Agreement and confers an additional benefit on the members of the class. All but one of these changes is without objection. Because the class members' rights are in no way impaired by the substance of the revisions, we find that notice to each and every member of the class is unnecessary to protect any absent member from any "harm."

For the foregoing reasons, the court will grant the Joint Motion to Approve and Implement the Fifth Amendment to the Nationwide Class Action Settlement with American Home Products.

A Pretrial Order follows.

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

PRETRIAL ORDER NO. 2677

AND NOW, this 10th day of December, 2002, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that:

(1) the Joint Motion to Approve and Implement the Revised Fifth Amendment to the Nationwide Class Action Settlement with American Home Products Corporation is GRANTED;

(2) the Revised Fifth Amendment is incorporated into the Settlement Agreement approved by Pretrial Order No. 1415; and

(3) the class member-claimants' cross-motion for an order extending the screening period through July 3, 2003 for all class members is DENIED.

BY THE COURT:

Harvey Bartle

J.