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. 2778

Bartle, J. March 12, 2003

Class Counsel, on behalf of the members of the class, and Wyeth (formerly American Home Products Corporation) have negotiated and jointly move for approval of the Sixth Amendment to the Nationwide Class Action Settlement Agreement involving the diet drugs commonly known as fen-phen. Movants assert that the proposed Sixth Amendment would provide Class Members with valuable rights and benefits not conferred upon them by the existing Settlement Agreement, including the right to sue Wyeth in the event that the fund which supplies so-called Matrix benefits to Class Members is someday depleted before paying all claims.

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 C. Bechtle entered Pretrial Order No. 1415, which approved the Settlement Agreement with the four amendments and ordered its implementation.[1] See Pretrial Order No. 1415 (Aug. 28, 2000). Certain Objectors appealed that order. By January 3, 2002, all of the appeals were resolved, and the Settlement Agreement obtained the imprimatur of final judicial approval.

The Settlement Agreement provides a host of remedies to those who took the diet drugs and those who as a result suffer from various levels of valvular heart disease ("VHD"). Under certain circumstances Class Members may exercise intermediate or Back-End Opt-Out rights, which allow them to sue Wyeth in the tort system.[2] However, in return for Wyeth's waiving the statute of limitations, these Class Members may not seek punitive, exemplary or multiple damages. The remaining Class Members who do not opt-out may not sue Wyeth and instead may elect to receive Matrix benefits from the AHP Settlement Trust (the "Trust")

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1. This court has since approved a Fifth Amendment to the Settlement Agreement on December 10, 2002. See Pretrial Order No. 2677 (Dec. 10, 2002).

2. Class Members also were given the right to exercise an initial opt-out, but the time for doing so has long since passed.

funded by Wyeth.[3] To qualify for these benefits, Class Members must submit to the Trust an application, known as a Green Form, containing information about their medical condition.[4] The benefits are determined by the Trust through a procedure established in the Settlement Agreement which awards payment based on a number of criteria related to the severity of the injury. Under the terms of the Settlement Agreement, Wyeth's total obligation to pay benefits to those foregoing the tort system is $3.75 billion, including $2.55 billion for Matrix benefits. See Settlement Agreement §§ I.1, III.B-C. Currently, the average payment on a Matrix claim is approximately $400,000.

The obvious question that immediately arose upon the signing of the Settlement Agreement in 1999 was whether the funds Wyeth agreed to pay into the Trust would be adequate to satisfy the Matrix claims of all those Class Members who were injured by ingesting fen-phen. As a result, there was extensive testimony on this subject at the Fairness Hearing in May, 2000 prior to final judicial approval of the Settlement Agreement. Based in part on a sound body of epidemiological evidence concerning the link between the diet drugs and valvular heart disease, Judge

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3. Class Members who demonstrate that they have a condition known as Primary Pulmonary Hypertension ("PPH") as defined in § I.46 of the Settlement Agreement may, however, pursue Wyeth on their PPH claims in the tort system and may seek punitive damages.

4. The Green Form consists of three parts: Part I is to be signed by the Class Member; Part II is to be signed by the Class Member's physician; and Part III is to be signed by the Class Member's attorney, if the Class Member is represented.

Bechtle determined that these amounts 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. Consequently, the court was not called upon to address the "what-if-the-fund-runs-out-of-money" scenario.

Despite Judge Bechtle's finding based on the uncontradicted evidence before him, speculation has persisted that the settlement fund could someday be exhausted before all proper claims are paid. In recent months, the number and the severity of Matrix claims alleged in the so-called Green Forms filed with the Trust has dramatically exceeded the number and severity of claims anticipated at the time of the Fairness Hearing. See Memorandum and Pretrial Order No. 2662 (Nov. 26, 2002) at 8-9. In an effort to ensure that the Trust pays only legitimate claimants, this court in November, 2002 authorized the Trust to audit each and every claim for Matrix benefits. See id. at ¶ 1.

II.

First and foremost, the Sixth Amendment would explicitly allow Class Members to sue Wyeth in the tort system if the Trust is unable to pay their Matrix benefits because of lack of funds.[5] The Settlement Agreement currently is silent on the

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5. The Amendment contains a detailed set of conditions pursuant to which this right to sue Wyeth would be triggered. Those not discussed in this Memorandum are not relevant for present purposes.

subject. In order to sue, Class Members would exercise the "Sixth Amendment Opt-Out."

Eligibility to assert the proposed Sixth Amendment Opt-Out right is subject to several conditions. Class Members must have filed a Green Form with the Trust by May 3, 2003, and the Trust must have determined after audit of the Class Member's claim that the Class Member qualifies and is medically eligible for Matrix compensation benefits.[6] Furthermore, a Class Member eligible to sue Wyeth pursuant to the proposed opt-out must first agree in writing: (1) not to name any defendant other than Wyeth; (2) not to join any plaintiff other than a derivative claimant; and (3) not to consent to or cause consolidation of his or her action with any other claims or actions and to dismiss such action, with the right to refile, if consolidation is ordered by any court. Consistent with the exercise of the other opt-out rights presently available under the Settlement Agreement, Class Members who elect to pursue the Sixth Amendment Opt-Out would be prohibited from seeking punitive, exemplary and/or multiple damages. It is important to note that this proposed opt-out right would be in addition to all other opt-out rights presently available under the Settlement Agreement.

The Sixth Amendment would make one other significant change to the Settlement Agreement. It would clarify what it

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6. The May 3, 2003 deadline would be extended for Class Members who are entitled to an extension of time under § I.49 of the Settlement Agreement, as amended by the Revised Fifth Amendment to the Nationwide Class Action Settlement Agreement. See PTO 2677 at 9-10, 12-14.

means to "claim" Matrix benefits. Whether or not a Class Member has "claimed" these benefits will determine, among other things, that person's eligibility to exercise a Back-End or Sixth Amendment Opt-Out.

Currently, a Class Member may obtain benefits by filing with the Trust a fully completed and signed Green Form. However, Class Members frequently have submitted incomplete forms from which it is difficult to determine if the Class Member actually intends to exercise his or her right to assert a Matrix claim. The Sixth Amendment will provide clarity to these Class Members on this subject. Specifically, the Sixth Amendment proposes that a Class Member will be considered to have "claimed" Matrix benefits and thereby forfeited any right to pursue a Back-End Opt-Out if he or she sends to the Trust (1) Part I of a Green Form signed by the Class Member; or (2) Part II of a Green Form signed by a physician and a Blue Form signed by the Class Member in which he or she has indicated a belief or assertion of a Matrix level condition.

III.

Class Counsel and Wyeth seek approval of the changes embodied in the Sixth Amendment as fair, adequate and reasonable to Class Members. In Memorandum and Pretrial Order No. 2677, we noted that 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. PTO 2667 at 10-11. Nonetheless,

as we have determined previously, those standards for analyzing the fairness of a proposed settlement under Rule 23(e) of the Federal Rules of Civil Procedure are applicable to the extent that they fit the situation before us. Id.

The Third Circuit has explained that a court may "approve a proposed class action settlement ... if it is 'fair, adequate, and reasonable' to Class 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); see Girsh v. Jepson, 521 F.2d 153, 156-57 (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 ....

Harris, 761 F. Supp. at 394 (citing Girsh, 521 F.2d at 157). In the final analysis we must decide whether the addition of the Sixth Amendment is fair, adequate and reasonable for the Class Members, considering that they already have been provided in the Settlement Agreement with benefits and rights found to be fair, adequate and reasonable. Moreover, we need keep in mind, as

Class Counsel has reminded us, that there is no reason to believe Wyeth would agree to an Amendment that is more favorable to the Class Members than what is before us.

IV.

The crux of the objections to the Sixth Amendment relates to the new opt-out provision. As Class Counsel and Wyeth assert, this opt-out right would provide Class Members who claim Matrix benefits with at least some protection against the risk that their injuries will go uncompensated if in the future the Settlement runs out of money. As it is now, Wyeth contends that once its $3.75 billion contribution is exhausted, it has no further obligation to pay otherwise eligible Class Members whose Matrix claims have not been satisfied. No one seriously argues that any provision of the Settlement Agreement itself obligates Wyeth beyond that amount if the Trust fund cannot pay all claims. The Objectors argue instead that if the settlement fund becomes insolvent, any unpaid Class Members would not have received the benefit of their bargain and would be released from the Settlement Agreement and permitted to sue Wyeth without restriction based on various equitable and contractual principles. Among other things, the Objectors would argue that any unpaid Class Members would not have received adequate notice and representation under Rule 23(e). They also would contend that unpaid Class Members should be released from the Settlement on a mutual mistake of fact theory.

The legal effect any funding insufficiency would have on unpaid Class Members and the viability of the Settlement Agreement has, of course, not been resolved. While it was an appropriate issue for consideration at the Fairness Hearing, the court, for good reasons at the time, did not need to decide it since the uncontradicted evidence strongly pointed away from any such eventuality. The Settlement Agreement thereafter received court approval, including the imprimatur of the Third Circuit, as fair and reasonable. Although the Objectors urge us to answer the question of what happens if the well runs dry, we believe that principles of justiciability prevent us from doing so at this time. To establish standing, litigants must allege harm that is "actual or imminent, not 'conjectural' or 'hypothetical.'" Whitmore v. Arkansas, 495 U.S. 149, 155 (1990) (citations omitted). As the Supreme Court has explained, "[a] claim is not ripe for adjudication if it rests upon 'contingent future events that may not occur as anticipated, or may not occur at all.'" Texas v. United States, 523 U.S. 296, 300 (1998) (citations omitted). There is no evidence before the court that any shortfall is actual or imminent. Any funding depletion in the future remains speculative at this point. Moreover, we do not know if Wyeth would decide voluntarily to supplement the funds beyond any contractual requirement in order to avoid further litigation. Under the Sixth Amendment, a Class Member's right to sue is conditioned on Wyeth's election not to deposit

additional funds into the Trust.[7] Therefore, any decision on our part to determine what effect a shortfall might have if it does in fact occur would be advisory in nature.

The avoidance of possible future problems resulting from exhaustion of funds nevertheless underscores the value of the Sixth Amendment. If Wyeth is correct that its financial obligation to the class is capped at $3.75 billion, all agree that the Sixth Amendment provides a valuable benefit. The Sixth Amendment would provide Class Members who have claimed Matrix benefits and otherwise would go unpaid with a specific contractual right to pursue their compensatory claims against Wyeth. Without this new opt-out opportunity, these Class Members would go empty handed.[8] If, on the other hand, the Objectors are correct that a funding shortfall would extinguish the class settlement, leaving them free to pursue their tort rights unfettered, then Class Members will have lost nothing by our approval of the Amendment.

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7. For example, under proposed § IV.D.5.a of the Amendment, a Class Member would be eligible to exercise a Sixth Amendment Opt-Out if, among other things, "[Wyeth] has elected not to deposit additional funds into [the settlement fund] to pay such Class Member's Matrix Compensation Benefits."

8. Several Objectors contend that the Sixth Amendment would eliminate an existing Financial Insecurity Opt-Out which, they claim, already guarantees Class Members the right to pursue an unrestricted remedy in tort if the Settlement runs out of money. See Settlement Agreement § III.E.6-10. The Financial Insecurity Opt-Out only applies if Wyeth fails to pay to the Trust the money it specifically agreed to provide under the Settlement Agreement. It has nothing to do with the situation where Wyeth fulfills its contractual obligation but the funds are still insufficient to pay all legitimate Matrix claims.

The Objectors further complain that the Sixth Amendment unfairly and unreasonably restricts the new opt-out right. First, the Objectors contend that the Sixth Amendment Opt-Out strips Class Members of their rights to join plaintiffs and name additional defendants in any lawsuit filed against Wyeth. They concede, however, that the Sixth Amendment would confer upon Class Members a right that does not currently exist under the Settlement Agreement and that Class Members may not have in the absence of the Amendment if the Settlement runs out of money. Although this right comes at the price of certain restrictions and may not go as far as the Objectors would like, this is no reason to reject the Amendment. As we have previously noted, and as even the Objectors acknowledge, the other options for the class are not without uncertainty. In the event of a funding shortfall, class members cannot be at all sure they would be able to undo the Agreement and sue Wyeth in tort. We therefore believe that this objection is without merit.[9]

Second, the Objectors contend that the Sixth Amendment would unfairly permit Wyeth to "pick and choose" the claims that

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9. We reject two other related objections. First, the Objectors contend that courts may order consolidation of opt-out cases notwithstanding the express provisions of the Amendment to the contrary. Aside from conjecture, there is nothing in the record to suggest that any court, federal or state, would ignore the language of the Settlement Agreement in this regard. Second, the Objectors assert that the new opt-out right is valueless because unless Class Members are permitted to consolidate their cases, they will be unable to afford to litigate them. Again, because the Sixth Amendment provides an avenue of possible relief that is not otherwise available under the Settlement Agreement and otherwise may not be available under the law, we reject this argument.

it will pay if the Settlement runs out of money. Pursuant to the Amendment, if the Settlement experiences a funding shortfall, Wyeth would have the option to pay any eligible, but unpaid claims or leave them unpaid and subject only to the Sixth Amendment Opt-Out. This argument also is not persuasive. If Wyeth elects to pay a claim even though the Settlement has run out of money, then the Class Member who submitted that claim will certainly have received the benefit for which he or she originally bargained - a fully compensated Matrix level claim. On the other hand, any unpaid Class Members would be permitted to sue Wyeth for their compensatory damages under the Sixth Amendment Opt-Out. Either way, the Class Member is protected against the risk that he or she will be left uncompensated if the Settlement ultimately becomes insolvent. Although the Objectors insist that Wyeth will not administer this provision fairly, their assertion has no support in the record. Moreover, we expect all provisions of the Amendment to be implemented fairly and objectively.[10]

Third, the Objectors argue that the Sixth Amendment will be used by Wyeth to thwart any effort by Class Members to

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10. The Objectors argue as well that the Sixth Amendment would preserve unfairly $255 million for progression claims from Class Members who have received Matrix benefits and who are entitled to additional compensation because their medical conditions have worsened. They suggest that this money should be earmarked to pay eligible Class Members who have claimed benefits, but have not been paid. However, if the Settlement experiences a funding shortfall, those Class Members who have already received benefits would have no ability to opt out of the Settlement. Instead, the $255 million reserve would be their sole source of compensation. We therefore dismiss this objection.

collaterally attack the Settlement Agreement if the fund ultimately runs out of money. They appear to argue that, if approved, the Sixth Amendment will have finally decided the issue of what happens in the event of a funding shortfall and will thus prevent them from even contesting in a subsequent law suit whether the Settlement Agreement is void as a result of that shortfall. We disagree. The Amendment would do nothing to undermine a Class Member in subsequent litigation from challenging the validity of the original Settlement Agreement because of a funding shortfall. The Objectors have advised the court that their arguments would be predicated on, among other things, lack of proper notice to the class and representation and mutual mistake of fact prior to court approval in 2000. The approval of the Sixth Amendment would not change the relevant facts as they existed at that time.

V.

The Objectors also take issue with the language in the Amendment that clarifies what it means to claim Matrix benefits. As noted above, Class Members who claim these benefits are currently prohibited from exercising a Back-End Opt-Out right. Settlement Agreement § IV.D.4.b. The Agreement, however, does not specifically define what comprises the act of "claiming" benefits. The Sixth Amendment fills this gap. By clarifying what it means to claim benefits under the Settlement Agreement, uncertainty and resultant litigation over this issue is minimized. The proposed Amendment will help protect against the

risk that Class Members will inadvertently assert a claim for Matrix benefits when they actually intend to preserve their Back-End Opt-Out rights. This guidance is especially important given that the Trust frequently receives from Class Members only partially completed claims forms.

The Objectors raise two principal arguments that this proposed revision is neither fair nor reasonable. First, the Objectors contend that the Settlement Agreement cannot be read so narrowly that Class Members would forfeit their right to assert a Back-End Opt-Out simply by filing with the Trust a Green Form, or in this case, part of a Green Form. Instead, they argue that a Class Member does not claim benefits until he or she receives payment of those benefits. We disagree.

The word "claim" means "[t]o demand as one's own or as one's right; to assert; to urge; to insist." Black's Law Dictionary 247 (6th ed. 1990). Both of the methods by which the Sixth Amendment proposes that Class Members claim benefits are consistent with this definition. By signing Part I of the Green Form, a Class Member is asserting that he or she has a Matrix level condition, that he or she qualifies for a specific level of benefits given the severity of his or her condition and that the diet drugs caused the condition. Furthermore, Part I requires the Class Member to attest under penalties of perjury that the information being submitted is "true and correct to the best of his/her knowledge, information and belief." Similarly, by registering for benefits with the Blue Form and submitting Part

II of the Green Form, a Class Member is representing that he or she took the diet drugs for a certain length of time (Blue Form) and is providing proof through a physician's certification that he or she has a condition that qualifies him or her for benefits (Part II Green Form). Although a Class Member is required to submit a completed Green Form before he or she can be paid, we believe that it is nonetheless appropriate to consider those Class Members to have claimed benefits under the Settlement Agreement if they have completed one of the acts proposed in the Sixth Amendment.

Second, the Objectors argue that § IV.D.4.b was not intended to preclude a Class Member from exercising a Back-End Opt-Out if he or she qualifies for and has claimed benefits, but cannot be paid because the settlement fund is insolvent. Because a funding shortfall has not yet occurred, we reiterate that principles of justiciability preclude us from determining this issue now. See Texas, 523 U.S. at 300 (citations omitted); Whitmore, 495 U.S. at 155 (citations omitted). However, none of the Objectors has shown that the Sixth Amendment would deprive Class Members of any right they currently may have under the Settlement Agreement or otherwise to raise this issue should a funding inadequacy ultimately occur.

VI.

It is most important to emphasize that none of the Objectors has demonstrated that the Sixth Amendment deprives any Class Member even one iota of a right or benefit currently

enjoyed under the Settlement Agreement - an agreement which has received final judicial approval as being fair and reasonable. Instead, the objections are really directed to the point that the Sixth Amendment is adding merely the proverbial half a loaf when the Objectors want the addition of a full loaf. It is obvious that if one fairly, adequately and reasonably has a loaf and is then given another half, that person is still better off with the additional half even though he or she may be unhappy that even more is not now being provided. The half a loaf is particularly beneficial when it is possible that the full loaf may not be available in the future because of a Trust funding shortfall.

For the foregoing reasons, and after considering the Sixth Amendment in light of the relevant factors set forth by the Third Circuit in Girsh, we find that the objections are without merit. The Sixth Amendment to the Nationwide Class Action Settlement Agreement is approved as fair, adequate and reasonable.

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

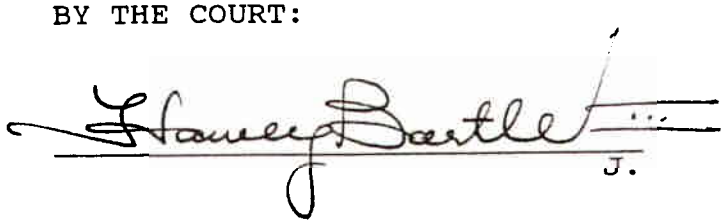
PRETRIAL ORDER NO. _____

AND NOW, this 12th day of March, 2003, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that:

(1) the Joint Motion for approval of the Sixth Amendment to the Nationwide Class Action Settlement Agreement with American Home Products Corporation is GRANTED; and

(2) the Sixth Amendment, attached hereto as Exhibit A, is incorporated into the Settlement Agreement approved by Pretrial Order No. 1415.

BY THE COURT:



J.