

# Exhibit 1

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

PRETRIAL ORDER NO. 2640

AND NOW, this 14<sup>th</sup> day of November, 2002, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that:

(1) the AHP Settlement Trust ("Trust") shall not pay the claims of the following class members submitted by the law firms of Hariton & D'Angelo, LLP and/or Napoli, Kaiser, Bern & Associates, LLP without prejudice to the right of said claimants to submit new echocardiograms and Green Forms signed by a certifying cardiologist other than Linda J. Crouse, M.D. or Richard L. Mueller, M.D.: James Axford; James Barone; Charline Bergman; Victor Bevilaqua; Fritz Blumenberg; Katherine Brandon; Ellen Brownstein; Lashauna Burkett; Judy Butts; Darlene Campbell; Christine Canton; Glenique Carter; Laura Chicchetti; Donald Clark; Mildred Creach; Vernessa Cruse; Chris Cunningham; Girard Curry, Jr.; Renita Dale; Scott Dale; Cathy Darpell; Silvio Dobry;

Frank Folsom; Debra Fuller; Peter Gehrt; Gail Gielarowski;  
Junetta Godwin; Jean Gomes; Patricia Guthrie; Carolyn Hackman;  
Bridget Hara; Vicky Hill; Brenda Hobeck; Janice Hodge; Patricia  
Jackson; Maryann James; Cathy Jefferson; Carly Jones; Mary  
Kimrey; Sheila Koch; Geralyn Kosofsky; Arlene Kule; Karen Lack;  
Kathleen Liggett; Josephine Lobuzzetta; Ron Lybarger; Cynthia  
Mallory; Linda Mark; Susan Marr; Louis Martorella; Barbara  
Meszaros; JoAnn Mina; Prudence Mougis; Carolyn Newman; Jessica  
Orr; Eugene Paulen; Amy Peters; Sharon Pickett; James Pierce;  
Michael Piper; Julia Purdy; Cynthia Read; Nancy Richard; Pamela  
Roberts; John Rodriguez; Joseph Rogers; Rick Ross; Betty  
Rutherford; Barbara Ryan; James Scaletty; Kathleen Scheve;  
Charles Schoenhair; Maretta Smith; Dorothy Snodgrass; Connie  
Stogsdill; Evette Vititoe; Brenda Williams; and Gwendolyn  
Winklbauer;

(2) the Trust has full authority to audit under the Settlement Agreement each and every echocardiogram and Green Form already submitted or to be submitted in the future on behalf of a class member wherein either Linda J. Crouse, M.D. or Richard L. Mueller, M.D. is the certifying cardiologist;

(3) the Trust has full authority to audit under the Settlement Agreement each and every echocardiogram and Green Form already submitted or to be submitted in the future on behalf of a class member by the law firms of Hariton & D'Angelo, LLP and/or Napoli, Kaiser, Bern & Associates, LLP or any attorneys

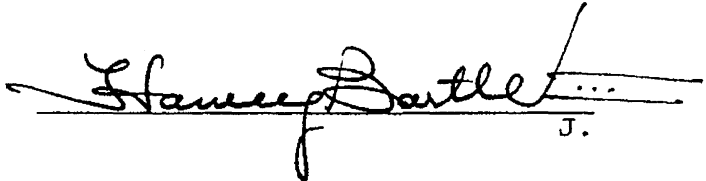
affiliated or associated in any way with those law firms,  
regardless of the identity of the attesting cardiologist;

(4) the Trust has full authority to withhold payment  
of any claims identified in paragraphs (1), (2), and (3) pending  
the completion of the audit process;

(5) notwithstanding anything to the contrary, the  
echocardiograms already submitted to the Trust or to be submitted  
in the future and certified by Linda J. Crouse, M.D. or Richard  
L. Mueller, M.D. may form the basis for a finding by the Trust  
that a class member is FDA positive or has mild mitral  
regurgitation for purposes of §§ IV.A.1.c, IV.A.2.c, IV.B.1 and  
IV.D.3-4 of the Settlement Agreement; and

(6) the movants' request for counsel fees is DENIED.

BY THE COURT:

  
J.

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MEMORANDUM AND PRETRIAL ORDER NO. 2640

Bartle, J.

November 14, 2002

The matter presently before the court concerns the propriety of seventy-eight claims for benefits under the class action settlement involving the diet drugs commonly known as fen-phen. The AHP Settlement Trust (the "Trust"), joined in by Wyeth (formerly American Home Products or AHP) and Class Counsel, has moved to prevent having to pay those claims which were all submitted to the Trust by the New York firms of Hariton & D'Angelo, LLP and Napoli, Kaiser, Bern & Associates, LLP (the "Hariton and Napoli firms") on behalf of their clients and which were certified by one or the other of two cardiologists the Hariton and Napoli firms engaged. The moving parties contend that these certifications were medically unreasonable. Accordingly, they assert that those class members on whose behalf

the medically unreasonable certifications were submitted do not meet the definition for payments under the court approved Settlement Agreement. Movants also seek authority "for good cause shown" to audit more claims than presently allowed under the Settlement Agreement as well as additional relief with respect to the two law firms and the two attesting physicians.

I.

The class action settlement of this massive tort litigation provides for payments 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"). One of the serious conditions caused by the use of these diet drugs was a form of valvular heart disease known as moderate or more severe mitral regurgitation. Whether a person has mitral regurgitation at these levels can be determined only after the administration and reading of an echocardiogram. Any claim for benefits must be attested to or certified by a cardiologist or cardiothoracic surgeon.

The Settlement Agreement contains a series of conditions that govern whether so-called Matrix benefits will be paid to a class member and, if so, in what amount. It is the Trust, established under the Settlement Agreement, which reviews submissions for benefits and administers what is known as Fund B out of which the benefits and associated administrative costs are paid with funds supplied by Wyeth. Pretrial Order No. 1415 at

62. The Trust is overseen by trustees appointed by the court. Under the Settlement Agreement, Wyeth agreed to contribute \$2.55 billion to Fund B. Id. From it, the Trust had paid claimants more than \$775 million as of June 30, 2002.

The motion before the court was originally filed by the Trust on July 11, 2002 as a "Motion for a Temporary Restraining Order and Preliminary Injunction." At the time, the Trust urged the court, among other things, to prevent the Hariton and Napoli firms from falsifying certain information that they were submitting to the Trust and from misleading class members about their association with the Trust. In large part, the Trust's motion was based on the declaration of C.V. Compton Shaw, a registered nurse who was hired by the Hariton and Napoli firms, albeit briefly, and who attended a training session that the firms conducted in Dallas, Texas on March 13, 2002. After a conference with counsel on July 16, 2002, this court scheduled a hearing for August 15, 2002. See Pretrial Order No. 2524.

At a prehearing conference on August 15, the moving parties advised the court that they were abandoning their reliance on Mr. Shaw's Declaration because of concerns about his credibility. Instead, after further review of certain claims submitted by the two law firms, movants had now determined that the certifications by several cardiologists of moderate or more severe mitral regurgitation were medically unreasonable. The Trust explained that it was on the verge of paying out nearly \$50 million for what it believed to be ineligible claims submitted by

the Hariton and Napoli firms.<sup>1</sup> This money would be difficult, if not impossible, to recoup if it turned out after a hearing that these claimants were not entitled to benefits. Moreover, a serious issue existed whether sufficient funds would be available to pay eligible claimants if non-qualified persons received payments. While Wyeth's obligation with respect to Fund B is certainly large, it is not unlimited, and there are thousands of potential beneficiaries. Due to the shift in the movants' focus, the court cancelled the August 15 hearing with the consent of all parties.

The Hariton and Napoli firms, however, were eager for a hearing to be held to seek to remove the cloud that now was hanging over them and to have resolved without undue delay the dispute over claims that they contend were legitimate. Taking into consideration these competing concerns, the court decided to maintain the status quo but to set a prompt hearing. It ordered the Trust:

temporarily [to] discontinue making payments associated with any Matrix Claims that either Hariton & D'Angelo, LLP or Napoli, Kaiser, Bern & Associates, LLP [has] submitted to the Trust and that are scheduled to be paid on or before August 30, 2002, (1) unless the Trust determines that the Class Member has the medical conditions necessary for eligibility for Matrix Compensation Benefits under the

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1. Specifically, the Trust was scheduled to pay more than \$2.1 million for six claims on August 16, 2002 and approximately \$4.3 million for ten claims on August 30, 2002. In addition, the Trust explained that it was likely to pay more than \$44 million for 104 claims on or after September 13, 2002. Based on a review by their expert, the Trust asserted that only seven claims totaling more than \$3.2 million were eligible for payment.

Settlement Agreement, or (2) until further order of the court.

Pretrial Order No. 2572.

The hearing was rescheduled for September 3, 2002. In an effort to expedite matters and to give the Hariton and Napoli firms a fair opportunity to prepare, the court advised the Trust and other moving parties that it would be limited to presenting evidence as to eighty-eight certifications submitted by those firms. Fifty-five of these certifications were signed by cardiologist Linda J. Crouse, M.D. and thirty-three by cardiologist Richard L. Mueller, M.D. Although the court was willing to set the hearing for a date later than September 3 to afford the non-movants more time to prepare, their counsel assured the court that they could and would be ready. The hearing went forward as planned and lasted six days. During the hearing, the number of contested attestations was reduced to seventy-eight, fifty-three by Dr. Crouse and twenty-five by Dr. Mueller.<sup>2</sup>

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2. The number of disputed claims was reduced from eighty-eight to seventy-eight as the hearing proceeded. The Trust declined to challenge attestations for claimants Kathleen Mannix and Michael Schulman because Dr. Mueller's certification was not the basis for the claim, although he had at one point performed an echocardiogram for each. In addition, the Trust withdrew its challenge to the attestation for claimant Susan Orgass. The Trust's expert did not contest the medical reasonableness of certifications for claimants Florence Adams, Toni Delligatti, Ruth Enloe, Linda Morales and Anthony Vaccaro. Finally, the Trust's expert did not opine as to the echocardiogram readings for claimants Patricia Cruz and Kathleen Kelly-Lyon because, in his opinion, the tapes were "not evaluable." See Movant's Ex. 94.

## II.

As noted above, moderate mitral regurgitation is among the medical conditions that qualify a claimant for Fund B Matrix level benefits from the Trust. This condition involves the backward or reverse flow of blood through a defective mitral valve which separates the left atrium of the heart from the left ventricle.

The heart consists of four chambers: the right atrium, the right ventricle, the left atrium and the left ventricle. These chambers are connected by valves consisting of two leaflets. They open to allow blood to pass through and then close. This rapid process ensures the proper directional flow of blood through the heart.

The chambers of the heart fill and empty in a seamless, two-phase cardiac cycle that comprises diastole, the filling cycle, and systole, the emptying cycle. Initially, deoxygenated blood enters the heart through the right atrium. During diastole, the tricuspid valve opens and blood is pumped into the right ventricle where it collects before being expelled. As systole begins, the right ventricle contracts and the blood is ejected into the pulmonary arteries. The blood is then carried through these arteries into the lungs where it is re-oxygenated before passing back into the left atrium of the heart through the pulmonary veins. During diastole, the mitral valve opens and blood moves from the left atrium into the left ventricle. Thereafter, the mitral valve shuts. As systole begins, the left

ventricle contracts and expels the blood through the open aortic valve into the aorta and the rest of the body. The aortic valve then closes to prevent any expelled blood from returning to the left ventricle.

Mitral regurgitation occurs during the systolic phase as the left ventricle contracts and pushes blood into the aorta. Because the leaflets comprising the mitral valve have failed to shut properly, blood leaks backward, or regurgitates, 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.

It is important to emphasize that not all levels of mitral regurgitation are medically significant. Mild and trace regurgitation, two lesser grades of valvular regurgitation identified in medical literature, are normal and exist in approximately ninety percent of the population. Only when mitral regurgitation reaches the moderate level does it become a serious medical condition.

Under the class action Settlement Agreement, to be entitled to Matrix benefits for mitral valve damage, a claimant must be diagnosed as having moderate or greater mitral regurgitation.<sup>3</sup> Settlement Agreement §§ IV.B.1-2. Moderate

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3. To qualify for benefits, a prospective claimant with moderate or more severe mitral regurgitation also must demonstrate that he or she has one of five medical conditions as set forth in the Settlement Agreement. See Settlement Agreement §§ IV.B.2.c.2.b.i-v. For present purposes, the movants do not dispute whether any of the claimants at issue satisfies these  
(continued...)

mitral regurgitation is defined as "20%-40% RJA/LAA." Id. at §IV.B.2.c.2.b. RJA in the numerator of the fraction represents Regurgitant Jet Area while LAA in the denominator stands for Left Atrial Area. For moderate mitral regurgitation to be present, the size of the reverse flowing jet of blood at its most expansive point must encompass between twenty percent and forty percent of the area of the left atrium.<sup>4</sup> Depending on other factors not currently relevant, a claimant with qualifying mitral regurgitation may receive between \$38,422 and \$643,500 in benefits from the Trust.<sup>5</sup> See id. at § IV.B.2.a.

Whether a claimant has moderate or more severe mitral regurgitation is determined according to the protocol outlined in the Settlement Agreement. First, a claimant must undergo a qualifying echocardiogram, that is, an ultrasound of the heart. During the procedure, a cardiologist or sonographer places a transducer on the patient's chest that directs high frequency

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3.(...continued)  
additional criteria. Movants only challenge the medical reasonableness of the findings of moderate or more severe mitral regurgitation.

4. A claimant with such regurgitation is eligible for compensation under Matrix A-1 unless he or she has one or more "reduction factors" as noted in the Green Form, in which case, benefits are determined in accordance with Matrix B-1. The presence of any one of these factors, which cannot be determined by echocardiogram, establishes for the purposes of this Settlement that a claimant's valvular regurgitation was caused by something other than the use of diet drugs.

5. By contrast, a claimant with mitral regurgitation at 19.9% RJA/LAA, a level just below moderate, is ineligible for benefits. Such a claimant may, however, become eligible in the future if his or her condition worsens. See Pretrial Order No. 1415 at 47.

sound waves into the heart. As the sound waves bounce off the surface of the body and back to the transducer, they create a moving image of the heart, its valves and blood flow. This moving image is recorded on a videotape throughout the procedure. In addition, the sonographer or cardiologist often will make a digitized version of the video, which will contain a subset of the videotaped images including still frames and loops.<sup>6</sup> Because the image being taken is constantly moving, the cardiologist or sonographer performing the echocardiogram must periodically freeze the image on the screen in order carefully to trace or planimeter the boundary of the regurgitant jet and left atrium. Only after reviewing multiple loops and still frames can a cardiologist reach a medically reasonable assessment as to whether the twenty percent threshold for moderate mitral regurgitation has been achieved.

The Settlement Agreement establishes specific criteria for conducting an echocardiogram. An echocardiogram must be:

- (1) conducted in accordance with the standards and criteria outlined in Feigenbaum (1994) or Weyman (1994);
- (2) evaluated following the grading system of valvular regurgitation defined in Singh (1999);
- (3) conducted by a Diagnostic Cardiac Sonographer who is able to produce and evaluate ultrasound images and related data used by physicians to render a medical diagnosis; and

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6. A loop shows the heart through one filling and emptying cycle.

(4) conducted under the supervision of, and read and interpreted by, a Board-Certified Cardiologist ... with level 2 training in echocardiography ....

Id. at § VI.C.1.b (citations omitted). In addition, according to the 1999 Singh article referenced in § VI.C.1.b.2, the sonographer or cardiologist conducting the echocardiogram must measure the presence and severity of mitral regurgitation using the color flow Doppler modality.<sup>7</sup> See Jagmeet P. Singh, M.D., et al., Prevalence and Clinical Determinants of Mitral, Tricuspid, and Aortic Regurgitation (The Framingham Heart Study), 83 Am. J. Cardiology 897-901 (March 15, 1999). Color flow Doppler provides information about the direction and speed of blood flow as well as the duration of any regurgitant jet. Under this modality, blood flow that is moving away from the transducer will appear as blue, while blood flow moving toward the transducer will appear as red.

As a condition for benefits, the echocardiogram also must reveal a regurgitant jet that consists of "blue, green or mosaic signals ... originating from the mitral valve and spreading into the left atrium during systole." Movant's Ex. 101 at 22. On a color flow Doppler echocardiogram, mitral

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7. Color flow Doppler is one of five modalities of echocardiography. The others include M-Mode, two dimensional echocardiography, continuous wave Doppler and pulsed-wave Doppler. A practicing cardiologist may use any or all of these modalities during an echocardiogram. However, the Settlement Agreement and Green Form refer to the use of color flow Doppler to measure the existence and severity of mitral regurgitation. Neither authorizes the use of continuous wave Doppler in measuring the severity of mitral regurgitation.

regurgitation will thus display as a high velocity, mosaic blue/green teardrop shaped jet that borders the mitral valve leaflets and expands into the left atrium throughout at least a portion of systole.<sup>8</sup> As a sign of the high velocity, the jet often will contain multicolored blue, green and yellow stripes, a phenomenon known as "aliasing." Aliasing is a hallmark characteristic of a high velocity mitral regurgitation jet.

The process of taking and interpreting an echocardiogram requires considerable skill and training. An echocardiogram displays the heart in constant motion, beating in real time. A regurgitant jet, which will appear only during systole, lasts for a mere fraction of a second. To confirm mitral regurgitation, a cardiologist will have to review numerous frames and loops. Moreover, by adjusting even slightly the settings on the machine, a cardiologist or sonographer can influence and even distort the quality of the image that he or she sees. Over-manipulated settings can produce false images, including artifacts and phantom jets.

One setting that is particularly important to the image displayed on an echocardiogram machine is the Nyquist limit. The Nyquist limit is determined in part by how the cardiologist or sonographer sets the Pulse Repetition Frequency. It is the highest velocity of blood flow that an echocardiogram machine can accurately measure in the color flow Doppler modality. For

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8. The jet is high velocity because of the difference in pressure between the contracting left ventricle and the left atrium.

example, if the Nyquist limit is set at 70 cm/second, the machine can only accurately calculate and display the velocity of blood that is moving slower than 70 cm/second. It cannot accurately measure the velocity or direction of blood flow moving faster than that limit. If the velocity of blood flow exceeds the Nyquist setting, then the machine will assign incorrect colors to the apparent regurgitant jet. The jet will appear splotchy and broken up. Although medical literature does not propose an optimal Nyquist limit for echocardiograms, the generally accepted practice is the higher the better. Accordingly, a Nyquist limit in the 30's or 40's may not be as ideal for identifying and measuring a mitral regurgitant jet as would a limit in the 60's or 70's.

When interpreting an echocardiogram, a cardiologist must be able to distinguish true regurgitation from artifacts, phantom jets and backflow. Backflow, a common phenomenon in most individuals and of no medical concern, is characterized as "backward displacement of blood into the left atrium that is due to the closure of the valve leaflets ...." Arthur E. Weyman, Principles and Practice of Echocardiography 431 (2d ed. 1994). It is low velocity blood flow that lasts one-tenth of a second or less and is a normal phenomenon that exists in virtually everyone. Backflow is like the "wind in your face [that you feel] from the closing of [a] door." Although it will appear in the echocardiogram as blue colored blood flow in the left atrium during the early part of systole, it is not to be confused with

mitral regurgitation. See Weyman, supra, at 263, 431. Mitral regurgitation has greater velocity and lasts longer than backflow. See id. at 431.

In addition to the echocardiogram, a claimant seeking benefits must submit to the Trust what is called a Green Form. Part II of the form contains questions related to the claimant's medical history and his or her eligibility for Matrix level benefits. It is to be completed and signed by a board-certified cardiologist or cardiothoracic surgeon. By signing the form, a physician specifically acknowledges that the Green Form is a court document and that the information being provided is submitted under penalty of perjury. The Green Form states:

[t]his form is an official Court document sanctioned by the Court that presides over the Diet Drug Settlement and submitting it to the AHP Settlement Trust is equivalent to filing it with a Court. I declare under penalty of perjury that the information provided in this form is correct to the best of my knowledge, information and belief.

Movant's Ex. 101 at 14.

### III.

The moving parties contend that seventy-eight of the attestations of moderate or more severe mitral regurgitation by Dr. Crouse and Dr. Mueller which the Hariton and Napoli firms submitted to the Trust were medically unreasonable. It was this factual issue that was the focus of the six-day hearing.

The movants called as an expert witness Dr. John Dent, a cardiologist and level three trained echocardiogram reader. Dr. Dent has served as Medical Director and Interpreter of

Echocardiograms at the Adult Echocardiography Laboratory at the University of Virginia since 1994. Prior to obtaining this position, he received extensive training in echocardiography as a resident and cardiovascular Fellow at the University of Virginia. During the course of his professional career, he has authored numerous peer-reviewed articles about echocardiography and given lectures on echocardiography at national and international meetings. As director of the Adult Echocardiography Laboratory, Dr. Dent supervises the echocardiography training programs and oversees the work of five echocardiogram readers. He reads approximately 3,000 echocardiograms during the course of a year and throughout his career has read more than 20,000 echocardiograms and conducted himself more than 1,000.

Dr. Dent initially focused on fifty-five Dr. Crouse echocardiograms and thirty Dr. Mueller echocardiograms. For each echocardiogram, he reviewed videotapes of the echocardiograms, digital loops where provided and still frames in order to evaluate valvular regurgitation in context.<sup>9</sup> He spent on average at least between fifteen and thirty minutes viewing the tapes certified by Dr. Crouse. It is not clear how much time he spent reviewing Dr. Mueller's tapes. However, he testified that Dr. Mueller's tapes were on average much longer than Dr. Crouse's. Because of limited time between his engagement and the hearing,

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9. Dr. Dent's review was blind in the sense that he did not have either the portion of the Green Forms filled out by Drs. Crouse and Mueller or the original echocardiogram reports from those doctors. He could, however, see the regurgitant jet and atrial measurements that Dr. Crouse's sonographer and Dr. Mueller made.

he focused his analysis on the amount of valvular regurgitation as shown via color Doppler modality (as opposed to the measurements of the left atrial size). To assess the extent of mitral regurgitation, he "eyeballed," that is visually inspected, the measurements, rather than retrace the regurgitant jet area or the left atrial area. "Eyeballing" the regurgitant jet to assess severity is well accepted in the world of cardiology. Where Dr. Dent found "a close call," he erred in favor of the claimant.

Dr. Dent's conclusions and opinions differed substantially from the conclusions and opinions reached by Drs. Crouse and Mueller. For the seventy-eight challenged echocardiograms, Dr. Dent found no significant levels of mitral regurgitation. Specifically, he determined that each of the readings by these cardiologists was outside the bounds of medical reasonableness.

Dr. Dent found several recurring flaws in the interpretation of echocardiograms by Drs. Crouse and Mueller. For example, Dr. Mueller consistently set a low Nyquist setting and traced spurious or "phantom" jets, which should be discarded when interpreting an echocardiogram. Both Drs. Crouse and Mueller misidentified backflow as mitral regurgitation in numerous instances. In addition, the backflow or mitral regurgitation was often overtraced with the result that the backflow or regurgitant jet as measured covered too large an area. These errors had the effect of enlarging the ratio of the area of purported mitral regurgitation to the area of the left

atrium and thus improperly increasing the percentage of the atrium covered by mitral regurgitation. As a result of the miscalculations, the twenty percent or greater level for moderate mitral regurgitation as set forth in the Settlement Agreement was improperly met.

We find Dr. Dent to have been extremely well qualified as a cardiologist and reader of echocardiograms. We accept his analysis, conclusions, and opinions concerning the medical unreasonableness of the readings by Dr. Crouse and Dr. Mueller. His presentation outlining the improper measurements and the misidentification of backflow as mitral regurgitation was cogent. Dr. Dent's credibility was further enhanced by his thorough analysis of the echocardiogram tapes of the claims in issue. He did not simply look at one frame of an echocardiogram and reach an opinion about the severity of mitral regurgitation.<sup>10</sup>

The Hariton and Napoli firms called as an expert witness Dr. Scott Lawrence Roth, a level three trained echocardiographer. As with the other doctors who testified, Dr. Roth has extensive experience in the field of cardiology and echocardiography. From 1992 to 1999, he served as Director of the adult echocardiography laboratory at Long Island Jewish Medical Center ("LIJ"). In this capacity, Dr. Roth supervised two to four sonographers and cardiology Fellows and was further

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10. The moving parties also presented as witnesses Drs. Richard Helmcke and Ernest Madu, both highly qualified cardiologists and echocardiographers. To a large extent, their testimony was repetitious of that of Dr. Dent. Where there were differences, we accept what Dr. Dent said.

responsible for training the Fellows. Following his tenure with LIJ, Dr. Roth began his own private clinical practice in which he continues to be engaged. In his practice, he performs or reads about 1,500 echocardiograms per year and over the course of his career has read more than 30,000. While he has authored peer-reviewed articles on echocardiography and cardiology, he has not written any articles or papers on the measurement of mitral regurgitation.

Dr. Roth reviewed the echocardiogram tapes for all the claims in issue. He examined Dr. Mueller's echocardiograms on videotape, but for Dr. Crouse, he primarily analyzed the digital loops and still frames. In very few cases did he also examine the videotapes of the echocardiograms she interpreted although the tapes were made available to him. In terms of methodology, Dr. Roth did not retrace any of the measurements supporting the Dr. Crouse and Dr. Mueller echocardiograms. If he thought the planimetry was reasonable, he simply recopied the measurements onto a form that he created for the purposes of his review. Of the echocardiograms that he examined, he agreed that he did not note on his review form a single interpretive disagreement with any of the measurements made by Dr. Crouse's sonographer or by Dr. Mueller.

In contrast to Dr. Dent, Dr. Roth testified that as to all challenged echocardiograms in issue there was a reasonable medical basis "for [Drs. Crouse and Mueller] to have looked at [the] tapes, generated a clinical echocardiography report ... and

conclude[d] that [the] patients had moderate mitral regurgitation." Dr. Roth did not opine whether the claimants had in fact moderate or more severe mitral regurgitation based on the echocardiograms. In his review, he simply found that there was a reasonable medical basis to support the planimetry of the regurgitant jets. He further testified that he believed that the traced blood flows were mitral regurgitation as opposed to backflow. With respect to this latter conclusion, Dr. Roth relied on continuous wave Doppler analysis to confirm the presence of mitral regurgitation. Significantly, he did not state that continuous wave Doppler confirmed the presence of moderate or more severe mitral regurgitation.

Having observed both Dr. Roth and Dr. Dent on the witness stand, we accept the testimony of Dr. Dent to the extent that they disagreed. As previously explained, Dr. Roth reviewed only a few of the Dr. Crouse tapes. Moreover, he improperly relied on continuous wave Doppler analysis to support his conclusions. Nowhere does the Green Form authorize the use of continuous wave Doppler to establish the severity or duration of mitral regurgitation. Indeed, the non-moving parties concede that continuous wave Doppler cannot accurately measure the severity of regurgitation. Dr. Roth undermined his own credibility with his demeanor on cross-examination. Often, he quibbled unnecessarily over semantics and attempted to avoid direct answers to questions.

The non-moving parties also called Dr. Linda J. Crouse, a level three echocardiographer whose echocardiogram interpretations are at issue here. Dr. Crouse has extensive training in echocardiography. She currently operates a private cardiology practice in Kansas City, Missouri and teaches echocardiography at the University of Missouri-Kansas City. Over the course of her career, Dr. Crouse has read or interpreted more than 150,000 echocardiograms. Dr. Crouse is an active member of various professional societies and associations, including the American Society of Echocardiography and the American Heart Association.

The fifty-three Dr. Crouse echocardiograms before us are a portion of 725 echocardiograms that she agreed to interpret for the Hariton and Napoli firms over a four and a half month period from late February, 2002 to July, 2002.<sup>11</sup> She initially met with both Mario D'Angelo and Ira Hariton from the Hariton firm about this engagement. She later met with Mark Bern from the Napoli firm when he visited her office to examine her equipment and discuss the scheduling of the echocardiograms. A law firm employee conducted a training session at Dr. Crouse's office to make certain, as she explained it, that her lead

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11. These 725 were only a fraction of the echocardiograms that Dr. Crouse reviewed over this period. In addition to seeing patients as part of her normal clinical practice, she interpreted 300-500 echocardiograms per week as part of her engagement with a second consortium of law firms active in the diet drug litigation. She received \$250 per echocardiogram from this second consortium of firms. Overall, she interpreted approximately 10,000 echocardiograms for this consortium over a ten-month period beginning in October, 2001.

sonographer "understood how to make the measurements" under the Green Form protocol. Dr. Crouse received a flat fee of \$1,000 to perform and interpret each echocardiogram for a total fee of \$725,000.

On days when echocardiograms were performed on Hariton and Napoli clients, Dr. Crouse's office scheduled twenty-four to twenty-five echocardiograms, each of which lasted for approximately thirty minutes. A representative of the firms was usually present while the client was in Dr. Crouse's office. Dr. Crouse's lead sonographer, Audrey Loeb, performed all but one of the echocardiograms at issue. Dr. Crouse was physically present in the room where the echocardiogram was being performed only about ten percent of the time.

Dr. Crouse normally reviewed the echocardiogram findings throughout the course of the day and then approved the echocardiogram reports using an electronic signature. She would begin by analyzing the digitized images and then would refer to the videotape. However, she did not always review the videotape of the echocardiograms. Generally, she would devote only two to three minutes when reviewing what she characterized as an easy case. For a more difficult echocardiogram that she believed showed borderline mild to moderate regurgitation, she might spend up to six or seven minutes. However, we credit her records that established she sometimes spent far less time reviewing the echocardiograms in issue. For one patient, she approved the

echocardiogram report merely seconds after the conclusion of the echocardiogram.

At some point after she approved the echocardiogram report, Dr. Crouse also signed a Green Form for each of the Hariton and Napoli claimants. She did so without ever reviewing medical records and without ever taking a medical history of any of the claimants. Surprisingly, she testified that "it is the law firm's duty to take a history." Furthermore, in a majority of cases, she signed the Green Form without personally completing Part II of the form, which expressly states "Part II of this form must be completed by a Board-Certified Cardiologist ...." Movant's Ex. 101 at 7. Instead, her sonographer would fill out the form based on the echocardiogram report that is prepared in conjunction with each echocardiogram. Although it is not clear who actually prepared the echocardiogram report, Dr. Crouse ultimately approved it.

In each of the challenged echocardiograms that she interpreted, Dr. Crouse found moderate or more severe mitral regurgitation. Overall, she found that sixty to seventy percent of the 725 Hariton and Napoli claimants her office saw had moderate or more severe regurgitation.<sup>12</sup> These percentages are significantly higher than the findings of a 1998 blinded clinical study in which she participated that examined the link between

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12. When considering the echocardiograms she interpreted for other law firms in conjunction with the diet drug litigation, Dr. Crouse determined that between forty percent and seventy percent of diet drug claimants had moderate or more severe mitral regurgitation.

the diet drugs and valvular abnormalities.<sup>13</sup> As part of the study, Dr. Crouse performed 600 echocardiograms over a six-month period and found, similar to the conclusions of the study, that only about five percent of the diet drug patients had moderate or greater mitral regurgitation. See Julius M. Gardin, M.D., et al., Valvular Abnormalities and Cardiovascular Status Following Exposure to Dexfenfluramine or Phentermine/ Fenfluramine, 283 (No. 13) JAMA 1703 (April 5, 2000).

As noted above, we agree with Dr. Dent that fifty-three of the echocardiograms Dr. Crouse interpreted were beyond the bounds of medical reason. Dr. Crouse frequently mistook backflow and mild mitral regurgitation for moderate or more severe regurgitation. Unlike Dr. Dent who based this assessment on reviews of both the digitized images and the videotapes, Dr. Crouse did not analyze the videotapes for all of the echocardiograms to which she attested. Moreover, the evidence demonstrated that Dr. Crouse approved echocardiogram reports where the regurgitant jet areas were overtraced and thus overestimated the level of mitral regurgitation. Dr. Crouse's sonographer frequently traced black-coded blood outside the border of the regurgitant jet. Blood that is observed as black on a color Doppler echocardiogram represents very low velocity, swirling blood. It was not part of a high velocity mitral regurgitant jet.

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13. A "blinded" study means that when she read the echocardiograms, Dr. Crouse did not know whether the person had taken diet drugs or not.

The circumstances under which the Dr. Crouse echocardiograms were performed and interpreted undermine her credibility. Despite her extensive experience with echocardiography, she relied on a law firm employee to instruct her staff on how to measure regurgitant jets. On days when Hariton and Napoli clients were scheduled, her office would conduct echocardiograms for twelve hours at half hour intervals, all with the same sonographer! Dr. Crouse spent little time actually reviewing and approving the results of these echocardiograms. She never met with the claimants, never reviewed their medical records, and largely relied on the law firms to provide the medical history required by the Green Form. Nonetheless, Dr. Crouse received \$725,000 from the Hariton and Napoli firms to say nothing of the \$2,000,000 or more that she earned from other law firms for interpreting fen-phen echocardiograms. When considering the thousands of echocardiograms that Dr. Crouse interpreted during the period that she worked for the Hariton and Napoli firms, her practice resembled a mass production operation that would have been the envy of Henry Ford.

The non-movants called as well Dr. Richard L. Mueller, a level two echocardiographer, whose echocardiogram readings were also in issue. Dr. Mueller operates a private clinical practice in New York City that covers the full scope of consultive cardiology. He has considerable experience in echocardiography and during his career has interpreted approximately 6,000-7,000

echocardiograms, or about 800 to 900 each year. He has personally conducted more than ninety-five percent of them.

The Hariton firm contacted Dr. Mueller about performing echocardiograms in conjunction with the diet drug settlement in early 2001. At the time, Mario D'Angelo, a member of the firm, asked him to perform only echocardiograms for a number of firm clients. The firm and Dr. Mueller eventually agreed that he would be paid \$900 for interpreting each echocardiogram and \$2,000 for filling out the seven pages in Part II of the Green Form. In total, he interpreted between 250 and 300 echocardiograms for the Hariton firm and completed between 50 and 100 Green Forms. After the firm developed cash flow problems, it initiated a new compensation arrangement with him. Dr. Mueller received \$500 up front for completing a Green Form with another \$1,500 due "upon receipt of the client's settlement proceeds or six months from the date of submission to the AHP Settlement Trust." See Wyeth Ex. 103.

Of the Dr. Mueller echocardiograms at issue here, he conducted almost all of them himself. Each session with a Hariton client would last between three and five hours. One, sometimes two, firm representatives would be present in his office during those sessions. For the first few clients, Dr. Mueller conducted medical histories and reviewed medical records. However, the Hariton firm eventually informed him that it preferred to take the medical history, and he deferred to the firm.

Dr. Mueller recorded each echocardiogram on videotape and took still frames of any pictures of interest.<sup>14</sup> He consistently performed the echocardiograms with a Nyquist limit set in the thirty to forty range. After the Trust complained to the Hariton firm about the low settings, Dr. Mueller agreed to "pay close attention to keeping it 50-60 on all subsequent studies." See Wyeth Ex. 114. According to correspondence between Dr. Mueller and the Hariton firm, the latter had represented to him that Dr. Crouse believed that the normal Nyquist range was within those parameters. Dr. Mueller usually completed an echocardiogram report the same day as the echocardiogram was conducted.

At some point after Dr. Mueller performed each echocardiogram, the Hariton firm sent him a Green Form. He would subsequently spend sixty-five to seventy minutes completing the questions in Part II. Initially, the firm sent blank Green Forms to his office. Later, the firm completed the answers with respect to the medical history of the claimant. While he questioned the firm about the propriety of this arrangement, he abided by it. When Dr. Mueller found that the firm had made an error, which happened on approximately ten percent of the forms, he corrected it and sent the form back. He did not know what information the firm ultimately submitted to the Trust.

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14. The still frames and original videotapes were not available to the parties during their preparation for the hearing. Dr. Mueller preferred to retain custody and control of all originals.

Dr. Mueller concluded as to each of the disputed echocardiograms that the Hariton clients had moderate or more severe mitral regurgitation. He did not provide an exact percentage measurement when assessing the severity of mitral regurgitation. Rather, he calculated for each client a range of the RJA/LAA. In one case, he determined that a client had a range of regurgitation that spanned twenty percentage points from twenty-one percent to forty-one percent. The low Nyquist settings used by Dr. Mueller resulted in sub-optimal echocardiograms that included spurious or artifactual signals on the color flow Doppler. He also measured some of these spurious jets, as well as backflow, as mitral regurgitation. Again, we accept the analysis, conclusions, and opinions of Dr. Dent that Dr. Mueller's interpretations were beyond the bounds of medical reason. To the extent the testimony of Dr. Mueller and Dr. Dent diverged, we accept Dr. Dent's testimony.

The contingent nature of a portion of Dr. Mueller's fee adversely affected his credibility. Green Forms are submitted to the Trust only if the documentation appears to support the claim for Matrix level benefits under the Settlement Agreement. Dr. Mueller stood to earn an additional amount when his echocardiogram reading showed moderate or more severe mitral regurgitation. As outlined in the letter from Mario D'Angelo, he received an extra \$1,500 if the claimant obtained a benefit or the claim was submitted to the Trust for payment.

The non-movants argue that there is nothing inherently improper with charging a reasonable fee to complete paperwork associated with a claim. We agree, but that is not what happened here. Dr. Mueller received additional compensation not for simply filling out the Green Forms but only if the claimant received a benefit or if the Green Form was forwarded to the Trust. Of course, a Green Form would be sent to the Trust by the Hariton and Napoli firms only if on its face the claimant was eligible for a benefit. Thus, Dr. Mueller's remuneration depended on how he interpreted the echocardiogram and on what he stated on the form. He had a financial incentive to reach a particular result. He and the law firms were fully aware that tendering a Green Form was in effect testimony under oath. The form itself stated that submitting it to the Trust was "equivalent to filing it with a court" and was subject to the penalties of perjury. Movant's Ex. 101 at 14. This highly questionable practice by Mario D'Angelo and the Hariton firm seems to violate a lawyer's ethical obligation not to compensate a witness on a contingent fee basis. See New York DR 7-109(c) and PA Rule of Professional Conduct 3.4(b).<sup>15</sup> We will refer the

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15. New York Disciplinary Rule 7-109(c) states:

A lawyer shall not pay, offer to pay, or acquiesce in the payment of compensation to a witness contingent upon the content of his or her testimony or the outcome of the case. But a lawyer may advance, guarantee, or acquiesce in the payment of: (1) [e]xpenses reasonably incurred by a witness in attending or testifying; (2) [r]easonable compensation

(continued...)

matter by separate order to the New York Disciplinary authorities for further review and consideration.

We are also concerned about the Hariton firm's involvement in supplying Dr. Mueller with information required in the Green Form. Although his testimony suggests he was not comfortable with the arrangement, Dr. Mueller nonetheless allowed the Hariton firm to take medical histories for him and at least preliminarily fill out the Green Form. As noted above, the Green Form explicitly states that Part II is to be "completed by a Board-Certified Cardiologist."

Neither the Hariton firm nor the Napoli firm is a novice in the fen-phen arena. Both have considerable experience and sophistication with the terms of the Settlement Agreement and how to process claims. The Hariton firm was formed in July, 2001 to practice solely in connection with the fen-phen litigation and the nationwide class action Settlement Agreement. The firm handles claims for diet drug clients and retains medical doctors from across the country to participate in their echocardiogram program. It has a medical staff of more than sixty, including nurses and eight per diem sonographers, and owns its own echocardiogram equipment. In training sessions it conducts, firm

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15. (...continued)

to a witness for the loss of time in attending, testifying ....

Rule 3.4(b) of the Pennsylvania Rules of Professional Conduct is similar.

personnel have instructed echocardiogram technicians on how to measure mitral regurgitation under the Settlement Agreement.

The Hariton firm has been formally associated with the Napoli firm since July, 2001 although members of both firms worked with one another informally on the diet drug litigation prior to that. The Napoli firm devotes slightly less than half of its resources to the diet drug litigation. Generally, the Hariton firm is responsible for processing a claimant's case through the initial intake and up until a decision is made to opt out of the settlement. If a claimant does decide to opt-out, the Napoli firm will represent the claimant in the ensuing lawsuit.

Despite the firms' seemingly distinct roles, the responsibilities of both overlap. A member of the Napoli firm has occasionally met with the physicians who work with the Hariton firm in order to further the working relationship. Mark Bern of the Napoli firm, for example, visited Dr. Crouse's office to examine her "set-up." The two firms operate a joint website related to the diet drug settlement, use a joint retainer agreement for their clients, and require clients to sign a hold harmless agreement that covers both firms.

In sum, we find that the seventy-eight disputed attestations of Dr. Crouse and Dr. Mueller submitted to the Trust by the Hariton and Napoli firms were medically unreasonable.

#### IV.

The Trust also seeks authority to conduct audits of all claims involving attestations of Drs. Crouse and Mueller and all

claims submitted by the Hariton and Napoli firms, regardless of what cardiologist was involved.

The Settlement Agreement only allows 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.

The moving parties argue that the fifteen percent cap on audits is totally inadequate in light of the evidence they have presented here. As things now stand, eighty-five percent of all claims must be paid merely upon the attestation of the certifying cardiologist engaged by the claimant or the claimant's attorney. The moving parties contend that without such

additional audits a serious risk exists that many ineligible claimants will receive a windfall.

The Settlement Agreement permits this court to order additional audits and adopt additional claims administration procedures for "good cause shown."<sup>16</sup> 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.

Good cause remains undefined by the Settlement Agreement. 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).

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16. The good cause provision was part of the Fourth Amendment to the Settlement Agreement and was approved in Pretrial Order No. 1415.

Movants argue that good cause may be established by showing that claims submitted to the Trust for payment lack a "reasonable medical basis." We agree. Section VI.E identifies two general situations that may provide good cause for instituting new claims processing procedures: the results of audits conducted on claims and/or Requests for Credits made by Wyeth. Settlement Agreement § VI.E. The audit procedures outlined in § VI.E. are designed to identify claims unsupported by a reasonable medical basis and thereby to ensure the integrity of the claims submissions process. This court has authority to address deficiencies or improprieties that arise during this process". See id. at § VI.E.8.

It is true as the non-movants suggest that the current motion was not prompted by the "results of audits" as established through the audit procedure set forth in §§ VI.E.1-8. Instead, the motion was driven by allegations of unreasonable medical attestations in the Green Forms before audits on the claims submitted by the Hariton and Napoli firms had taken place. We do not believe, however, that we are required to wait until after claims have navigated through audit to consider whether good cause exists to modify the claims administration and auditing procedures. The situations enumerated in § VI.E. as giving rise to good cause are not exclusive. The language specifically reads "for good cause shown including, without limitation, the results of audits conducted on one or more claims ...." Id. at § VI.E. (emphasis added). The heart of the good cause provision lies in

allowing the court to order corrective measures to prevent the settlement from being subverted.

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).

The settlement at issue was intended to provide individuals who took diet drugs and manifested the established Matrix level conditions with a streamlined process for seeking compensation as an alternative to filing a lawsuit. The Settlement Agreement, of course, requires those seeking Matrix level benefits to demonstrate they are entitled to payments. The funds contributed by Wyeth, though large, are finite, particularly with thousands of potential beneficiaries. Movants have clearly demonstrated that the Trust's ability to meet its part of the bargain and pay legitimate claims is being undercut by the tender of claims that have no reasonable medical basis. This court's involvement therefore acts to preserve the bargain struck so that Matrix level benefits go only to those whose

medical conditions qualify them for payment. Our involvement is consistent with the powers of the court to administer a massive class action settlement such as this.

Had the events before us gone undetected, persons not entitled to Matrix benefits under the Settlement Agreement would have been paid, in some cases, large sums of money. Obviously, this cannot be tolerated. Good cause under the Settlement Agreement clearly exists to modify the audit procedures to enhance the safeguards against any repetition of what has occurred here.

Accordingly, the Trust may audit all pending and future attestations of Dr. Crouse and Dr. Mueller. Based on the evidence in the record, prudence dictates no less. The two cardiologists have made medically unreasonable judgments on a broad scale. One cardiologist has read echocardiograms on a rapid fire basis and has received \$725,000 from the law firms for her efforts. The other cardiologist spent more time with each echocardiogram but his compensation from those law firms depended on whether the Green Forms with attestations were submitted to the Trust for payment.

There is also good cause to allow the Trust to audit the Green Forms submitted on behalf of all claimants by the Hariton and Napoli law firms, regardless of the identity of the certifying cardiologist. These two firms concentrate on fen-phen cases and are highly knowledgeable of the claims process. They retained the two cardiologists who interpreted, not one or two,

but a significant number of echocardiograms in a medically unreasonable manner. The Hariton firm worked out the questionable financial arrangement with Dr. Mueller, and the firm was deeply involved with the completion of the medical portions of the Green Forms for both cardiologists. Our goal is to preserve the limited funds for those who are entitled to them. Allowing audits of all their clients will contribute to the legitimacy of the claims process and help achieve this goal. If the client is entitled to benefits, he or she has nothing to fear.

V.

The moving parties have also requested that we enjoin the Hariton and Napoli firms from representing clients in filing for Matrix benefits with the Trust. Although their conduct has certainly not been totally exemplary and in at least one respect there has been highly questionable behavior, we will not at this point take such a drastic step. To bar them now could cause needless harm to innocent claimants who are eligible for benefits. We believe the remedy to be implemented including the audit of all claims filed by clients of the Hariton and Napoli firms will be adequate at present to prevent unqualified claimants from receiving benefits from the Trust. If future events with respect to the Hariton law firm or any attorney or firm associated with it dramatically change the picture, additional relief may be in order.

Further, the moving parties seek to prohibit claimants from relying on the attestations of Dr. Crouse and Dr. Mueller to support their right to exercise an intermediate or back-end opt-out. Under the Settlement Agreement, claimants may exercise intermediate or back-end opt-outs and, with certain limitations, sue in the tort system while still remaining class members. Settlement Agreement §§ IV.D.3-4. Thus, instead of seeking benefits from the Trust, they may file lawsuits against Wyeth. In order to exercise such an opt-out, the claimant must submit to "the Court, the Trustees and/or Claims Administrator(s) and to AHP," a form expressing an intent to do so. Settlement Agreement §§ IV.D.3.b and IV.D.4.b. The form also requires the claimant to certify that he or she has been found by a "qualified physician as FDA positive." One of the findings for an FDA positive condition is "moderate or greater regurgitation of the mitral valve of the heart." While we do not condone the performances of Dr. Crouse or Dr. Mueller in the cases before us, we will not go so far as to prohibit such attestations. This issue must be resolved in the lawsuit filed by the opt-out claimant and not before this court. The Settlement Agreement is quite explicit that Wyeth "shall have the right to challenge, in such lawsuit only, whether the opt-out was timely and proper, including whether the Class Member was eligible to exercise such an opt-out right." Id. at §§ IV.D.3.c. and IV.D.4.c. (emphasis added). Wyeth will be able through the adversary process to dispute any

questionable conclusions or findings of either Dr. Crouse or Dr. Mueller which might surface.

Finally, the movants seek counsel fees. We note that the Settlement Agreement itself does not explicitly provide for such relief. While not foreclosing such an award under other circumstances, we will not exercise any authority we have to make such an award here.

#### VI.

The original motion filed by the Trust was captioned "AHP Settlement Trust's Motion for Temporary Restraining Order and Preliminary Injunction." Although a motion for a preliminary injunction rather than for permanent relief does not seem to fit this proceeding as it has developed and the non-moving parties have not indicated that they have additional evidence to present at a final hearing, we find that the necessary elements for a preliminary injunction have been met. See Swartzwelder v. McNeilly, 297 F.3d 228, 234 (3d Cir. 2002).

First, the moving parties have clearly established that the Hariton and Napoli firms, through the attestations of Dr. Crouse and Dr. Mueller, have submitted numerous claims that are medically unreasonable. The moving parties have established more than a reasonable likelihood of success on the merits. Second, irreparable harm would occur if payment of the medically unreasonable claims before us was not stopped and of the expanded audits of the attestations of Dr. Crouse and Dr. Mueller and of the claims submitted by the Hariton and Napoli firms to the Trust

were disallowed. The payment of money by the Trust from a limited fund to ineligible persons would seriously increase the danger that eligible persons would not be compensated under the Settlement Agreement. Realism dictates that money once paid to improper recipients is unlikely ever to be recouped. Third, the harm to legitimate claimants in not granting this relief clearly outweighs any harm to legitimate claimants or to any others in granting relief. The only possible detriment is some delay as a result of additional audits. Permitting these additional audits before the payment of benefits is really no different in substance than prohibiting a bank from paying out funds of a customer's account until it can be determined if the person seeking to withdraw the money is authorized to do so. The two law firms and the two cardiologists simply have no interest that is as compelling as the interest of rightful claimants in the protection of Fund B. After all is said and done, Fund B exists for the benefit of these rightful claimants who suffered from fen-phen and not as a pot of gold for lawyers, physicians and non-qualifying claimants. Finally, the public interest compels the court to preserve the integrity of this court-approved class action settlement by enjoining the Trust from making improper payments and by authorizing additional audits. See Prudential, 261 F.3d at 367-68.

## Exhibit 2

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December 9, 2003

**VIA FACSIMILE**

Paul J. Napoli, Esquire  
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Re: **Request for Extension of Time to Submit  
Completed Medical Practice Questionnaires**

Dear Mr. Napoli:

Thank you for your December 4, 2003 letter.

My December 2, 2003 letter to you asks that you provide me with a specific request for extension for your clients to submit completed Medical Practices Questionnaires. Your December 4, 2003 letter fails to do so. Accordingly, we will grant your request for an extension and allow you an additional 120 days to submit completed Medical Practices Questionnaires on behalf of the claimants who were subject to your original request. Accordingly, the Medical Practices Questionnaires for these claimants are now due on April 15, 2004.

As you know, a motion was filed in September, 2003 challenging the Trust's Claims Integrity Program and specifically the Medical Practices Questionnaires. Judge Bartle denied that motion and permitted the Claims Integrity Program to continue in the manner as formulated by the Trust. Accordingly, to the extent your December 4 letter challenges the legitimacy of the Medical Practices Questionnaire, I believe that issue has been raised before Judge Bartle.

In our telephone conversation of December 2, 2003, you stated that you would make a proposal to remedy the situation which you described as your inability to have Drs. Mueller and Crouse complete Medical Practices Questionnaires. Your letter states that you have been advised by their respective counsel that they will refuse to complete the Medical Practices Questionnaires. This is to advise you that the Trust has not been so advised either by counsel for Drs. Crouse or Mueller or by Drs. Crouse or Mueller directly. As you know, the Trust adopted

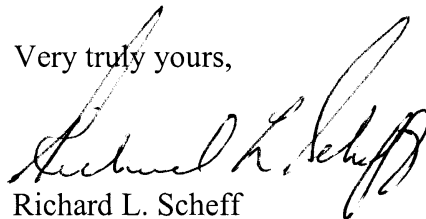
Paul J. Napoli, Esquire  
December 9, 2003  
Page 2

policies relating to the Medical Practices Questionnaires on November 6, 2003 which permitted physicians who were required to complete Medical Practices Questionnaires to submit to a deposition in lieu of completing the forms. Neither Drs. Crouse or Mueller, nor their counsel, have advised us that depositions will not be acceptable alternatives to completing the Medical Practices Questionnaire.

The Trust continues to discuss various alternatives to assure the integrity of claims. Obviously, you will be advised if and when additional policies relating to the Claims Integrity Program are adopted. In the meantime, I respectfully request that you take whatever steps are necessary to have Drs. Mueller and Crouse submit completed Medical Practices Questionnaires for your claimants or, in the alternative, submit to a deposition as stated in the Trust policy adopted on November 6, 2003.

Please contact me if I can be of any further assistance.

Very truly yours,



Richard L. Scheff

RLS:dk

cc: Andrew Chirls, Esquire  
Robert A. Mitchell, Jr.

# Exhibit 3

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

IN RE: DIET DRUGS (PHENTERMINE/ : MDL NO. 1203  
FENFLURAMINE/DEXFENFLURAMINE) :  
PRODUCTS LIABILITY LITIGATION :  
:  
SHEILA BROWN, ET AL. :  
:  
V. : CIVIL ACTION  
: NO. 99-20593  
AMERICAN HOME PRODUCTS :  
CORPORATION :

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PHILADELPHIA, PENNSYLVANIA  
WEDNESDAY, NOVEMBER 19, 2003  
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BEFORE: HONORABLE HARVEY BARTLE, III, J.

STATUS HEARING

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1 (1:00 P.M.)

2 (THE CLERK OPENS COURT.)

3 THE COURT: GOOD AFTERNOON. YOU MAY BE  
4 SEATED.

5 THE FIRST ITEM ON THE AGENDA THIS AFTERNOON  
6 IS THE MOTION OF WYETH CHALLENGING THE ELIGIBILITY OF  
7 CERTAIN PLAINTIFFS BASED ON THE ECHOCARDIOGRAM READINGS  
8 OF DR. WILLIAM SHELL. MR. ZIMROTH.

9 MR. ZIMROTH: GOOD MORNING, YOUR HONOR.

10 THE COURT: WILL WE BE TALKING ABOUT 71 OR  
11 51?

12 MR. ZIMROTH: WELL, ACTUALLY, THERE ARE  
13 THREE GROUPS OF CLAIMANTS HERE, YOUR HONOR. THERE IS A  
14 GROUP OF 50, IN WHICH THERE ARE NO CONTESTED FACTUAL  
15 ISSUES. UP UNTIL ABOUT 15 MINUTES AGO, THE ONLY ISSUE  
16 WAS RELIEF. I WILL TELL YOU THAT IN THE HALLWAY MR.  
17 PIRTLE SAID THAT HE WAS GOING TO DISMISS THOSE 50 CASES  
18 SO I DON'T NEED TO GIVE MY ARGUMENT ABOUT THOSE.

19 THE COURT: IS MR. PIRTLE HERE I ASSUME?

20 MR. PIRTLE: YES, YOUR HONOR.

21 THE COURT: IS THAT AGREEABLE, MR. PIRTLE,  
22 JUST FOR THE RECORD, YOU ARE GOING TO DISMISS THOSE 50?

23 MR. PIRTLE: FOR THE RECORD, I WANT TO TALK  
24 TO YOU ABOUT IT AFTER HE SITS DOWN BUT THE ANSWER IS  
25 YES.

1 FACTOR, PERHAPS THAT THE EJECTION FRACTION IS LESS THAN  
2 60 PERCENT OR SOMETHING LIKE THAT.

3 THE ISSUE THEN ON APPEAL, OR THE SHOW CAUSE  
4 HEARING, IS THE SECONDARY FACTOR, NOT THE UNDERLYING  
5 LEVEL OF REGURGITATION. THAT LEVEL OF REGURGITATION  
6 STILL ENTITLES THEM TO THAT CASH PAYMENT UNDER THE  
7 SETTLEMENT. AND THE TRUST, WRITTEN IN THEIR OPERATIONS  
8 PLAN, AND BY THEIR ACTIONS IS NOT -- ARE NOT PAYING  
9 THOSE CLAIMS. I WOULD ASK THAT THE OPERATIONS PLAN NOT  
10 BE APPROVED WITH THAT IN IT.

11 THE COURT: THANK YOU.

12 ANYONE ELSE?

13 MS. RUBIN: GOOD AFTERNOON, YOUR HONOR.  
14 DENISE RUBIN FROM NAPOLI KAISER BERN & ASSOCIATES FOR  
15 THE CLAIMANTS.

16 I JUST WANTED TO POINT OUT TWO POINTS WITH  
17 REGARD TO THE ARGUMENTS THAT HAVE BEEN MADE HERE. THE  
18 FIRST IS THAT IN TERMS OF THE -- I THINK THE PROMISE  
19 THAT THE CLAIMS INTEGRITY PROGRAM, THAT THE  
20 PRIORITIZATION, THAT THESE ARE ALL THINGS THAT ARE  
21 GOING TO MOVE CLAIMANTS ULTIMATELY THROUGH THE SYSTEM  
22 FASTER, I THINK THAT'S AN ILLUSION. BECAUSE IF YOU  
23 READ THE TENANTS OF THE CLAIMS INTEGRITY PROGRAM, IF  
24 YOU LOOK AT THE MEDICAL PRACTICES QUESTIONS --

25 THE COURT: ISN'T IT A NECESSARY CONSEQUENCE

1 OF FINDING OUT WHO IS FILING A DESERVING CLAIM, WHO IS  
2 NOT FILING A DESERVING CLAIM? I THINK EVERYBODY WOULD  
3 AGREE IF WE WENT BACK TO THE 15 PERCENT AUDIT THINGS  
4 WOULD MOVE FASTER. BUT AT WHAT PRICE?

5 MS. RUBIN: I UNDERSTAND WHAT YOUR HONOR IS  
6 SAYING.

7 THE COURT: SPEED IS NOT THE ONLY  
8 CONSIDERATION.

9 MS. RUBIN: OF COURSE. BUT ISN'T THAT THE  
10 PURPOSE OF THE AUDIT PROGRAM, TO DETERMINE WHICH CASES  
11 ARE MERITORIOUS? IT WAS NOT GIVEN TO THE TRUSTEES AND  
12 TO THE TRUST TO TAKE AN INTERMEDIATE STEP, IF YOU WILL,  
13 BEFORE THE PROCESS TO SAY, OH, WELL, THIS GROUP OF  
14 CLAIMS WE'RE NEVER EVEN GOING TO LET GET TO THE FRONT  
15 DOOR OF THE AUDIT, WE ARE GOING TO PULL THEM OUT. IT'S  
16 NOT JUST HOLDING THEM BACK.

17 THE COURT: SHOULDN'T THEY HAVE A CERTAIN  
18 AMOUNT OF DISCRETION TO DETERMINE HOW BEST TO FERRET  
19 OUT ILLEGITIMATE CLAIMS?

20 MS. RUBIN: NO, YOUR HONOR. I DON'T THINK  
21 THEY HAVE THAT DISCRETION. THEY HAVE THE DISCRETION TO  
22 PROCESS THE CLAIMS TO AUDIT, AND TO LET THE AUDITORS  
23 DETERMINE MEDICALLY WHETHER IT IS REASONABLE OR NOT AND  
24 TO LET THE CLAIMS THEN GO THROUGH THE CONTEST PROCESS  
25 AND THE SHOW CAUSE PROCESS THAT THE COURT HAS

1 ENVISIONED IN THE SETTLEMENT AGREEMENT IN THE TRUST  
2 AGREEMENT, IN THE AUDITORS TRAINING -- AUDITORS  
3 TRAINING PROGRAMS, SO ON, IN THE MANY AMENDMENTS TO THE  
4 SETTLEMENT AGREEMENT.

5 THE PEOPLE WHO CAME INTO THIS SETTLEMENT  
6 AGREEMENT MADE CERTAIN BARGAINS BASED ON CERTAIN  
7 REPRESENTATIONS. AND NOW THEY ARE TOLD, OH, BY THE  
8 WAY, IF YOU HAVE A LAWYER, YOU GO TO THE END OF THE  
9 LINE. IF YOUR DOCTOR DOES NOT WANT TO SIGN THAT  
10 MEDICAL PRACTICES QUESTIONNAIRE, YOU ARE JUST OUT OF  
11 THE SETTLEMENT. WHERE DID THEY HAVE THE DISCRETION  
12 UNDER THIS SETTLEMENT AGREEMENT TO DO THAT? IT'S JUST  
13 NOT THERE. THEY ARE NOT JUST HOLDING THESE PEOPLE  
14 ASIDE. IF THEY DON'T GET THAT MEDICAL PRACTICES  
15 QUESTIONNAIRE BY DECEMBER 15TH, WHICH WE HAVE BEEN TOLD  
16 REPEATEDLY IS A HARD AND REAL DEADLINE, THESE PEOPLE  
17 ARE OUT OF THE GAME. AND THE ABILITY TO TESTIFY, FOR  
18 THE DOCTORS TO COME IN AND TESTIFY, IS ALSO, IT'S AN  
19 ILLUSION, BECAUSE THOSE DOCTORS DON'T JUST COME IN AND  
20 TESTIFY ABOUT THE QUESTIONS ON THE MEDICAL PRACTICES  
21 QUESTIONNAIRE. THEY HAVE TO STIPULATE, BEFORE  
22 TESTIMONY, THAT THEY WILL ANSWER QUESTIONS, ALL THE  
23 QUESTIONS ABOUT ALL OF THE PENDING CASES. AND IT SAYS  
24 SPECIFICALLY IN THE NEW GUIDELINES, POSTED IN THE LAST  
25 48 HOURS, NOT JUST THE QUESTIONS ON THE MEDICAL

1 PRACTICES QUESTIONNAIRE. THAT DECISION HAS TO BE MADE  
2 BEFORE DECEMBER 1ST, ON OR BEFORE DECEMBER 1ST, BECAUSE  
3 IT HAS TO BE 15 DAYS BEFORE THE DEADLINE TO PUT IN THE  
4 MEDICAL PRACTICES QUESTIONNAIRE, WHICH IS DECEMBER  
5 15TH.

6 NOW, IF YOU WERE A DOCTOR, YOUR HONOR, WHO  
7 WAS LOOKING AT THE POSSIBILITY OF BEING SUED UNDER  
8 CIVIL RICO, HOW MANY THINGS WOULD YOU WANT TO SIGN  
9 UNDER OATH RELATED TO THIS LITIGATION? I SUGGEST THAT  
10 YOU WOULD NOT WANT TO BE INVOLVED IN IT AT ALL. AND AS  
11 A LAWYER WHO HAS SPENT A LOT OF YEARS REPRESENTING  
12 DOCTORS, THAT WOULD BE MY ADVICE TO ANY DOCTOR. WHY  
13 WOULD YOU PUT YOUR NAME UNDER OATH ON ANYTHING WHEN  
14 DOCTORS ARE BEING SUED FOR CIVIL RICO IN CONNECTION  
15 WITH THIS CASE? IT'S LIKE ASKING TO BE SUED.

16 AND WITH THAT, UNLESS THE COURT HAS FURTHER  
17 QUESTIONS FOR ME, I THANK YOU, YOUR HONOR.

18 THE COURT: THANK YOU.

19 ANYONE ELSE?

20 MR. CHIRLS: IF I MAY BE HEARD.

21 THE COURT: YES.

22 MR. CHIRLS: YOUR HONOR, I'M FORTUNATE TO  
23 FOLLOW MR. FISHBEIN BECAUSE, WITH THE EXCEPTION OF  
24 THREE OR FOUR WORDS, HE SAID WHAT WE WOULD HAVE SAID  
25 AND ENCAPSULATED WHAT WAS STATED IN OUR BRIEFS