

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

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

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, J. December , 2004

Before the court is the motion of the AHP Settlement Trust ("Trust") "for instruction regarding auditing cardiologists." The Trust has now reported to the court that ten auditing cardiologists have received compensation from Wyeth¹ either shortly before or during the time they were auditing claims of class members who were seeking benefits from the AHP Settlement Trust. To avoid even the appearance of bias, the Trust contacted each of these auditors to request that they cease presenting Wyeth-sponsored lectures. In addition, these ten physicians are not currently auditing claims. The Trust now seeks to continue to use their services and avoid re-audit of the claims with which they were involved. Claimants represented by

1. Wyeth was previously known as American Home Products Corporation.

Napoli Kaiser Bern & Associates, LLP and Hariton & D'Angelo, LLP have filed a cross motion to remove these cardiologists or auditors and require re-audits of claims previously reviewed by them. Wyeth and Class Counsel have also responded to both motions.

The Nationwide Class Action Settlement Agreement ("Settlement Agreement") in this massive litigation involving Wyeth's diet drugs Pondimin and Redux provides for certain matrix compensation benefits for class members who ingested these drugs. The payments, funded by Wyeth, are made by the Trust, which was created under the Settlement Agreement. See Settlement Agreement § III; Pretrial Order ("PTO") No. 1415. The Settlement Agreement provided for audits of fifteen percent of the claims by board-certified cardiologists engaged by the Trust. See Settlement Agreement §§ VI.E & F. The Settlement Agreement also provided that where there is good cause shown, the court may order additional audits and/or adopt additional claims procedures as it deems appropriate. Settlement Agreement § VI.E.8. For the reasons set forth in PTO No. 2662, this court ordered that all claims for matrix benefits be audited.

The Trust has retained 90 cardiologists, 72 of which are currently available to audit claims for Matrix Compensation Benefits under the Settlement Agreement with Wyeth.² The Trust recently discovered that ten of these ninety physicians have been

2. The ten auditing cardiologists at issue in this motion are included in the 18 cardiologists not currently available to audit claims.

paid by Wyeth's Speakers' Bureau to lecture about ACE inhibitors, a type of heart medication unrelated to Pondimin and/or Redux. These ten received remuneration from Wyeth ranging from between \$500 and \$11,000 as described in the table below:

Auditor number in current motion	Date employed by the Trust	Date of Wyeth-sponsored lecture	Concurrent engagement by Wyeth & Trust	Money received from Wyeth	Audit Not-Payable (failure) rate
1	8/19/2003	2000 or 2001	No	\$500	39%
2	7/16/2003	9/21/2001 through 11/19/2003	Yes	\$3,500	85%
3	5/15/2003	9/21/2001 through 10/17/2003	Yes	\$5,750	82%
4	7/22/2003	7/10/2003 through 10/14/2003	Yes	\$1,000	78%
5	5/16/2003	10/2002 through 12/2002	No	\$1,500	36%
6	7/15/2003	3/2003 through 12/2003	Yes	\$1,000	38%
7	7/11/2001	9/2002 through 11/2003	Yes	\$5,150	54%
8	6/26/2001	3/2001 through 8/2003	Yes	\$4,000	69%
9	2/6/2003	2/2003 through 9/2003	Yes	\$11,000	28%
10	5/19/2003	1/2000 through 12/2002	No	\$4,000	55%

Each of the ten cardiologists completed the Trust's conflict questionnaires before being engaged as auditors. Each physician was asked:

Have you or a member of your immediate family ever received any compensation in the form of payments or other distributions from AHP, Wyeth or any manufacturer, wholesaler or distributor of Phentermine hydrochloride or Phentermine resin pharmaceutical product?

Have you or a member of your immediate family ever been an officer, director, employee, agent of or had a consultant relationship with AHP, Wyeth or any manufacturer, wholesaler or distributor of Phentermine hydrochloride or Phentermine resin pharmaceutical product? For the purposes of this paragraph, the term "consultant relationship" includes service as an investigator for research or clinical studies funded by AHP, Wyeth or any manufacturer, wholesaler or distributor of Phentermine hydrochloride or Phentermine resin pharmaceutical product?

Each responded that he had not received any compensation from AHP or Wyeth or any distributor or manufacturer of Phentermine products. See AHP Settlement Trust Auditing/Reviewing Cardiologist Questionnaire, attached as Ex. B to the Trust's Mot. for Instruction. On March 12, 2004, the Trust sent to the auditors a request for an information update for the purposes of clarifying its initial engagement questionnaire. The auditors were asked:

Have you ever trained for, registered with, been engaged by or given lectures for or on behalf of Wyeth, AHP or any manufacturer, wholesaler or distributor of Phentermine hydrochloride or Phentermine resin pharmaceutical products?

When the Trust learned that these cardiologists had participated in Wyeth-sponsored lectures, it asked them why they had not indicated their participation in these lectures on their conflicts questionnaires. Apparently, most of the auditors believed that the Trust's engagement questionnaires related to diet drugs because these auditors were being retained to audit claims for benefits under the diet drug Settlement Agreement. Thus, they did not consider their lectures on ACE inhibitors to be relevant or to raise concern about their independence. Many of these auditors also believed that the pharmaceutical marketing company (not Wyeth) that had recruited them to speak was responsible for their compensation. In addition, two of the auditors completed their initial conflicts questionnaires which referenced "AHP" rather than Wyeth, before they gave any of their lectures for the Wyeth Speakers' Bureau. These two auditors have advised the Trust that they were not aware that AHP had changed its name to Wyeth.

These ten auditing cardiologists performed a total of 841 audits. As to 363 of these audits, they accepted the attesting physicians' conclusions that benefits were due. As to the remaining audits, they rejected the conclusions of the attesting physicians. The auditing cardiologists found no reasonable medical basis with respect to 453 claims and a reasonable medical basis for payment but at a lower Matrix level for the remaining 25 claims.

We previously addressed the conflict of interest of an auditing cardiologist in PTO No. 3164. In that case, we held that one of the Trust's auditing cardiologists who had received remuneration from Wyeth for participation in several heart-related studies could not be considered an independent auditing cardiologist as required by the Settlement Agreement and PTO No. 2807.

Rule 2 of PTO No. 2807 provides:

1. Qualifications of Auditing Cardiologists.

The Trust shall maintain a pool of qualified Auditing Cardiologists for reviewing Claims in Audit. Each Auditing Cardiologist shall be an independent Board-Certified Cardiologist Absent Court approval, no person shall serve as an Auditing Cardiologist if that person is a Trustee of the Trust, has served as an Attesting Physician in more than ten Claims, or would be disqualified from serving as a Trustee under the provisions of Section VI.A.4.b of the Settlement Agreement.

Section VI.A.4.b of the Settlement Agreement provides that the following persons may not serve as Trustees and thus may not serve as auditing cardiologists:

i. Past or present officers, directors, agents, or employees of AHP [Wyeth] ... or any successor or any affiliates thereof.

...

vi. Persons ... who have any other financial interest in AHP [Wyeth] ... or any successor corporations or any affiliates thereof.

As in PTO No. 3164, the ten auditors who are the subject of the Trust's motion for instruction are or have been financially affiliated with Wyeth. Having received payments from

Wyeth for participation in Wyeth-sponsored lectures, they should not and cannot be considered independent auditing cardiologists as that term is used in PTO No. 2807 and in the Settlement Agreement. The fact that they may have misread the engagement questionnaire or did not understand what entity was paying them does not undermine our conclusion. Nor is it relevant that the auditors in issue were not in fact biased or that their services for Wyeth had nothing to do with diet drugs. Finally we are not persuaded that all is well simply because the ten auditing cardiologists did not deny claims in any greater numbers or percentages than other auditors. We reject the notion that the award of benefits by the Trust is merely a statistical exercise. What has occurred here adversely affects the integrity of the audit process as a whole as well as the integrity of individual audits. The appearance of conflicts of interest, as well as actual conflicts of interest, must be scrupulously avoided. In sum, those auditors who accepted compensation from Wyeth for serving on Wyeth's Speakers' Bureau have a "financial interest" in Wyeth and are accordingly not "independent Board-Certified Cardiologists" as required by the Settlement Agreement. See Settlement Agreement at § VI.A.4.b.vi.

The Trust and Wyeth argue that if the ten auditing cardiologists are disqualified and re-audits are ordered, we should require the re-audit of all 841 claims in which they were involved. Claimants represented by the law firms of Napoli Kaiser Bern & Associates and Hariton & D'Angelo also request that

qualified auditors redo all the audits performed by these ten physicians. Class Counsel maintains that if this court finds that a re-audit is necessary, it would be inappropriate to re-audit claims that passed an audit or those of claimants who did not contest them through the show cause process provided in PTO No. 2807.³

First, we see no reason at this point to require a re-audit of those 363 claims in which the auditing cardiologist found in favor of the claimants. Clearly, these claimants have not been harmed by any conflict of interest and they cannot, in hindsight, be concerned about the fairness of the process as it applies to them. For its part, Wyeth knew that these auditors had received compensation from it and should not now be entitled to a second bite at the apple. Any re-audits, of course, would

3. Under the show cause process, if a claimant contests the Trust's final post-audit determination, the Trust must file an application for issuance of an order to show cause seeking relief requested by the Trust. After the court has issued an order directing the claimant to show cause why the relief requested by the Trust should not be granted and referring the application to the Special Master for further proceedings, the claimant has the burden of proving to the court that there was a reasonable medical basis for the attesting physician's answer to each Green Form question at issue and/or the truth of all of claimant's representations of material fact in connection with the claim. If the court determines that there was no reasonable medical basis to support the attesting physician's answer to each Green Form question at issue and/or the claimant intentionally made a material misrepresentation of fact in connection with the claim, the court shall confirm the Trust's post-audit determination and may grant such other relief as it finds appropriate. If the court determines that there was a reasonable medical basis and/or that the claimant did not make an intentional misrepresentation of a material fact, the court shall enter an order directing the Trust to pay the claim in accordance with the Settlement Agreement. See PTO No. 2807.

cause further delay in the payment of benefits to these class members. Under the circumstances, we will not compel the Trust to incur the significant added expense and administrative burden of re-audits with respect to these 363 claims.

The remaining claimants present a far different picture. Of these, 453 claimants received audit determinations of "no reasonable medical basis" and 25 claimants were found to be entitled to a reduced benefit level. The only equitable remedy is to require the Trust to re-audit these claims if the claimants involved wish to have this done and to disqualify these ten auditors from performing future audits. The Trust must promptly advise these 478 claimants that the court has disqualified their auditing cardiologists and that the claimants may elect to have their claims re-audited by advising the Trust in writing within thirty days after notice. Any re-audits should be expedited.

We disagree with the argument of class counsel that no re-audit should occur for the claimants who did not challenge the auditing cardiologists' decisions through the show cause process under PTO No. 2807. Had claimants known when they received their audit results that the auditors in question may not have been independent, they may very well have contested the results through the show cause process. As explained in PTO No. 3164, the show cause process adds significantly to the time and expense of a final decision and is a process which one might decide to

avoid but only if an independent auditor had performed the initial review.

Finally, claimants contend that the Trust should be ordered to disclose the identities of the ten auditing cardiologists who are the subject of this motion and produce all communications between these auditors and the Trust and Wyeth. None of this would serve any useful purpose. The situation has now been remedied. The Trust has already provided the facts relating to these auditors' participation in Wyeth's Speakers' Bureau, the compensation received, and the number of claims they accepted, denied, or reduced to a lower Matrix level. Moreover, Class Counsel has identified the auditor codes that correlate to the Trust's audit statistics report filed in April, 2004. See Class Counsel's Resp. to the Trust's Mot. for Instruction and to Claimants' Cross Mot. at 10. Thus, all appropriate information concerning these ten auditors is available to the claimants and their counsel, appropriate re-audits are being ordered, and these non-independent cardiologists are being removed.

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SHEILA BROWN, et al.	:	
	:	
v.	:	
	:	
AMERICAN HOME PRODUCTS	:	
CORPORATION, et al.	:	CIVIL ACTION NO. 99-20593

PRETRIAL ORDER NO.

AND NOW, this day of December, 2004, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that:

(1) the motion of the AHP Settlement Trust ("Trust") for instruction regarding auditing cardiologists (Doc. #1381) is GRANTED in part and DENIED in part;

(2) the cross motion of certain claimants in opposition to the Trust's motion for instruction regarding auditing cardiologists (Doc. #1394) is GRANTED in part and DENIED in part;

(3) the Trust remove as auditing cardiologists the ten cardiologists who are the subject of its motion;

(4) no further audits are required for the 363 claims where the auditing cardiologists concurred with the attesting physicians that the claims were payable;

(5) the Trust shall promptly give notice to the claimants whose claims were audited by the ten auditing cardiologists at issue and received audit determinations of "no reasonable medical basis" or a reduced Matrix level that their auditing cardiologists have been disqualified as auditors. Each such class member shall be given an opportunity to have his or her claim re-audited by an independent auditing cardiologist. Any such election by a class member for a re-audit must be made in writing within thirty days after notice is sent by the AHP Settlement Trust. The election must be signed and dated by the class member, or in the case of a deceased class member, by his or her personal representative. Any such re-audits shall be expedited; and

(6) the motion of certain claimants for further discovery with respect to the identification of the ten auditing cardiologists and communications by the Trust and Wyeth with them is DENIED.

BY THE COURT:

J.