

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

MEMORANDUM AND PRETRIAL ORDER NO. 5632

Bartle, J.

August 26, 2005

Before the court is the motion of the AHP Settlement Trust ("Trust") for permission to conduct new audits of certain Matrix claims. These are claims which the Trust's auditing cardiologists preliminarily approved prior to the Seventh Amendment stay but which had not been the subject of Post-Audit Determination Letters because of the intervening stay.

The court approved the Nationwide Class Action Settlement Agreement ("Settlement Agreement") involving Wyeth's diet drugs Pondimin and Redux in Pretrial Order ("PTO") No. 1415 on August 15, 2000. Under the Settlement Agreement, the Trust was established to administer and pay claims, including what are known as Matrix claims. A class member claiming Matrix benefits must demonstrate entitlement to them by submitting to the Trust an echocardiogram read by a board-certified cardiologist who has attested that the class member's condition meets the definitions

set forth in the Settlement Agreement. Settlement Agreement § VI.C. The Settlement Agreement and various subsequent pretrial orders entered by the court also provided for certain audit procedures. See PTO No. 2807 (E.D. Pa. Mar. 26, 2003). These audits were to be conducted by board-certified cardiologists engaged by the Trust on fifteen percent of the claims for Matrix benefits submitted to 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 court stayed Matrix claim processing on May 10, 2004 while the parties were negotiating the Seventh Amendment to the Settlement Agreement. See PTO Nos. 3511 (E.D. Pa. May 10, 2004); 3725 (E.D. Pa. July 13, 2004); 3747 (E.D. Pa. July 22, 2004); 3786 (E.D. Pa. Aug. 15, 2004). Among other things, the purpose of the Seventh Amendment was to streamline the benefit-eligibility criteria by removing the bulk of Matrix processing from the Trust and to cause the benefits process to be administered more efficiently.

In our Memorandum and PTO approving the Seventh Amendment, we documented the concerns of Wyeth, Class Counsel, and the Trust about the integrity of Matrix claims submitted to the Trust. See PTO No. 4567 (E.D. Pa. Mar. 15, 2005). As a

result of allegations surrounding the validity of these claims, the Trust requested a panel of cardiologists led by Dr. Joseph Kisslo to review the integrity of pre-stay payable PADL claims before they were paid. The panel discovered several alterations of echocardiogram machine controls, exaggeration of the size or duration of regurgitant jets, and other manipulations that make normal flow patterns appear to qualify for Level II Matrix benefits. In addition, the Panel found anachronistic frames inserted in approximately 85 of the 968 pre-stay payable PADL claims.<sup>1</sup>

Prior to entry of the May 10, 2004 stay on processing Matrix claims, the Trust had conducted audits of 934 claims that were the subject of a preliminary audit result but for which no Post-Audit Determination Letter ("PADL") had been issued.<sup>2</sup> In 597 of those claims, the Trust auditing cardiologists returned data from their review of the claims that appears to support the presence of medical conditions required for a Matrix claim. The Post-Audit Determination ("PAD") claimants were informed of their right to remain in the Seventh Amendment or to complete and

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1. In Memorandum and PTO No. 5517 (E.D. Pa. July 27, 2005), we addressed the issue of how the Trust should handle any claim based upon an echocardiogram with an inserted frame.

2. In addition, before we entered the stay, approximately 968 claimants had received PADL's advising that their claims were potentially payable. We recently addressed the Trust's allegations that some pre-stay payable PADL claims lack integrity in our Memorandum and PTO denying the motion of Wyeth and Class Counsel's "for the entry of an order adopting a Court-Approved Procedure ("CAP") with regard to the 'Pre-Stay Payable PADL Claims.'" See PTO No. 5625 (Aug. 24, 2005).

submit a Seventh Amendment Opt-Out Form if they wanted to remain in the existing Trust. Of the 597 PAD claims that preliminarily passed audit, 202 opted out of the Seventh Amendment.<sup>3</sup>

In the instant motion, the Trust seeks permission to perform additional audits of the 202 PAD claims that were reviewed by Trust auditing cardiologists and for which the data returned from audit preliminarily appeared favorable. The Trust contends that there is good cause for the court to authorize new audits of the PAD claims because the majority of claims submitted to the Trust are medically unreasonable or the product of deceptive sonographic techniques. In April, 2005, the Trust's auditing cardiologists received additional training to help them identify true valvular regurgitation that meets the requirements of the Settlement Agreement and to detect the most common manipulations. The Trust asserts that a re-audit of the 202 PAD claims under its new quality assurance procedures would allow the Trust to pay benefits with a greater degree of certainty to those claimants who have demonstrated compensable injuries. It further maintains that absent new audits, it will be required to litigate

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3. In its motion for permission to conduct new audits, the Trust seeks to re-audit 201 PAD claims. However, in its reply, the Trust indicates that there are 202 claimants with PAD claims. Accordingly, we will address the Trust's motion as it pertains to the 202 claimants listed on Exhibit A of the Trust's reply.

The 202 PAD claims do not include any claims that remain in the Trust and were submitted by the Napoli, Kaiser & Bern and Hariton & D'Angelo law firms, all of which are subject to the stay imposed by PTO Nos. 4485, 4749, and 5399.

with the PAD claimants over millions of dollars of claims on the issue of whether echocardiograms were improperly manipulated.

Many of the 202 PAD claims are supported by echocardiogram images that are alleged to have been generated by "echocardiogram mills," or facilities in hotels and other non-medical sites utilized to conduct large numbers of echocardiograms. Wyeth and Class Counsel contend many of the echocardiograms generated from such facilities were manipulated and lack any reasonable medical basis to support a Matrix claim. See Seventh Amendment Fairness Hearing Tr. 1/18/05 at 39.

We previously addressed similar issues involving claims based on echocardiograms that appear to have intentional manipulations in our Memorandum and PTO denying Class Counsel and Wyeth's proposed CAP that would govern pre-stay payable PADL claims. See PTO No. 5625 (Aug. 24, 2005). The same concerns about intentional manipulation of echocardiogram tapes or discs are at issue here. As with the pre-stay payable PADL claims, these are serious charges, with some tens of millions of dollars in potential payments at stake.

Of the 202 claimants with PAD claims, 185 have not objected to the Trust's motion to re-audit. Three class members represented by Carey & Danis, L.L.C. (the "Cary & Danis claimants") oppose the Trust's motion on the ground that "clean" echocardiograms should not be subjected to "double jeopardy" regarding "the auditing cardiologists' subjective findings." Carey & Danis Mem. at 1. These class members submitted claims

supported by echocardiograms that were performed in medical environments and not in "echocardiogram mills." We do not agree that a re-audit for good cause shown pursuant to § VI.E.8 of the Settlement Agreement constitutes "double jeopardy." This court has previously authorized re-audits when confronted with similar allegations of misconduct. See e.g., PTO No. 5517 (E.D. Pa. July 27, 2005).

In response to the Carey & Danis claimants' objection, the Trust asserts that it will not perform re-audits for PAD claimants who do not want them. However, for each PAD claim where the claimant elects to stand on his or her original audit, the Trust will review the claim under the Claims Integrity Program ("CIP") and issue a PADL within 60 days of receiving the claimant's election. The Carey & Danis claimants agree with the Trust's proposed modification. See Carey & Danis Surreply at 1.

Eleven claimants represented by Brent Gordon, Esquire (the "Gordon claimants"), also object to the Trust's motion. They argue that under § VI.E.7 of the Settlement Agreement, once a claim passes audit, the claimant "is paid without any further appeal." However, the Settlement Agreement also provides that a Matrix claim "shall be allowed" only if the claim has a "reasonable medical basis" and "if there is no substantial evidence that the Class Member or AHP intentionally made a material misrepresentation of fact in connection with a Claim." Settlement Agreement § VI.E.7. Accordingly, a favorable audit result is a necessary but not a sufficient prerequisite to

payment. Moreover, as previously noted, the good cause provision of the Settlement Agreement authorizes re-audits where there is evidence of intentional, material misrepresentation. Settlement Agreement § VI.E.8.

Both the Carey & Danis claimants and the Gordon claimants allege that the "Special Notice" did not warn claimants with PAD claims about the potential for a full re-audit. We disagree. The Special Notice to PAD claimants approved by the court in PTO No. 3926 stated:

Although the Trust's Auditing Cardiologist has found your claim to be potentially payable, the Trust has not concluded the post-Audit processing of your claim ... Your claim is still subject to the Trust's Claims Integrity Program which may include review of the Echocardiogram tape or disk you submitted with your claim to make sure that the tape or disk has not been improperly altered or is otherwise indicative of possible fraud.

See Special Notice to Category One Claimants ("Special Notice"), attached to PTO No. 3926 as Ex. 1. The Special Notice further explained that a "claim will not be paid unless and until the Trust concludes any permissible investigations and determines that payments are warranted." Id.

In our Memorandum and PTO approving the Seventh Amendment, we found that the notice program as a whole, including the Special Notice to PAD claimants, was "highly effective" and complied with the requirements of due process and Rules 23(c)(2) and 23(e) of the Federal Rules of Civil Procedure. To the extent claimants object to the Trust's proposed re-audit on the basis

that they did not receive notice of the potential for re-audit, these objections are without merit.

The Gordon claimants have also filed a motion to enforce the Settlement Agreement and compel payment of Matrix Compensation Benefits. The Trust asserts that the eleven claims at issue in the Gordon claimants' motion are based upon echocardiograms in which the settings and measurements exaggerate the size of a regurgitant jet to create the false impression of a payable Matrix claim. All of the echocardiograms supporting the Gordon claimants' claims were performed by the Sound Source mobile echocardiogram company. In its opposition to the Gordon claimants' motion, the Trust has submitted evidence of misrepresentations in each of the eleven claims for which these claimants seek to compel payment. Based on this evidence, the Trust intends to deny the claims of these eleven claimants pursuant to § VI.E.7 of the Settlement Agreement.

Although we recognize that some of the 202 PAD claims may ultimately be payable, paying any of these claimants Matrix benefits when their claims are found to contain intentional misrepresentations would be improper and deplete the limited funds of the Trust. As we explained in our Memorandum and PTO denying Wyeth and Class Counsel's application for a pre-stay payable PADL CAP, "[s]imply because an undeserving claim has slipped through the cracks so far is no reason for this court to put its imprimatur on a procedure which may allow it to be paid." See PTO No. 5625 (Aug. 24, 2005). We will deny the motion of the



Gordon claimants to enforce the Settlement Agreement and to compel payment of Matrix benefits.

In addition, two claimants represented by Morris & McAnnally, LLC and K. Stephen Jackson, P.C. oppose the Trust's motion. These claimants have also filed a motion to enforce the Settlement Agreement and compel payment of benefits. They rely on the same arguments asserted by the Gordon claimants. Thus, we will deny their motion.

For all the foregoing reasons, we will grant the motion of the Trust for permission to conduct new audits. The Trust shall promptly give notice to each class member listed on Exhibit A that it will re-audit the class member's claim unless the class member notifies the Trust of his or her election not to undergo re-audit. Any such election by a class member must be made in writing within thirty days after notice is sent by the 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. Within sixty days after receipt of a claimant's election not to have a re-audit, the Trust shall issue a Post-Audit Determination Letter. Claimants may contest such determinations and, after considering any contested materials, the Trust shall issue Final Post-Audit Determinations. If any claimant challenges a Final Audit Determination, his or her claim shall then proceed through the show cause process as established in PTO No. 2807.

The Trust shall promptly conduct new audits pursuant to the Rules for the Audit of Matrix Compensation Claims for each of the 202 PAD claims listed on the attached Exhibit A unless a claimant elects not to have a re-audit. See PTO No. 2807.

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

PRETRIAL ORDER NO. 5632

AND NOW, this 26th day of August, 2005, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that:

(1) the motion of the AHP Settlement Trust ("Trust") for permission to conduct new audits (Doc. # 2091) is GRANTED;

(2) the Trust shall promptly give notice to each class member listed on Exhibit A that it will re-audit the class member's claim unless the class member notifies the Trust of his or her election not to undergo re-audit. Any such election by a class member must be made in writing within thirty days after notice is sent by the 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;

(3) within sixty days after receipt of a claimant's election not to have a re-audit, the Trust shall issue a Post-

Audit Determination Letter, and, after any contest, a Final Post-Audit Determination Letter;

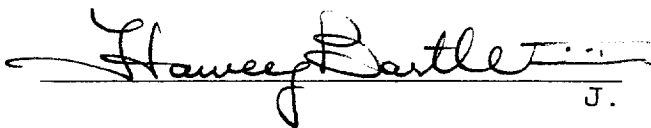
(4) any claimant may contest a Post-Audit Determination and may challenge any Final Post-Audit Determination through the show cause process pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), which were established in Pretrial Order No. 2807;

(5) the Trust shall promptly conduct new audits pursuant to the Audit Rules for each of the PAD claims listed on the attached Exhibit A unless a claimant elects not to have a re-audit;

(6) the motions of claimants represented by Brent Gordon, Esquire, Morris & McAnnally, LLC, and K. Stephen Jackson, P.C. to enforce the Settlement Agreement and to compel payment of benefits (Docs. #2114, #2134) are DENIED; and

(7) the motion of claimants Sherial Wiser, Larry Rocher and Linda Baitz for leave to file a "surreply to the Trust's reply memorandum in further support of its motion for permission to conduct new audits" (Doc. #2125) is GRANTED.

BY THE COURT:

  
J.

**Exhibit A**

61184	8024758	8173384
202846	8025517	8173428
415034	8026924	8173439
1235969	8028482	8175727
1289669	8031281	8176439
1328848	8032643	8177083
1607860	8036242	8177324
1648591	8038374	8178101
1959279	8038899	8178204
1967116	8041347	8178295
2173482	8042803	8178361
2258549	8043651	8178444
2264497	8046222	8178520
2348621	8046682	8178733
2423846	8046973	8178742
2430189	8049449	8178792
2556421	8054124	8179044
2634640	8056043	8179249
2700086	8062026	8180267
2713865	8063690	8180513
2775377	8063732	8181135
2778116	8064217	8181428
2843068	8074029	8182193
2859486	8078432	8182927
3172228	8080042	8182960
3181039	8090014	8182994
3442431	8092505	8183335
3541513	8096764	8183353
3548740	8122673	8183522
3614666	8122933	8183530
8002291	8126892	8183532
8002857	8127198	8183630
8012310	8149411	8183633
8014400	8152979	8183675
8014586	8160339	8183678
8014749	8160764	8183703
8018141	8162678	8183712
8018578	8168315	8183719
8018899	8170587	8184129
8019330	8171073	8184241
8020202	8171730	8184242
8021518	8172924	8184243
8024451	8172996	8184282
8024544	8173058	8184316

8184336	8186738	8195606
8184382	8186746	8195609
8184687	8186765	8195884
8184786	8186831	8196526
8184837	8186848	8197161
8184904	8186930	8197175
8184906	8187409	8197184
8185183	8188276	8198927
8185195	8188518	8199404
8185425	8188593	8200070
8185518	8188658	8203536
8185571	8188667	8214479
8185879	8189025	8215247
8185909	8189268	8215974
8185918	8189606	8219341
8186067	8189862	8221193
8186091	8189975	8230978
8186287	8190122	8233768
8186344	8192049	8242984
8186636	8192089	8244440
8186644	8192752	8246140
8186649	8193292	8256708
8186696	8195482	
3186590	8195532	