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

IN RE: DIET DRUGS (Phentermine/ Fenfluramine/Dexfenfluramine) PRODUCTS LIABILITY LITIGATION	MDL Docket No. 1203
THIS DOCUMENT RELATES TO: SHEILA BROWN, SHARON GADDIE, VIVIAN NAUGLE, QUINTIN LAYER, and JOBY JACKSON-REID, individually and all others similarly situated, Plaintiffs, v. AMERICAN HOME PRODUCTS CORPORATION, Defendant.	CIVIL ACTION NO. 99-20593 **NOTICE OF MOTION**

CLAIMANTS' MOTION TO REMOVE AUDITORS CRAIG OLINER, M.D, DONNA ZWAS, M.D. AND JOHN GOTTDIENER, M.D. AS AUDITORS FROM THE AHP SETTLEMENT TRUST

For the reasons set forth in the accompanying affidavit and evidence annexed hereto as exhibits, the undersigned, counsel for claimants, will move this Court for entry of an Order in the form appended to these papers, compelling the AHP Settlement Trust to remove auditor Craig Oliner, M.D., Donna Zwas, M.D. and John Gottdiener, M.D., without further delay as required under the Nationwide Class Action Settlement Agreement with American Home Products Corporation and the prior orders of this Court, and to have all the audits of Craig Oliner, M.D., Donna Zwas, M.D. and John Gottdiener, M.D. redone by qualified auditors.

Respectfully submitted,

NAPOLI KAISER BERN & ASSOCIATES, LLP
Claimants' Counsel

By: _____
Denise A. Rubin (DR-5591)
An Associate of the Firm

3500 Sunrise Hwy., Suite T-207
Great River, New York 11739

HARITON & D'ANGELO, LLP
Claimants' Counsel

By: _____
Mario D'Angelo (MD-7550)
A Member of the Firm

3500 Sunrise Hwy., Suite T207
Great River, NY 11739

To:

Andrew A. Chirls Esq.
Wolf, Block, Schorr & Solis-Cohen, LLP
1650 Arch Street, 22nd Floor
Philadelphia, PA 19103

Michael D. Schissel Esq.
Arnold & Porter
399 Park Avenue, 34th Floor
New York, New York 10022-4690

Michael Fishbein, Esq.
Levin Fishbein Sedran & Berman
510 Walnut Street, Suite 500
Philadelphia, Pennsylvania 19106

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

IN RE: DIET DRUGS (Phentermine/ Fenfluramine/Dexfenfluramine) PRODUCTS LIABILITY LITIGATION	:	MDL Docket No. 1203
THIS DOCUMENT RELATES TO: SHEILA BROWN, SHARON GADDIE, VIVIAN NAUGLE, QUINTIN LAYER, and JOBY JACKSON-REID, individually and all others similarly situated, Plaintiffs, v. AMERICAN HOME PRODUCTS CORPORATION, Defendant.	:	CIVIL ACTION NO. 99-20593 **AFFIDAVIT**

STATE OF NEW YORK)
) s.s.:
COUNTY OF NEW YORK)

DENISE A. RUBIN, being duly sworn, hereby deposes and says:

1. I am associated with the law firm Napoli, Kaiser, Bern & Associates, LLP, attorneys for several class member claimants who have filed Matrix claims, as well as other class members, in the above-captioned matters now pending before this Honorable Court.

2. I offer this affidavit, the annexed exhibits, proposed order and the annexed Memorandum in support of the instant motion to remove the AHP Settlement Trust Auditors. The facts cited in these papers are based on my personal knowledge and review of the files, orders, correspondence and other documents related to this matter,

in support of claimants'[1] motion for an Order compelling the AHP Settlement Trust to remove auditors Craig Oliner, M.D., Donna Zwas, M.D. and John Gottdiener, M.D., without further delay and to re-audit any claims previously denied by Drs. Oliner, Zwas and Gottdiener, in accord with the NATIONWIDE CLASS ACTION SETTLEMENT AGREEMENT WITH AMERICAN HOME PRODUCTS CORPORATION, INC. and the prior orders of this Court.

3. All documents attached here as exhibits are true and correct copies of the cited original documents.

4. Those Exhibits are:

a. Excerpts of testimony from the September 2002 hearings;

b. Dr. Crouse's evaluation of claimant Ruth Enloe's echocardiogram;

c. Dr. Dent's evaluation of Ruth Enloe's echocardiogram;

d. Summary table of Dr. Dent-reviewed echocardiograms;

e. Dr. Gangopadhyay's evaluation of Ruth Enloe's echocardiogram;

f. Dr. Crouse's report on Linda Morales' echocardiogram;

g. Dr. Dent's evaluation of Linda Morales' echocardiogram;

h. Pretrial Order 2640 (Westlaw format);

i. Ruth Enloe and Linda Morales' post-audit rejection letters;

j. Ruth Enloe's auditing cardiologist report;

k. Linda Morales' auditing cardiologist report;

l. Gottdiener Article – New England Journal of Medicine;

m. Gottdiener Article – Journal of the Am. College of Cardiology;

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[1] This motion is made on behalf of the claimants represented by Napoli Kaiser Bern & Associates LLP and/or Hariton D'angelo who have filed Matrix claims which are subject to audit.

n. Gottdiener Article Abstract – Jrnl. of Am. Coll. of Echocardiology;

o. Gottdiener Article – American Heart Journal;

p. Deposition excerpts from John Pittelli;

q. Excerpt from "Rules for the Audit of Matrix Compensation Claims".

Denise A. Rubin (DR-5591)

Sworn to before me this 4 th day
Of August, 2003

Betsy Barranco
Notary Public

BETSY BARRANCO
Notary Public, State of New York
No. 01BA6043158
Qualified in Richmond County
Commission Expires June 12, 2006

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

IN RE DIET DRUGS (Phentermine/ Fenfluramine/Dexfenfluramine) PRODUCTS LIABILITY LITIGATION	MDL DOCKET NO. 1203
THIS DOCUMENT RELATES TO:	
SHEILA BROWN, et al. Plaintiffs, v. AMERICAN HOME PRODUCTS CORPORATION, Defendant.	CIVIL ACTION NO. 99-20593

PRETRIAL ORDER NO.

And now, to wit, this _____ day of _____, 2003, upon consideration of the Class Members' Motion to Remove the AHP Settlement Trust Auditors Dr. Craig Oliner, Dr. John Gottdiener and Dr. Donna Zwas, the Opposition thereto and the Reply to the Opposition, and upon hearing argument by the parties on _____, 2003, it is ORDERED that said motion is Granted.

By the Court:

_____
Hon. Harvey Bartle, III, J.

Exhibit A

1

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

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

PHILADELPHIA, PENNSYLVANIA
TUESDAY, SEPTEMBER 3, 2002

BEFORE: HONORABLE HARVEY BARTLE, III, JUDGE,

HEARING DAY ONE

- - - - - -

SUZANNE R. WHITE, C.M.
CERTIFIED REALTIME REPORTER
601 MARKET STREET
1234 U.S. COURTHOUSE
PHILADELPHIA, PA
(215) 627-1882

THAT IS UNUSUALLY LOW FOR THIS AGAIN, FOR THIS SO THAT PRF, IS SET UNUSUALLY LOW. ALSO I THINK I CALLED WINDSHIELD WIPER EFFECT. THE FRAME RATE IS LOW, I BELIEVE IT CALLED TEN HERTS HERE, WE PREFER 20 OR 30 WHEN WE ARE LOOKING AT THINGS AS FINE AS DETAILED AS THIS.

Q. IS THERE THIS THING THAT YOU WANT TO SHOW US WITH RESPECT TO MR. BLUMENBERG?
A. NO THERE ISN'T.
Q. NOW, LET'S TURN TO YOUR --
THE COURT: BEFORE WE DO. WE WILL TAKE OUR 15 MINUTE RECESS, PLEASE BE BACK IN YOUR SEATS READY TO GO IN 15 MINUTES.
(BREAK TAKEN.).
THE CLERK: ALL RISE.
THE COURT: YOU MAY BE SEATED.
THE COURT: MISS FLETMAN, YOU MAY PROCEED.
MS. FLETMAN: THANK YOU, YOUR HONOR.
BY MS. FLETMAN:
Q. DR. DENT, LET'S RETURN TO THE ISSUE OF HOW YOUR READINGS COMPARE TO THOSE OF DR. HELMCKE. WERE THERE CASES WHERE YOU BELIEVED THE CLAIMANT HAD MODERATE LEAKAGE AND DR. HELMCKE DID NOT?
A. YES, THERE WERE.
Q. HOW MANY?
A. THERE WERE FOUR CASES THAT WE DISAGREED ABOUT SUBSTANTIALLY IN TERMS OF THERE THEY WOULD HAVE BENNED FOR MATRIX LEVEL 2 BENEFITS. I BELIEVE THREE OF THEM INVOLVE CASES WHERE I REPORTED THEM AS MODERATE AND HE REPORTED THEM AS LESS THAN MODERATE.
Q. OKAY. AND THEN WERE THERE CORRESPONDING CASES WHERE HE REPORTED THEM AS MODERATE AND YOU DID NOT?
A. THERE WAS ONE WHERE HE RECORDED IT AS SEVERE AND I REPORTED IT AS MILD. AND THAT WAS THE FOURTH CASE.
Q. DO YOU REMEMBER THE NAMES OF THE PATIENTS?
A. I KNOW THAT THE ONE, THE SEVERE ONE WAS MR. BA RON, B.A. R O N E.
Q. I'M SORRY, HE SAID SEVERE?
A. YES.
Q. AND YOU SAID MODERATE?
A. I BELIEVE MILD.
Q. AND WAS THAT AORTIC OR MITRAL REGURGITATION?
A. IT WAS MITRAL IN A PATIENT WITH VERY COMPLEX HEART DISEASE.
Q. OKAY, DO YOU REMEMBER ANYTHING WITH RESPECT TO PATIENT LOB BA SETH TA*?
A. LO* BA* SH*ET THAT.
A. I BELIEVE WE WERE VERY CLOSE TO TOGETHER, I SAID MILD AND HE SAID MODERATE. I BELIEVE SO WHEN I LOOKED AT IT AGAIN THE MEASUREMENT WAS RIGHT ON THE EKG OF MILD TO MODERATE. I COULD SEE HOW YOU COULD GO EITHER WAY WITH IT.
Q. WHAT ABOUT MISS MORALES, DO YOU REMEMBER ANY DIFFERENCES BETWEEN YOUR OPINION AND DR. HELMCKE'S WITH RESPECT TO MISS MORALES?
A. I LOOKED AT MISS MORALES'S TAPE, I HAD REPORTED

MODERATE, MITRAL REGURGITATION. HE HAD REPORTED MILD. I LOOKED AT IT AGAIN AND WAS SATISFIED WITH THE STONE HER'S MEASUREMENT. THAT WAS THE FIRST CASE THAT I SHOWED TODAY.
Q. WHEN YOU SAY YOU WERE SATISFIED WITH THE SONOGRAPHER'S MEASUREMENT WHICH WAY DID THAT QUUT?
A. MODERATE.
Q. I THINK THE FINAL WAS MISS ENLOE?
A. YES.
THE COURT: ROUTE ENLOE, E N L O E. I BELIEVE I REPORTED HER AS MODERATE MITRAL REGURGITATION. DR. HELMCKE REPORTED HER AS MILD MITRAL REGURGITATION.
Q. HOW MANY CASES OF THE 88 AND HOW MANY CASES DID BOTH YOU AND DR. HELMCKE LOOK AT THE RESULTS?
A. I COMPARED MY RESULTS TO 73 PATIENTS IN WHOM HE HAD PROVIDED INTERPRETATIONS FOR ME TO COMPARE.
Q. AND THERE WERE SIGNIFICANT DIFFERENCE TAKE OUT HOW MANY OUT OF THE 73?
A. FOUR.
Q. DID THAT SURPRISE YOU?
A. NO. THAT IS WITHIN THE RANGE OF APPROXIMATELY FIVE TO TEN PERCENT DISAGREEMENT. I WOULD EXPECT BETWEEN ANY TWO ECHO EXPERTS LOOKING AT THAT THAT MANY TAPES.
Q. VERY BRIEFLY, HAVE YOU EVER CONSULTED WITH THE TRUST THAT WOULD BE THE AHP SETTLEMENT TRUST BEFORE THIS MATTER?
A. I WAS ASKED TO GIVE CADVISE BY THE TRUST EARLY ON WHEN THEY WERE SETTING UP THE PLAN FOR ACQUIRING THE VIDEOTAPES AND STORING THE IMAGES.
Q. WERE YOU PAID FOR THAT CONSULTATION?
A. NO, I WASN'T.
Q. DID YOUR PRIOR RELATIONSHIP WITH THE TRUST INFLUENCE YOUR READINGS OF THE ECHOCARDIOGRAMS IN THIS MATTER?
A. NO, IT DIDN'T.
Q. HAVE YOU EVER DONE ANY WORK FOR OTHER LAW FIRMS IN CONNECTION WITH DIET DRUGS?
A. YES, I HAVE.
Q. WHAT WORK WAS THAT?
A. I WAS HIRED ABOUT FOUR YEARS AGO BY A FIRM THAT WAS REPRESENTING ONE OF THE OTHER COMPANIES IN ORDER TO GIVE LECTURES, INSTRUCTIONAL MATERIAL TO THEIR ATTORNEYS IN 1998.
Q. DO YOU REMEMBER WHAT THE OTHER COMPANY WAS?
A. IT WAS ABOUT FIVE NAMES BEGINNING SNEAK, WALT MAN.
Q. NO, NO, NOT THE LAW FIRM BUT THE DRUG COMPANY?
A. I HAVE NO -- I DON'T KNOW.
Q. AND THE SNEAK ET CETERA, WHO IS THAT?
A. I BELIEVE A GROUP OF ATTORNEYS BASED IN NEW YORK.
Q. I THINK YOU SAID. WHEN DID THIS RELATIONSHIP START?
A. 1998.
Q. HAVE YOU EVER BEEN ASKED TO ACTUALLY DO ANY WORK FOR THE SHEEK FIRM?
A. NO.

MS. FLETMAN: YES, WE WOULD.
THE WITNESS: THAT HAS NOT BEEN MARKED.
MS. FLETMAN: IT HAS NOT BEEN MARKED.
THE COURT: YOU CAN THINK ABOUT THAT.
MS. FLETMAN: WE WILL THINK ABOUT THAT. WE WILL PROVIDE THE COURT WITH NUMBERS POSSIBLY NOT UNTIL TOMORROW MORNING.
THE COURT: ALL RIGHT. ALL RIGHT MR. HARPER, YOU MAY PROCEED.
CROSS EXAMINATION.
MR. HARPER: I MEANT ONLY TO ASK YOUR HONOR WHETHER TO DO IT DURING THE EXAMINATION.
THE COURT: THAT'S ALL RIGHT. HHH.
Q. HARITON LAR?
Q. DID AFTERNOON MY NAME IS THE GERRY HARPER I REPRESENT THE LAW FIRM OF NAPOLI KAISER AND BERN SO IT IS?
A. GOOD AFTERNOON.
Q. A FEW QUESTIONS THAT I WOULD LIKE TO ASK YOU IF I MAY. FIRST OF ALL, AM I CORRECT THAT EVERY SINGLE MEASUREMENT WITH WHICH YOU DISAGREE OF DR. MUELLER AND DR. CROUSE'S IS ALSO IN YOUR SWORN OPINION OUTSIDE THE BOUNDARIES OF MEDICAL REASON?
A. LET ME EXPLAIN THAT IT MAY NOT BE EVERY SINGLE MEASUREMENT IN THE ENTIRE ECHOCARDIOGRAM BUT THE MEASUREMENTS THAT APPEAR IN THEIR REPORTS, YES.
Q. SO EVERY SINGLE TIME THAT YOU DISAGREE WITH A CONCLUSION OR INTERPRETATION REACHED BY DR. MUELLER, OR DR. CROUSE AS SET FORTH IN THE GREEN FORMS, YOU BELIEVE THAT DR. CROUSE AND DR. MUELLER DEVIATED FROM ANY REASONABLE STANDARD OF MEDICAL CARE?
A. IF THAT IS THE DEFINITION OF MEDICALLY UNREASONABLE, THEN I AGREE WITH THAT.
Q. COULD YOU HELP ME BY -- CAN I GET TO USE SOME OF YOUR ANIMATED HEART AGAIN.
A. SURE. PUT IT UP ON THE SCREEN. .
A. CAN YOU PUT IT UP ON THE SCREEN. IF I COULD SHOW ME THAT GREAT PICTURE OF WHERE YOU WERE GOING FROM THE CHANGE FROM DIASTOLE TO SYSTOLE.
A. SURE. CAN I HAVE THE LAPTOP CONNECTED, PLEASE.
Q. I'M SORRY, WE NEED TECHNICAL HELP. HIT DISPLAY. I'M SORRY, YOUR HONOR.
A. I HAVE THE TURN MY COMPUTER OFF AND THEN ON AGAIN.
Q. I APOLOGIZE, YOUR HONOR?
THE COURT: THAT'S ALL RIGHT.
THE WITNESS: APPARENTLY WHEN IT SITS FOR A LONG TIME IT TURNS ITSELF OFF.
Q. CAN YOU MULTI TASK?
A. JUST BEARLY.
Q. I CAN ASK YOU QUESTIONS IF YOU WAIT?
A. I WILL BE COMFORTABLE WITH THAT.
Q. YOU SAID AT LEAST 1 OR 17 TIMES BY MY COUNT, THAT MEASUREMENTS TAKEN BY DR. MUELLER AND DR. CROUSE WERE MEDICALLY UNREASONABLE. NOW I UNDERSTOOD THAT TO MEAN BEYOND BOUNDS OF ANY REASONABLE MEDICAL BASIS. AM I MISUNDERSTANDING YOUR TESTIMONY?
A. NO, THAT WOULD BE CORRECT.

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

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

PHILADELPHIA, PENNSYLVANIA
TUESDAY, SEPTEMBER 10, 2002

BEFORE: HONORABLE HARVEY BARTLE, III, JUDGE,

HEARING DAY FIVE

- - - - - -

SUZANNE R. WHITE, C.M.
CERTIFIED REALTIME REPORTER
601 MARKET STREET
1234 U.S. COURTHOUSE
PHILADELPHIA, PA
(215) 627-1882

MAYBE WE CAN -- LET'S GO TO MORALES FIRST AND THEN COMPARE THE TWO.

A. I'M GOING TO LEAVE WILLIAMS UP BECAUSE IT'S EASIER. IT WILL SAVE TIME TO PULL IT BACK.

Q. I'M SORRY. THAT IS MISS MORALES?

A. YES, THIS IS THE COLOR FLOW DOPPLER FRAME THAT I BELIEVE MR. JOHNSON PROJECTED ON MRS. MORALES.

Q. JUST FOR THE RECORD, THIS IS HN 138. YOU FOUND THAT MS. MORALES HAD MODERATE MITRAL REGURGITATION?

A. YES, I DID.

Q. COULD YOU PLEASE PUT SIDE-BY-SIDE MORALES AND WILLIAMS, AND EXPLAIN TO US WHY YOU BELIEVE MS. WILLIAMS HAD MILD MITRAL REGURGITATION AND MS. MORALES HAD MODERATE?

A. THIS DOES NOT -- WHEN THEY'RE SIDE-BY-SIDE, THIS SIDE, IT DOES NOT PROJECT AT ALL WELL ON THAT SCREEN UPFRONT. I WOULD RECOMMEND LOOK AT THE SMALLER MONITORS OR I SHOULD ENLARGE ONE SHOW ONE AND THEN SHOW THE OTHER.

Q. YOU CAN DO ONE AND THEN THE OTHER.

A. OKAY. UP THERE IT'S VERY FAINT. YOU CAN SEE IT NOW. THIS IS A -- WHEN I VIEWED THE VIDEOTAPE AND LOOKED AT THE LOOPS, THIS IS A REPRESENTATIVE SAMPLE OF THE MITRAL REGURGITATION WHICH IS CORRECTLY TRACED HERE BY THE SONOGRAPHER. IT HAS THE CHARACTERISTIC

Exhibit B

MOVANT EXHIBIT 26

APR 01 2002

The Women's Cardiovascular Center

4320 Womall Road Suite 240
Kansas City, MO 64111 ph# (816)531-7474

Enloe, Ruth M 500-42-61
61 year old Female DOB: 04/18/1940
Procedure Date: Mar 19, 2002

Echocardiography Report

Final Report
Printed: 03/19/2002 12:37:54 PM

Procedure performed at *Hariton & D'Angelo; Long Island, NY–Echo L. Crouse Office*
Medical Record # (I.D.) No ID type Hospital Room # ABN&PAP

Procedures Performed

Transthoracic Echocardiogram
2-D and M-Mode combination.
Spectral Analysis Doppler
Color Flow Doppler

Reason for Test

Phen-Fen

Measurements

			Normal Range
Resting			
M-MODE	LV Diam Dias	4.80 cm	3.5 - 5.7
	LV Diam Sys	2.40 cm	2.3 - 3.9
	LVEF	70.00 (%)	45 - 84
	LV Septum	1.00 cm	0.6 - 1.1
	LV Post Wall	1.00 cm	0.6 - 1.1
	Ao Root Size	3.00 cm	2 - 3.7

Echocardiographic Interpretation

Resting

LV (left ventricle)	LVEF : 70 %
	Normal Left Ventricular Function
MV (mitral valve)	Moderate MV Regurgitation
AV (aortic valve)	Normal aortic valve
LA (left atrium)	The left atrial size is mildly increased
RV (right ventricle)	Normal right ventricle
TV (tricuspid valve)	Moderate tricuspid valve regurgitation
	PAP Based on Tricuspid Regurgitant Jet estimated at: 46 mm Hg
RA (right atrium)	Normal right atrium
PV (pulmonic valve)	Normal pulmonary valve

Conclusion

EF–70%
Normal LV function
Mild LA enlargement; 4.26 cm in the PLAX view
Moderate MR; 4.07/16.12=25% of the LA area
No AR
Moderate TR
PAP–46 mmHg

Staff

Sonographer: Ms. Audrey Loeb RDCS,RVT Department: Height: in

Enloe, Ruth M
Procedure Date: Mar 19, 2002

500-42-617

Reviewed by: Dr. Linda J. Crouse MD, FACC

Tape Group:

Weight: lbs
BSA: sqm

Reviewed by: Linda J. Crouse MD 3-19-02
Dr. Linda J. Crouse MD, FACC

Exhibit C

ENLOE, RUTH | DDR# 8007411

Date of Echocardiogram (mm/dd/yyyy) 03/19/2002

Study Type ☒ TTE ☐ TEE ☐ Stress Echo (resting portion only)

Part 1 M-Mode Quantitative Measurements (parasternal long axis view)

Is the patient in: ☒ Sinus rhythm ☐ Atrial fibrillation / flutter ☐ Other: specify

Aortic Root (1 beat)	3.1 cm	Not evaluable ☐
Left atrium (1 beat)	3.5 cm	Not evaluable ☐
Left Ventricular Internal Dimension – End Systole (2 beats)	___ cm	Not evaluable ☒
Left Ventricular Internal Dimension – End Diastole (2 beats)	___ cm	Not evaluable ☒

Comments:

Part 2 Pulmonary Artery Pressure (continuous wave doppler)

Peak tricuspid regurgitation jet velocity 2.5 meters/second 35 mm Hg — Not evaluable ☐

PASP — Not evaluable ☐

Compute from TR velocity using the following equation: PASP = 4 · $(TRvel)^2$ + 10 mmHg

Comments

Part 3 Left Ventricular Systolic Function (Assessed visually integrating information from all views)

Ejection Fraction

☒	>60%	If Ejection Fraction >60%, please quantify: 70 %
☐	50% - 60%	
☐	40% - 49%	
☐	35% - 39%	
☐	30% - 34%	
☐	< 30%	

T 00054

Part 4 Valvular Regurgitation

Mitral (Assessed visually in any apical view)

MOVANT EXHIBIT

☐	None	No regurgitant color flow
☐	Physiologic	Non-sustained jet immediately (within 1 cm) behind the annular plane or ≤ 5% RJA/LAA
☐	Mild	(1) Either the RJA/LAA ratio is more than 5% or the mitral regurgitant jet height is greater than 1 cm from the valve orifice, and (2) the RJA/LAA ratio is less than 20%
☐	Moderate	RJA is equal to or greater than 20% of the LAA but less than or equal to 40% (20% -40% RJA/LAA).
☐	Severe	RJA/LAA greater than 40%.
☐	Not Evaluable	

Comments:

Aortic Based on Jet Diameter (Assessed visually in the parasternal long axis view or in the apical long-axis view, if the parasternal long-axis view is unavailable)

☐	None	No regurgitant color flow.
☐	Trace	JH/LVOTH is less than 10%.
☐	Mild	JH/LVOTH is greater than or equal to 10% and less than or equal to 24% (10% - 24% JH/LVOTH).
☐	Moderate	JH/LVOTH is greater than or equal to 25% and less than or equal to 49% (25% - 49% JH/LVOTH).
☐	Severe	JH/LVOTH is greater than 49%.
☐	Not Evaluable	

Comments:

Part 5 Other Pathology

Are echocardiographic findings observed indicative of other recognized valvular disease?

☐ Yes *If yes, check all applicable box(es) below:*

☐ No *If no, proceed to Part 6 :*

Claimant Name: ENLOE, RUTH
Claimant Number: 8007411

Aortic Valve Pathology

- ☐ Congenital Aortic Valve Abnormality
  Please specify:
  - ☐ Bicuspid valve ☐ Unicuspid valve ☐ Quadricuspid valve
  - ☐ Ventricular septal defect associated with aortic regurgitation
- ☐ Aortic dissection involving the aortic root and /or aortic valve
- ☐ Aortic sclerosis
- ☐ Aortic root dilatation > 5.0cm
- ☐ Aortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation
- ☐ Evidence of aortic valve surgery
- ☐ Aortic valve pathology of a type associated with bacterial endocarditis
- ☐ Aortic valve lesions of the type associated with systemic lupus erythematosis
- ☐ Aortic valve lesions of the type associated with rheumatoid arthritis
- ☐ Aortic valve lesions of the type associated with carcinoid tumor
- ☐ Aortic valve lesions of the type associated with methysergide and/or ergotamine use

Comments on aortic valve pathology:

Mitral Valve Pathology

- ☐ Mitral valve prolapse (Assessed in the parasternal long axis view and defined as displacement of one or bo mitral leaflets > 2mm above the atrial-ventricular border during systole, and > 5mm leaflet thickening during diastole)
- ☐ Congenital Mitral Valve Abnormality
  Please specify:
  - ☐ Parachute valve ☐ Cleft of the mitral valve associated with atrial septal defect
- ☐ Chordae tendineae rupture
- ☐ Papillary muscle rupture
- ☐ Papillary muscle dysfunction
- ☐ Acute myocardial infarction associated with acute mitral regurgitation

Mitral Valve Pathology (continued)

- ☐ Mitral annular calcification
- ☐ Rheumatic mitral valve
  (Defined as doming of the anterior leaflet and/or anterior motion of the posterior leaflet and/or commissural fusion)
- ☐ Evidence of mitral valve surgery
- ☐ Mitral valve lesions of a type associated with bacterial endocarditis

Claimant Name: ENLOE, RUTH
Claimant Number: 8007411

☐ Yes *If Yes, please comment:*

☐ No

[1] H. Feigenbaum, *Echocardiography* 68-133 (5th ed. 1994).
[2] A. E. Weyman, *Principles and Practice of Echocardiography* 75-97 (2nd ed. 1994).

Part 7 Technical Quality of Echocardiogram Tape

☐	*Excellent*	Ideal image quality
☑	*Good*	Diagnostic images in all views for all cardiac structures that need to be assessed
☐	*Fair*	Image quality that allows adequate assessment of most of the cardiac structures (aor mitral, and tricuspid valves) but not necessarily in all views.
☐	*Poor*	Image quality is marginal to assess the aortic and/or mitral valve(s).
☐	*Non-interpretable*	Image quality is inadequate to assess the aortic and mitral valves.

Part 8 Cardiologist Signature

[signature] [initials] 7/26/02

Cardiologist Signature | Initials | Date of Reading

John DeGr

Print Name

Exhibit D

Exhibit A

e	date echo	dent mr	gi dent ar	gri reader mr	reader mr	reader ar	reader ar	dent other	reader oth	reader ar	agree?	
rd, James	3/28/02	1	0	3	0.21	0	0	0	0	Crouse	0	
rman, Charline	3/27/02	2	0	3	0.20	0	0	0	0	Crouse	0	
don, Katherin	3/25/02	2	2	3	0.34	3	0.49	1	0	Crouse	0	
ett, Lashanna	3/26/02	1	0	3	0.21	0	0	0	0	Crouse	0	
s, Judy	3/19/02	1	0	3	0.27	0	0	0	0	Crouse	0	
phel, Darlene	3/12/02	1	0	3	0.24	0	0	0	0	Crouse	0	
er, Glenicqua	3/20/02	1	0	3	0.23	3	0.36	0	0	Crouse	0	
k, Donald	3/29/02	1	0	3	0.21	3	0.29	0	0	Crouse	0	
ich, Mildred	3/27/02	1	0	3	0.26	0	0	0	0	Crouse	0	
ingham, Chris	3/14/02	1	0	3	0.27	0	0	0	0	Crouse	0	
, Renita	2/25/02	1	0	3	0.27	2	0.23	0	0	Crouse	0	
, Scott	2/25/02	1	0	3	0.27	0	0	0	0	Crouse	0	
ell, Cathy	3/27/02	2	2	3	0.21	3	0.3	0	0	Crouse	0	
e, Ruth	3/19/02	3	0	3	0.25	0	0	0	0	Crouse	1	
on, Frank	3/19/02	0	0	3	0.30	0	0	0	0	Crouse	0	
r, Debra	3/19/02	2	0	3	0.27	0	0	0	0	Crouse	0	
t, Peter	2/25/02	1	0	3	0.28	3	0.3	0	0	Crouse	0	
vin, Junetta	3/28/02	1	0	3	0.23	0	0	0	0	Crouse	0	
man, Carolyn	3/13/02	1	0	3	0.21	0	0	0	0	Crouse	0	
/icky	3/25/02	2	0	3	0.24	0	0	0	0	Crouse	0	
son, Patricia	3/28/02	3	2	4	0.49	4	0.53	0	0	Crouse	0	
s, Maryann	3/28/02	1	0	3	0.21	0	0	0	0	Crouse	0	
son, Cathy	3/19/02	0	0	3	0.21	0	0	0	0	Crouse	0	
s, Carlyn	3/12/02	2	2	3	0.28	3	0.42	0	0	Crouse	0	
y, Mary	2/13/02	1	0	3	0.27	3	0.27	0	0	Crouse	0	
ll, Kathleen	3/27/02	2	0	3	0.28	0	0	0	0	Crouse	0	
ger, Ron	3/14/02	1	0	3	0.23	0	0	0	0	Crouse	0	
y, Cynthia	3/27/02	2	0	3	0.36	0	0	0	0	Crouse	0	
Susan	3/28/02	2	0	3	0.38	0	0	0	0	Crouse	0	
JoAnne	3/27/02	2	0	3	0.24	0	0	0	0	Crouse	0	
es, Linda	3/14/02	3	0	3	0.24	0	0	0	0	Crouse	1	
nan, Carolyn	3/20/02	2	0	3	0.22	0	0	0	0	Crouse	0	
essica	3/12/02	1	0	3	0.27	0	0	0	0	Crouse	0	
s, Amy	3/27/02	2	0	3	0.34	0	0	0	0	Crouse	0	
ll, Sharon	3/28/02	2	0	3	0.25	0	0	0	0	Crouse	0	
e, James	3/19/02	2	0	3	0.20	0	0	0	0	Crouse	0	

Michael	3/29/02	1	0	3	0.24	0	0	0	0	Crouse	0	
Julia	3/27/02	2	0	3	0.22	0	0	0	0	Crouse	0	
Cynthia	3/26/02	2	0	3	0.21	0	0	0	0	Crouse	0	
l, Nancy	3/29/02	1	0	3	0.25	0	0	0	0	Crouse	0	
s, Pamela	3/13/02	1	0	3	0.21	0	0	0	0	Crouse	0	
s, Joseph	3/20/02	1	0	3	0.28	0	0	0	0	Crouse	0	
ez, John	3/25/02	2	0	4	0.31	0	0	0	0	Crouse	0	
lick	3/29/02	1	0	3	0.21	0	0	0	0	Crouse	0	
ord, Betty	3/14/02	2	0	3	0.22	0	0	0	0	Crouse	0	
Barbara	3/25/02	2	0	3	0.26	0	0	0	0	Crouse	0	
y, James	2/25/02	2	0	3	0.24	0	0	0	0	Crouse	0	
, Kathleen	3/29/02	2	0	3	0.25	0	0	0	0	Crouse	0	
air, Charles	3/25/02	1	0	3	0.26	0	0	0	0	Crouse	0	
Marietta	3/26/02	1	0	3	0.24	0	0	0	0	Crouse	0	
ass, Dorothy	3/26/02	2	0	3	0.20	0	0	0	0	Crouse	0	
ll, Connie	3/14/02	2	0	3	0.23	0	0	0	0	Crouse	0	
Evette	3/29/02	1	0	3	0.27	3	0.33	0	0	Crouse	0	
s, Brenda	3/29/02	1	2	3	0.25	3	0.41	0	0	Crouse	0	
auer, G	3/12/02	2	0	3	0.23	0	0	0	0	Crouse	0	
Florence	8/24/2002	2	3	3	0.33	3	0.26	0	0	Mueller		1
James	12/1/2001	2	0	3	0.24	3	0.27	1	1	Mueller		0
ia, Victor	11/8/2001	1	1	3	0.22	3	0.26	0	0	Mueller		0
berg, Fritz	12/6/2001	1	0	3	0.22	3	0.25	0	0	Mueller		0
ein, Ellen	11/1/2001	1	3	4	0.41	3	0.34	1	1	Mueller		0
Christine	##########	0	0	3	0.2	3	0.25	0	0	Mueller		0
l, Laura	2/12/2002	2	2	3	0.22	2	0.16	0	0	Mueller		0
Vernessa	##########	2	0	3	0.22	1	0	0	0	Mueller		0
tricia												
, Girard	1/24/2002	1	0	3	0.26	3	0.26	0	1	Mueller		0
i, Toni	1/12/2001	3	2	4	0.41	3	0.33	0	0	Mueller		1
Silvio	2/6/2002	1	0	3	0.25	2	0.17	0	0	Mueller		0
rski, Gail	##########	1	1	3	0.2	2	0.2	0	0	Mueller		0
Juan	2/9/2002	1	0	3	0.2	2	0.19	0	0	Mueller		0
Patricia	1/10/2001	1	0	3	0.2	2	0.23	0	0	Mueller		0
idgot	0/22/2001	2	0	3	0.24	2		0	0	Mueller		0
Brenda	12/6/2001											

on, Kathleen	**										
heila	##########	1	1	3	0.32	2	0.17	0	0 Mueller	0	
y, Geralyn	8/23/2001	1	1	3	0.24	3	0.26	0	0 Mueller	0	
lana	4/3/2002	2	0	3	0.21	2	0.19	0	0 Mueller	0	
aren	2/4/2002	1	0	3	0.26	2	0.24	0	0 Mueller	0	
ella, Jo	1/21/2002	1	2	3	0.28	3	0.43	0	0 Mueller	0	
inda	8/22/2001	2	0	3	0.21	2	0.38	0	0 Mueller	0	
lla, Louis	##########	0	0	3	0.2	3	0.3	0	0 Mueller	0	
os, Barbara	##########	2	1	3	0.38	3	0.29	0	0 Mueller	0	
, Prudence	2/4/2002	2	0	3	0.2	2	0.15	0	0 Mueller	0	
Eugene	1/31/2002	2	0	3	0.22	3	0.26	0	0 Mueller	0	
, Anthony	8/23/2001	3	1	3		1	0	1	1 Mueller	1	

** Tape not evaluable

Echocardiographic Report

Name: Rent Enloe — Date: 12/8/09

MITRAL VALVE REGURGITATION (RJA/LAA) 20 % (3/15) — CVC ~~ne~~

☐none ☐trace(1-4%) ☐mild(5-19%) ☐moderate(20-40%) ☐severe(>40%)

☒Structurally normal valve ☐mild (RJH<1cm from valve orifice)

A

OTHER FINDINGS (Check All Conditions Present)

☐Thickened leaflet(s) ☐parachute valve ☐cleft associated with ASD ☐Prosthetic Valve

☐Mitral Valve Prolapse (>2mm LA displacement of leaflets and>5mm thick in diastole)

☐acute myocardial infarct associated with acute regurgitation ☐papillary muscle rupture

☐rheumatic MV ☐mitral annular calcification ☐stenosis ☐chorda tendinea rupture

Comments:

AORTIC VALVE REGURGITATION (RJH/LVOT) _____ % (PSLX or Apical Long-Axis if Parasternal is unavailable)

☒none ☐trace (1-9%) ☐mild (10-24%) ☐moderate (25-49%) ☐severe (>49%)

☒Structurally normal valve

OTHER FINDINGS (Check all Conditions Present)

☐Thickened leaflet(s) ☐unicusp ☐bicuspid ☐quadricuspid ☐aortic sclerosis diagnosed at <60yr. old

☐Prosthetic Valve ☐Aortic root dilatation >5.0cm ☐Aortic dissection involving root or valve

☐Aortic stenosis with a valve area <1.0 sq.cm. by continuity equation

Comments: Normal Tricuspid & Pulmonary Valves. Trace TR

LEFT ATRIAL SIZE (CM) Mildly Enlarged LA

☐ Within normal limits 4.2 LA (PSLX nl≤4.0) _____ LA (Apical 4 chamber ≤5.3)

ATRIAL FIBRILLATION ☐ ASD NOTED ☐

LEFT VENTRICULAR FUNCTION (Ejection Fraction)

☒ >60% ☐ 50-60% ☐ 40-49% ☐ 30-39% ☐ <30% 62 % Normal RVSP

LEFT VENTRICULAR SIZE

☐ Within normal limits ☐ abnormal LVESD>50mm ☐ abnormal LVEDD>70mm

☐ abnormal LVESD≥45mm

PEAK TR VELOCITY 2.7 m/s PAP(RA=10) 39 mm Hg

IMAGE QUALITY: ☐ diagnostic ☐ nondiagnostic

Comments:

ATTORNEY WORK PRODUC

Subroto Gangopadhyay

Subroto Gangopadhyay, M.D.

The Women's Cardiovascular Center

4320 Wornall Road Suite 240
Kansas City, MO 64111 ph# (816)531-7474

Morales, Linda L
57 year old **Female** DOB: **01/10/1945**
Procedure Date: **Mar 14, 2002**

Echocardiography Report
Final Report
Printed: 03/14/2002 4:07:01 PM

Procedure performed at ***Hariton & D'Angelo; Long Island, NY--Echo L. Crouse Office***
Medical Record # (I.D.) No ID type Hospital Room # ABNORMAL

Procedures Performed

Transthoracic Echocardiogram
2-D and M-Mode combination.
Spectral Analysis Doppler
Color Flow Doppler

Reason for Test

Phen-Fen

Measurements

Resting			Normal Range
M-MODE	LV Diam Dias	4.60 cm	3.5 - 5.7
	LV Diam Sys	2.00 cm ***	2.3 - 3.9
	LVEF	70.00 (%)	45 - 84
	LV Septum	1.20 cm ***	0.6 - 1.1
	LV Post Wall	1.20 cm ***	0.6 - 1.1
	Ao Root Size	2.50 cm	2 - 3.7

Echocardiographic Interpretation

Resting

LV (left ventricle)	LVEF : 70 %
	Mild Concentric Hypertrophy
MV (mitral valve)	Moderate MV Regurgitation
AV (aortic valve)	Normal aortic valve
LA (left atrium)	The left atrial size is mildly increased
RV (right ventricle)	Normal right ventricle
TV (tricuspid valve)	Mild tricuspid valve regurgitation
	PAP Based on Tricuspid Regurgitant Jet estimated at: 33 mm Hg
RA (right atrium)	Normal right atrium
PV (pulmonic valve)	Normal pulmonary valve

Conclusion

EF--70%
Normal LV function
Mild Concentric Hypertrophy
Mild LA enlargement; 4.35 cm in the PLAX view
Moderate MR; 4.73/19.73=24% of the LA area
No AR
Mild TR
PAP--33 mmHg

Staff			
Reviewed by:	**Ms. Audrey Loeb RDCS,RVT** **Dr. Linda J. Crouse MD, FACC**	Department: Tape Group:	Height: Weight: BSA:

Reviewed by Linda J Crouse MD

Dr. Linda J. Crouse MD, FACC

3/14/02

MORALES, LINDA

DDR# 8006806

Date of Echocardiogram (mm/dd/yyyy) 03/14/2002

Study Type ☒ TTE ☐ TEE ☐ Stress Echo (resting portion only)

Part 1 M-Mode Quantitative Measurements (parasternal long axis view)

Is the patient in: ☒ Sinus rhythm ☐ Atrial fibrillation / flutter ☐ Other: specify

Aortic Root (1 beat)	2.5 cm	Not evaluable ☐
Left atrium (1 beat)	4.2 cm	Not evaluable ☐
Left Ventricular Internal Dimension – End Systole (2 beats)	___ cm	Not evaluable ☐
Left Ventricular Internal Dimension – End Diastole (2 beats)	___ cm	

Comments:

Part 2 Pulmonary Artery Pressure (continuous wave doppler)

Peak tricuspid regurgitation jet velocity	___ meters/second	Not evaluable ☒
	___ mm Hg	Not evaluable ☐

PASP

Compute from TR velocity using the following equation: PASP = 4 $TRvel^2$ + 10 mmHg

Comments

Part 3 Left Ventricular Systolic Function (Assessed visually integrating information from all views)

Ejection Fraction

☒ >60%	If Ejection Fraction >60%, please quantify: 65%
☐ 50% - 60%	
☐ 40% - 49%	
☐ 35% - 39%	
☐ 30% - 34%	
☐ < 30%	

T 00465

Part 4 Valvular Regurgitation

Mitral (Assessed visually in any apical view)

MOVANT EXHIBIT 159

Claimant Name: MORALES, LINDA
Claimant Number: 8006806

☐	None	No regurgitant color flow
☐	Physiologic	Non-sustained jet immediately (within 1 cm) behind the annular plane or ≤ 5%
☐	Mild	(1) Either the RJA/LAA ratio is more than 5% or the mitral regurgitant jet heigh than 1 cm from the valve orifice, and (2) the RJA/LAA ratio is less than 20%
☐	Moderate	RJA is equal to or greater than 20% of the LAA but less than or equal to 40% RJA/LAA).
☐	Severe	RJA/LAA greater than 40%.
☐	Not Evaluable	

Comments:

Aortic Based on Jet Diameter (Assessed visually in the parasternal long axis view or in the api axis view, if the parasternal long-axis view is unavailable)

☐	None	No regurgitant color flow.
☐	Trace	JH/LVOTH is less than 10%.
☐	Mild	JH/LVOTH is greater than or equal to 10% and less than or equal to 24% (10% JH/LVOTH).
☐	Moderate	JH/LVOTH is greater than or equal to 25% and less than or equal to 49% (25% JH/LVOTH).
☐	Severe	JH/LVOTH is greater than 49%.
☐	Not Evaluable	

Comments:

Part 5 Other Pathology

Are echocardiographic findings observed indicative of other recognized valvular disease?

☐ Yes ☐ No

If yes, check all applicable box(es) below: *If no, proceed to Part 6 :*

Claimant Name: MORALES, LINDA
Claimant Number: 8006806

Aortic Valve Pathology

- ☐ Congenital Aortic Valve Abnormality
  Please specify:
  - ☐ Bicuspid valve ☐ Unicuspid valve ☐ Quadricuspid valve
  - ☐ Ventricular septal defect associated with aortic regurgitation
- ☐ Aortic dissection involving the aortic root and /or aortic valve
- ☐ Aortic sclerosis
- ☐ Aortic root dilatation > 5.0cm
- ☐ Aortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation
- ☐ Evidence of aortic valve surgery
- ☐ Aortic valve pathology of a type associated with bacterial endocarditis
- ☐ Aortic valve lesions of the type associated with systemic lupus erythematosis
- ☐ Aortic valve lesions of the type associated with rheumatoid arthritis
- ☐ Aortic valve lesions of the type associated with carcinoid tumor
- ☐ Aortic valve lesions of the type associated with methysergide and/or ergotamine use

Comments on aortic valve pathology:

Mitral Valve Pathology

- ☐ Mitral valve prolapse (Assessed in the parasternal long axis view and defined as displacem mitral leaflets > 2mm above the atrial-ventricular border during systole, and > 5mm leaflet thi diastole)
- ☐ Congenital Mitral Valve Abnormality
  Please specify:
  - ☐ Parachute valve ☐ Cleft of the mitral valve associated with atrial septal defect
- ☐ Chordae tendineae rupture
- ☐ Papillary muscle rupture
- ☐ Papillary muscle dysfunction
- ☐ Acute myocardial infarction associated with acute mitral regurgitation

Mitral Valve Pathology (continued)

- ☐ Mitral annular calcification
- ☐ Rheumatic mitral valve
  (Defined as doming of the anterior leaflet and/or anterior motion of the posterior leaflet and/or fusion)
- ☐ Evidence of mitral valve surgery
- ☐ Mitral valve lesions of a type associated with bacterial endocarditis

Claimant Name: MORALES, LINDA
Claimant Number: 8006806

- ☐ Mitral valve lesions of the type associated with systemic lupus erythematosis
- ☐ Mitral valve lesions of the type associated with rheumatoid arthritis
- ☐ Mitral valve lesions of the type associated with carcinoid tumor
- ☐ Mitral valve lesions of the type associated with methysergide and/or ergotamine use

Comments on mitral valve pathology:

General Pathology

- ☐ Endocardial fibrosis
- ☐ Other: *please specify abnormality:*

Are any secondary causations of valvular pathology suggested but not clearly visualized?

☐ Yes *If Yes, please comment:*

☐ No

Part 6 Echocardiogram Evaluation

Was this echocardiogram conducted in accordance with the standards and criteria as outlined in (1994) or Weyman[2] (1994)?

☑ Yes

☐ No

If No, please comment on all observed deviations:

Has this tape been edited, modified or altered in any respect?

Claimant Name: MORALES, LINDA
Claimant Number: 8006806

☐ Yes *If Yes, please comment:*

☑ No

[1] H. Feigenbaum, *Echocardiography* 66-133 (5th ed. 1994).
[2] A. E. Weyman, *Principles and Practice of Echocardiography* 75-97 (2nd ed. 1994).

Part 7 Technical Quality of Echocardiogram Tape

☐	*Excellent*	Ideal image quality
☑	*Good*	Diagnostic images in all views for all cardiac structures that need to be a
☐	*Fair*	Image quality that allows adequate assessment of most of the cardiac s mitral, and tricuspid valves) but not necessarily in all views.
☐	*Poor*	Image quality is marginal to assess the aortic and/or mitral valve(s).
☐	*Non-interpretable*	Image quality is inadequate to assess the aortic and mitral valves.

Part 8 Cardiologist Signature

Cardiologist Signature — Initials — Date of Readi

JOHN DENT
Print Name

236 F.Supp.2d 445
Prod.Liab.Rep. (CCH) P 16,489
(Cite as: 236 F.Supp.2d 445)

H

United States District Court,
E.D. Pennsylvania.

In re: DIET DRUGS (PHENTERMINE, FENFLURAMINE, DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION.
This Document Relates to:
Sheila Brown, et al.
v.
American Home Products Corporation.

No. MDL 1203.
Civil Action No. 99-20593.

Nov. 14, 2002.

Settlement trust moved for order that it did not have to pay certain claims for benefits under class action settlement involving prescription diet drugs that caused heart ailments in some consumers, and also sought authority to audit more claims than allowed under settlement's terms. The District Court, Bartle, J., held that: (1) trust's expert was qualified to testify as cardiologist and reader of echocardiograms; (2) doctor's readings of 53 echocardiograms were medically unreasonable; (3) echocardiograms and echocardiogram readings performed by second doctor were medically unreasonable; (4) good cause existed to authorize trust to audit claims for which two doctors provided medical condition attestations or which were submitted by certain law firms; (5) trust was not entitled to attorney fee award; and (6) preliminary injunctive relief was warranted.

Ordered accordingly.

West Headnotes

[1] Evidence ⇐537
157k537 Most Cited Cases

Expert was qualified to testify as cardiologist and reader of echocardiograms in connection with disputed claims for benefits in settled class action involving prescription diet drugs which caused heart ailments in some consumers; expert served as medical director and interpreter of echocardiograms at university for approximately eight supervised echocardiography training prog had authored numerous peer-reviewed ar about, and given lectures on, echocardiography throughout his career read more than 2 echocardiograms and conducted more than 1 and, with respect to disputed claims, revi videotapes of echocardiograms, digital loops v provided, and still frames to evaluate consu condition in context.

[2] Compromise and Settlement ⇐72
89k72 Most Cited Cases

Doctor's readings of 53 echocardiograms medically unreasonable, and thus did not su award of benefits to claimants under class a settlement involving prescription diet drugs ca heart ailments; doctor frequently mistook back and mild mitral regurgitation for the moderat more severe regurgitation required to esta entitlement to benefits, did not analyze video for all of echocardiogram for which she si attestations, and approved echocardiogram re in which regurgitant jet areas were overtraced thus overestimated level of mitral regurgitation, circumstances under which echocardiograms performed, which included reliance on law employee to instruct staff on how to mea regurgitant jets and an assembly line-like appr undermined doctor's credibility.

[3] Compromise and Settlement ⇐72
89k72 Most Cited Cases

Echocardiograms and echocardiogram read performed by doctor were medically unreasona and thus did not support award of benefit claimants under class action settlement invol prescription diet drugs causing heart ailme doctor used low Nyquist settings that resulte sub-optimal echocardiograms which incl spurious or artifactual signals on color Doppler, doctor measured some spurious jets backflow as mitral regurgitation required establish entitlement to benefits, and contin nature of portion of fee to be received by dc adversely affected doctor's credibility.

[4] Compromise and Settlement ⇐72
89k72 Most Cited Cases

236 F.Supp.2d 445
Prod.Liab.Rep. (CCH) P 16,489
(Cite as: 236 F.Supp.2d 445)

Pursuant to provision in settlement agreement in class action involving prescription diet drugs, which allowed court to order additional benefit claim audits and administrative procedures for good cause shown, including the results of audited claims, district court had authority to allow settlement trust to conduct additional audits of claims submitted on behalf of claimants represented by certain law firms or for whom attestations of required medical condition were provided by certain cardiologists, even though motion to allow trust to conduct additional audits was not triggered by results of audited claims; court was not required to wait until challenged claims were audited to consider whether good cause existed to modify claims administration and auditing procedures.

[5] Compromise and Settlement ⚿72
89k72 Most Cited Cases

Good cause existed in class action involving prescription diet drugs for district court to authorize settlement trust to audit all claims for benefits for which medical condition attestations showing entitlement to benefits under settlement terms were provided by either of two cardiologists, and all claims for benefits submitted on behalf of claimants represented by two law firms, regardless of identity of cardiologist providing attestation, given evidence that two cardiologists had made medically unreasonable judgments on a broad scale, that law firms retained cardiologists, and that one firm worked out questionable financial arrangement with one cardiologist and was deeply involved in completing medical portions of claims forms for both cardiologists.

[6] Injunction ⚿138.27
212k138.27 Most Cited Cases

Enjoining law firms from representing claimants in filing for benefits under settlement trust in class action involving prescription diet drugs was not warranted, even though firms' conduct had not been completely exemplary, inasmuch as barring firms' representation would harm innocent claimants who were eligible for benefits and order allowing trust to audit claims submitted by firms' clients was sufficient to prevent unqualified claimants from receiving benefits.

[7] Injunction ⚿138.27
212k138.27 Most Cited Cases

Pursuant to settlement agreement in class involving prescription diet drugs, which a defendant to challenge in individual lawsuit w claimant's exercise of opt-out right was p injunction was not warranted in class action claimants from relying on attestations of cardiologists to support their exercise of o right, despite evidence that certain attest provided by cardiologists in support of clai benefits filed with settlement trust were mec unreasonable.

[8] Federal Civil Procedure ⚿2737.13
170Ak2737.13 Most Cited Cases

Settlement trust was not entitled to awa attorney fees in connection with its motion se authorization not to pay contested claim benefits in settled class action inv prescription diet drugs and seeking authorizat audit certain claims, inasmuch as settl agreement did not provide for such relief.

[9] Injunction ⚿138.27
212k138.27 Most Cited Cases

Trust administering settlement fund in class involving prescription diet drugs was entitl preliminary injunction barring it from m improper payments and authorizing trust to co additional audits of certain claims, inasmuch as established that two law firms, through attest of two cardiologists, submitted numerous med unreasonable claims on behalf of clients, irrep harm through depletion of trust funds would if payment of medically unreasonable claims not stopped and expanded audits were not all possible delay in payment of claims was only that legitimate claimants would suffer, and p interest in preserving integrity of settlement fa injunctive relief.

447 *MEMORANDUM AND PRETRIAL ORDER NO. 2640

BARTLE, District Judge.

The matter presently before the court concern propriety of seventy- eight *448 claims for be under the class action settlement involving the

236 F.Supp.2d 445
Prod.Liab.Rep. (CCH) P 16,489
(Cite as: 236 F.Supp.2d 445)

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 f the Trust on July 11, 2002 as a "Motion Temporary Restraining Order and Preli Injunction." At the time, the Trust urged the among other things, to prevent the Harit Napoli firms from falsifying certain informati they were submitting to the Trust and misleading class members about their assc with the Trust. In large part, the Trust's moti based on the declaration of C.V. Compton S registered nurse who was hired by the Harit Napoli firms, albeit briefly, and who atte training session that the firms conducted in Texas on March 13, 2002. After a conferenc counsel on July 16, 2002, this court sched hearing for August 15, 2002. *See* Pretrial No. 2524.

At a prehearing conference on August 1 moving parties advised the court that they abandoning their reliance on Mr. Declaration because of concerns abou credibility. Instead, after further review of claims submitted by the two law firms, movar now determined that the certifications by cardiologists of moderate or more seve mitral regurgitation were medically unreasc The Trust explained that it was on the ve paying out nearly $50 million for what it belie be ineligible claims submitted by the Harit Napoli firms. [FN1] This money would be di if not impossible, to recoup if it turned out hearing that these claimants were not entit benefits. Moreover, a serious issue existed w sufficient funds would be available to pay e claimants if non-qualified persons re payments. While Wyeth's obligation with resp Fund B is certainly large, it is not unlimite there are thousands of potential beneficiaries to the shift in the movants' focus, the cancelled the August 15 hearing with the cons all parties.

FN1. Specifically, the Trust was sch to pay more than $2.1 million fc claims on August 16, 2002 approximately $4.3 million for ten on August 30, 2002. In addition, the explained that it was likely to pay

236 F.Supp.2d 445
Prod.Liab.Rep. (CCH) P 16,489
(Cite as: 236 F.Supp.2d 445)

> 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.

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 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. [FN2]

> FN2. 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 I Schulman because Dr. M certification was not the basis i claim, although he had at one performed an echocardiogram for e addition, the Trust withdrew its ch to the attestation for claimant Orgass. The Trust's expert did not the medical reasonableness certifications for claimants F Adams, Toni Delligatti, Ruth Enloe, Morales and Anthony Vaccaro. I the Trust's expert did not opine as echocardiogram readings for cla Patricia Cruz and Kathleen Kelly because, in his opinion, the tapes we evaluable." *See* Movant's Ex. 94.

***450 II.**

As noted above, moderate mitral regurgita among the medical conditions that qua claimant for Fund B Matrix level benefits fr Trust. This condition involves the backw reverse flow of blood through a defective valve which separates the left atrium of the from the left ventricle.

The heart consists of four chambers: the atrium, the right ventricle, the left atrium a left ventricle. These chambers are connect valves consisting of two leaflets. They op allow blood to pass through and then close rapid process ensures the proper directional fl blood through the heart.

The chambers of the heart fill and empty seamless, two-phase cardiac cycle that com diastole, the filling cycle, and systole, the em cycle. Initially, deoxygenated blood enters the through the right atrium. During diastole tricuspid valve opens and blood is pumped in right ventricle where it collects before expelled. As systole begins, the right ve contracts and the blood is ejected int pulmonary arteries. The blood is then c through these arteries into the lungs where re-oxygenated before passing back into th atrium of the heart through the pulmonary During diastole, the mitral valve opens and moves from the left atrium into the left ven

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. [FN3] Settlement Agreement §§ IV.B.1-2. Moderate 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. [FN4] Depending on other factors not currently ***451** relevant, a claimant with qualifying mitral regurgitation may receive between $38,422 and $643,500 in benefits from the Trust. [FN5] *See id.* at § IV.B.2.a.

FN3. 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 claimants at issue satisfies these criteria. Movants only chall medical reasonableness of the f moderate or more severe regurgitation.

FN4. A claimant with such regur eligible for compensation und A-1 unless he or she has one "reduction factors" as noted in Form, in which case, ben determined in accordance with M The presence of any one of thes which cannot be determi echocardiogram, establishes purposes of this Settlement claimant's valvular regurgitat caused by something other than t diet drugs.

FN5. By contrast, a claimant w regurgitation at 19.9% RJA/LAA just below moderate, is ineli benefits. Such a claimant may, become eligible in the future if l condition worsens. *See* Pretrial C 1415 at 47.

Whether a claimant has moderate or mo mitral regurgitation is determined accordi protocol outlined in the Settlement A First, a claimant must undergo a echocardiogram, that is, an ultrasound of During the procedure, a cardiologist or so places a transducer on the patient's chest th high frequency sound waves into the hear sound waves bounce off the surface of the back to the transducer, they create a movi of the heart, its valves and blood flow. Thi image is recorded on a videotape throug procedure. In addition, the sonogra cardiologist often will make a digitized v the video, which will contain a subse videotaped images including still frames a [FN6] Because the image being taken is c moving, the cardiologist or sonographer pe the echocardiogram must periodically fr image on the screen in order carefully to

236 F.Supp.2d 445
Prod.Liab.Rep. (CCH) P 16,489
(Cite as: 236 F.Supp.2d 445)

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.

FN6. A loop shows the heart through one filling and emptying cycle.

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
(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. [FN7] *See* Jagmeet P. Singh, M.D., et al., *Prevalence and Clinical Determinants of Mitral, Tricuspid, and Aortic Regurgitation (The Framingham *452 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.

FN7. 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 a echocardiogram. However, the Settlemer Agreement and Green Form refer to th use of color flow Doppler to measure th existence and severity of mitra regurgitation. Neither authorizes the us of continuous wave Doppler in measurin the severity of mitral regurgitation.

As a condition for benefits, the echocardiogran also must reveal a regurgitant jet that consists o "blue, green or mosaic signals ... originating fron the mitral valve and spreading into the left atriun during systole." Movant's Ex. 101 at 22. On color flow Doppler echocardiogram, mitra regurgitation will thus display as a high velocity mosaic blue/green teardrop shaped jet that border the mitral valve leaflets and expands into the lef atrium throughout at least a portion of systole. [FN8] As a sign of the high velocity, the jet often wil contain multicolored blue, green and yellow stripes a phenomenon known as "aliasing." Aliasing is a hallmark characteristic of a high velocity mitra regurgitation jet.

FN8. The jet is high velocity because of the difference in pressure between the contracting left ventricle and the left atrium.

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 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] ***453** 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 Diet Drug Settlement and submitting it to AHP Settlement Trust is equivalent to filin with a Court. I declare under penalty of per that the information provided in this form correct to the best of my knowledge, informa and belief.

Movant's Ex. 101 at 14.

III.

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

The movants called as an expert witness Dr. J Dent, a cardiologist and level three trai echocardiogram reader. Dr. Dent has served Medical Director and Interpreter Echocardiograms at the Adult Echocardiogra Laboratory at the University of Virginia since 19 Prior to obtaining this position, he recei extensive training in echocardiography as a resid and cardiovascular Fellow at the University Virginia. During the course of his professio career, he has authored numerous peer-reviev articles about echocardiography and given lectu on echocardiography at national and internatio meetings. As director of the Ac Echocardiography Laboratory, Dr. Dent supervi the echocardiography training programs oversees the work of five echocardiogram read He reads approximately 3,000 echocardiogra during the course of a year and throughout career has read more than 20,000 echocardiogra and conducted himself more than 1,000.

Dr. Dent initially focused on fifty-five Dr. Cro echocardiograms and thirty Dr. Mue echocardiograms. For each echocardiogram, reviewed videotapes of the echocardiograms, dig loops where provided and still frames in order evaluate valvular regurgitation in context. [FN He spent on average at least between fifteen thirty minutes viewing the tapes certified by Crouse. It is not clear how much time he sp reviewing Dr. Mueller's tapes. However, testified that Dr. Mueller's tapes were on aver much longer than Dr. Crouse's. Because of limi

236 F.Supp.2d 445
Prod.Liab.Rep. (CCH) P 16,489
(Cite as: 236 F.Supp.2d 445)

time between his engagement and the hearing, he focused his analysis on the amount of valvular regurgitation as shown ***454** 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.

> FN9. 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.

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.

[1] We find Dr. Dent to have been extreme qualified as a cardiologist and rea echocardiograms. We accept his a conclusions, and opinions concerning the unreasonableness of the readings by Dr. Cro Dr. Mueller. His presentation outlinir improper measurements and the misidentific backflow as mitral regurgitation was coge Dent's credibility was further enhanced thorough analysis of the echocardiogram t the claims in issue. He did not simply look frame of an echocardiogram and reach an about the severity of mitral regurgitation. [FN

> FN10. The moving parties also pr as witnesses Drs. Richard Helmc Ernest Madu, both highly q cardiologists and echocardiographe a large extent, their testimon repetitious of that of Dr. Dent. Whe were differences, we accept what D said.

The Hariton and Napoli firms called as an witness Dr. Scott Lawrence Roth, a leve trained echocardiographer. As with the doctors who testified, Dr. Roth has ex experience in the field of cardiology echocardiography. From 1992 to 1999, he as Director of the adult echocardio laboratory at Long Island Jewish Medical ("LIJ"). In this capacity, Dr. Roth supervis to four sonographers and cardiology Fellov was further responsible for training the F Following his tenure with LIJ, Dr. Roth beg own private clinical practice in which he co to be engaged. In his practice, he performs o about 1,500 echocardiograms per year and o course of his career has read more than While he has authored peer-reviewed artic echocardiography and cardiology, he ha written any articles or papers on the measuren mitral regurgitation.

***455** Dr. Roth reviewed the echocardiogram for all the claims in issue. He examine Mueller's echocardiograms on videotape, b Dr. Crouse, he primarily analyzed the digital

236 F.Supp.2d 445
Prod.Liab.Rep. (CCH) P 16,489
(Cite as: 236 F.Supp.2d 445)

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. Lir Crouse, a level three echocardiographer echocardiogram interpretations are at issue Dr. Crouse has extensive training echocardiography. She currently operates a p cardiology practice in Kansas City, Missour teaches echocardiography at the Universit Missouri-Kansas City. Over the course o career, Dr. Crouse has read or interpreted more 150,000 echocardiograms. Dr. Crouse is an member of various professional societies associations, including the American Socie Echocardiography and the American Association.

The fifty-three Dr. Crouse echocardiograms b us are a portion of 725 echocardiograms tha agreed to interpret for the Hariton and Napoli over a four and a half month period from February, 2002 to July, 2002. [FN11] She ini ***456** met with both Mario D'Angelo and Ira Ha from the Hariton firm about this engagement. later met with Mark Bern from the Napoli when he visited her office to examine equipment and discuss the scheduling of echocardiograms. A law firm employee cond a training session at Dr. Crouse's office to certain, as she explained it, that her sonographer "understood how to make measurements" under the Green Form protocol Crouse received a flat fee of $1,000 to perform interpret each echocardiogram for a total fe $725,000.

> FN11. These 725 were only a fractic the echocardiograms that Dr. Cr reviewed over this period. In additio seeing patients as part of her nc clinical practice, she interpreted 30(echocardiograms per week as part o engagement with a second consortiur law firms active in the diet drug litiga She received $250 per echocardio from this second consortium of f Overall, she interpreted approxim 10,000 echocardiograms for consortium over a ten-month p beginning in October, 2001.

On days when echocardiograms were performe

236 F.Supp.2d 445
Prod.Liab.Rep. (CCH) P 16,489
(Cite as: 236 F.Supp.2d 445)

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 th sixty to seventy percent of the 725 Hariton a Napoli claimants her office saw had moderate more severe regurgitation. [FN12] The percentages are significantly higher *457 than t findings of a 1998 blinded clinical study in whi she participated that examined the link between t diet drugs and valvular abnormalities. [FN13] A part of the study, Dr. Crouse performed 6 echocardiograms over a six-month period a found, similar to the conclusions of the study, th only about five percent of the diet drug patients h moderate or greater mitral regurgitation. *See* Juli M. Gardin, M.D., et al., *Valvular Abnormaliti and Cardiovascular Status Following Exposure Dexfenfluramine or Phentermine/ Fenfluramin* 283 (No. 13) JAMA 1703 (April 5, 2000).

FN12. When considering t echocardiograms she interpreted for oth law firms in conjunction with the diet dr litigation, Dr. Crouse determined th between forty percent and seventy perce of diet drug claimants had moderate more severe mitral regurgitation.

FN13. A "blinded" study means that wh she read the echocardiograms, Dr. Crou did not know whether the person had take diet drugs or not.

[2] As noted above, we agree with Dr. Dent th fifty-three of the echocardiograms Dr. Crou interpreted were beyond the bounds of medic reason. Dr. Crouse frequently mistook backflo and mild mitral regurgitation for moderate or mo severe regurgitation. Unlike Dr. Dent who base this assessment on reviews of both the digitize images and the videotapes, Dr. Crouse did n analyze the videotapes for all of t echocardiograms to which she attested. Moreove the evidence demonstrated that Dr. Crou approved echocardiogram reports where th regurgitant jet areas were overtraced and th overestimated the level of mitral regurgitation. D Crouse's sonographer frequently traced black-code blood outside the border of the regurgitant je Blood that is observed as black on a color Dopple echocardiogram represents very low velocit

236 F.Supp.2d 445
Prod.Liab.Rep. (CCH) P 16,489
(Cite as: 236 F.Supp.2d 445)

swirling blood. It was not part of a high velocity mitral regurgitant jet.

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 ***458** 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 initiatec new compensation arrangement with him. I Mueller received $500 up front for completing Green Form with another $1,500 due "upon recei of the client's settlement proceeds or six mont from the date of submission to the AHP Settleme Trust." *See* Wyeth Ex. 103.

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

Dr. Mueller recorded each echocardiogram c videotape and took still frames of any pictures interest. [FN14] He consistently performed th echocardiograms with a Nyquist limit set in th thirty to forty range. After the Trust complained the Hariton firm about the low settings, Dr. Muell agreed to "pay close attention to keeping it 50-6 on all subsequent studies." *See* Wyeth Ex. 11 According to correspondence between Dr. Muell and the Hariton firm, the latter had represented him that Dr. Crouse believed that the norm Nyquist range was within those parameters. D Mueller usually completed an echocardiogra report the same day as the echocardiogram wa conducted.

> FN14. The still frames and origin videotapes were not available to the parti during their preparation for the hearin Dr. Mueller preferred to retain custody an control of all originals.

At some point after Dr. Mueller performed eac echocardiogram, the Hariton firm sent him a Gree Form. He would subsequently spend sixty-five t seventy minutes completing the questions in Part I Initially, the firm sent blank Green Forms to h office. Later, the firm completed the answers wit respect to the medical history of the claiman While he questioned the firm about the propriety c this arrangement, he abided by it. When D

236 F.Supp.2d 445
Prod.Liab.Rep. (CCH) P 16,489
(Cite as: 236 F.Supp.2d 445)

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.

[3] 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 *459 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 part result. He and the law firms were fully awar tendering a Green Form was in effect testi under oath. The form itself stated that submitt to the Trust was "equivalent to filing it with a and was subject to the penalties of pe Movant's Ex. 101 at 14. This highly questio practice by Mario D'Angelo and the Hariton seems to violate a lawyer's ethical obligation compensate a witness on a contingent fee basi New York DR 7- 109(c) and PA Rul Professional Conduct 3.4(b). [FN15] We will the matter by separate order to the New Disciplinary authorities for further review consideration.

> FN15. New York Disciplinary 7-109(c) states:
> A lawyer shall not pay, offer to pa acquiesce in the payment of compens to a witness contingent upon the conte his or her testimony or the outcome c case. But a lawyer may adv guarantee, or acquiesce in the paymer (1)[e]xpenses reasonably incurred witness in attending or testif (2)[r]easonable compensation to a wi for the loss of time in attending, testi .... Rule 3.4(b) of the Pennsylvania of Professional Conduct is similar.

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

Neither the Hariton firm nor the Napoli firm novice in the fen- phen arena. Both considerable experience and sophistication with terms of the Settlement Agreement and hov process claims. The Hariton firm was forme July, 2001 to practice solely in connection with fen-phen litigation and the nationwide class a Settlement Agreement. The firm handles claim

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 personnel have instructed echocardiogram ***460** 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 selec for audit up to ten percent of the claims filed eacl quarter. *See id.* at § VI.F.2. When a claim is selected for audit, the Trust forwards relevan documentation, including the claimant's medica 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." [FN16] The ***461** moving parties assert that this standard has been met. Specifically, the Settlement Agreement states:

> FN16. The good cause provision was part of the Fourth Amendment to the Settlement Agreement and was approved in Pretrial Order No. 1415.

> [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.

[4] 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).

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 retaine "exclusive jurisdiction over this action and each o the Parties, including [Wyeth] and the clas members, to administer, supervise, interpret an enforce this Settlement in accordance with its term ... and to enter such other and further orders as ar needed to effectuate the terms of the Settlement." Pretrial Order No. 1415 at ¶ 11. This court i responsible for overseeing the settlement of thi massive class action, particularly to make sure tha the Settlement Agreement, as approved by thi court, is properly enforced. *See In re Prudentia Ins. Co. of Am. Sales Practice Litig.*, 261 F.3d 355 367-68 (3d Cir.2001).

***462** [5] The settlement at issue was intended t provide individuals who took diet drugs an manifested the established Matrix level condition with a streamlined process for seekin 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 potentia 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.

236 F.Supp.2d 445
Prod.Liab.Rep. (CCH) P 16,489
(Cite as: 236 F.Supp.2d 445)

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.

[6] 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 ***463** firm associated with it dramatically change the picture, additional relief may be in order.

[7] 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 m exercise intermediate or back-end opt-outs a with certain limitations, sue in the tort system wh still remaining class members. Settleme Agreement §§ IV.D.3-4. Thus, instead of seeki benefits from the Trust, they may file lawsu against Wyeth. In order to exercise such an o out, the claimant must submit to "the Court, t Trustees and/or Claims Administrator(s) and AHP," a form expressing an intent to do Settlement Agreement §§ IV.D.3.b and IV.D.4 The form also requires the claimant to certify th he or she has been found by a "qualified physici as FDA positive." One of the findings for an FD positive condition is "moderate or great regurgitation of the mitral valve of the hear While we do not condone the performances of D Crouse or Dr. Mueller in the cases before us, v will not go so far as to prohibit such attestatior This issue must be resolved in the lawsuit filed b the opt-out claimant and not before this court. Th Settlement Agreement is quite explicit that Wye "shall have the right to challenge, *in such lawsı only,* whether the opt-out was timely and prope *including whether the Class Member was eligible exercise such an opt-out right." Id.* at §§ IV.D.3. and IV.D.4.c. (emphasis added). Wyeth will b able through the adversary process to dispute ar questionable conclusions or findings of either D Crouse or Dr. Mueller which might surface.

[8] Finally, the movants seek counsel fees. W note that the Settlement Agreement itself does n explicitly provide for such relief. While n foreclosing such an award under oth circumstances, we will not exercise any authori we have to make such an award here.

VI.

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

236 F.Supp.2d 445
Prod.Liab.Rep. (CCH) P 16,489
(Cite as: 236 F.Supp.2d 445)

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 ***464** 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.

PRETRIAL ORDER NO. 2640

AND NOW, this 14th 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 F signed by a certifying cardiologist other than L J. Crouse, M.D. or Richard L. Mueller, M James Axford; James Barone; Charline Berg Victor Bevilaqua; Fritz Blumenberg; Kath Brandon; Ellen Brownstein; Lashauna Bur Judy Butts; Darlene Campbell; Christine Ca Glenique Carter; Laura Chicchetti; Donald C Mildred Creach; Vernessa Cruse; C Cunningham; Girard Curry, Jr.; Renita Dale; S Dale; Cathy Darpell; Silvio Dobry; Frank Fol Debra Fuller; Peter Gehrt; Gail Gielarov Junetta Godwin; Jean Gomes; Patricia Gut Carolyn Hackman; Bridget Hara; Vicky Brenda Hobeck; Janice Hodge; Patricia Jack Maryann James; Cathy Jefferson; Carlya Jo Mary Kimrey; Sheila Koch; Geralyn Kosof Arlene Kule; Karen Lack; Kathleen Lig Josephine Lobuzzetta; Ron Lybarger; Cyr Mallory; Linda Mark; Susan Marr; L Martorella; Barbara Meszaros; JoAnn M Prudence Mougis; Carolyn Newman; Jessica Eugene Paulen; Amy Peters; Sharon Pic James Pierce; Michael Piper; Julia Purdy; Cyn Read; Nancy Richard; Pamela Roberts; J Rodriguez; Joseph Rogers; Rick Ross; B Rutherford; Barbara Ryan; James Scal Kathleen Scheve; Charles Schoenhair; Mar Smith; Dorothy Snodgrass; Connie Stogs Evette Vititoe; Brenda Williams; and Gwend Winklbauer;

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

(3) the Trust has full authority to audit under Settlement Agreement each and ev echocardiogram and Green Form already submi or to be submitted in the future on behalf of a c member by the law firms of Hariton & D'Ang LLP and/or Napoli, Kaiser, Bern & Associates, L or any attorneys affiliated or associated in any with those law firms, regardless of the identity the attesting cardiologist;

***465** (4) the Trust has full authority to withh payment of any claims identified in paragraphs

(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.

236 F.Supp.2d 445, Prod.Liab.Rep. (CCH) P 16,489

END OF DOCUMENT

Exhibit I

AHP Settlement Trust

P.O. Box 42805, Philadelphia, PA 19101 • 215-923-5211 • Fax: 215-923-5217

January 21, 2003
VIA 2nd Day Air

Ruth Enloe
c/o Hariton & D'Angelo, LLP
Attn: Mario D'Angelo, Esquire
3500 Sunrise Highway, Suite T-207
Great River, NY 11739

RE: Post Audit Determination Letter
Diet Drug Recipient: Ruth Enloe
Claim No.: 183/00 8007411

Dear Class Member c/o Counsel:

In accordance with the requirements of the Nationwide Class Action Settlement Agreement with American Home Products Corporation (the "Settlement Agreement") yc Claim for Matrix Compensation Benefits ("Claim") was selected for audit and reviewed Auditing Cardiologist. Your Claim was selected and audited to determine whether there reasonable medical basis for the answers given by the physician who completed your Gr Form with respect to the question(s) identified in the enclosed Attestation of Auditing Cardiologist Form ("Attestation Form").

The Auditing Cardiologist found that there was no reasonable medical basis for tl answers given by the physician who completed your Green Form with respect to the que identified in the Attestation Form. The reason(s) for the Auditing Cardiologists findings explained in the enclosed Attestation Form. Based on the findings of the Auditing Cardic set forth in the enclosed Attestation Form, the Trust has determined that you do not quali any Matrix Compensation Benefits under the Settlement Agreement.

Since the Auditing Cardiologist found that there is no reasonable medical basis t support the answers in the Green Form that were placed into audit, the Settlement Agree directs the Trust to apply to the Court for an Order to Show Cause why the Claim shoulc as submitted. Such an application will require you to prove to the Court why your Clain be paid as submitted and the relief requested by the Trust in its application should not be Post Audit Determinations and Show Cause Proceedings are described in Sections IV th VIII of the Policies and Procedures for Audit and Disposition of Matrix Claims in Audit approved by the court May 31, 2002 ("Polices and Procedures"). A copy of the Policies Procedures was previously sent to you. Pursuant to the terms of the Settlement Agreeme Court will then determine whether there was no reasonable medical basis to support the in the Green Form that were placed into audit.

If you do not want your Claim to proceed through the audit process, you may withdra your Green Form without prejudicing your ability to submit a new Matrix Compensation Cla (new Green Form) in accordance with the terms of the Settlement Agreement. Submission of new Green Form will constitute a new Claim and may be based on a new echocardiogram an any other medical evidence previously submitted that you believe supports your eligibility fc Matrix Compensation Benefits at the level of severity you are requesting. Accordingly, you must complete fully all portions of the Green Form and may not rely on any answer provided a previous Green Form. You may withdraw your Matrix Compensation Claim by completing returning the enclosed Withdrawal Without Prejudice form. Withdrawal of your Claim will prejudice your ability to submit a new Claim if your condition changes in the future and mee the criteria for Matrix Compensation and you have complied with the requirements and dead date(s) contained in the Settlement Agreement for making a Matrix Compensation Claim.

If you dispute this Post Audit Determination and wish to proceed to the commencem of show cause proceedings before the Court, you must so advise the Trust in writing. Your written notice disputing the Post Audit Determination must be postmarked or placed in the h of a delivery carrier no later than thirty (30) days from the date of this letter, addressed as follows: **AHP Settlement Trust, Post Audit Determination Dispute/Show Cause, P.O. B 42290, Philadelphia, PA 19101.** Pursuant to Section IV.C.3 of the Policies and Procedures Audit Disposition of Matrix Compensation Claims in Audit, failure to deliver to the Trust a written response disputing this Post Audit Determination may be deemed acceptance of the Trusts determination.

If you have any questions concerning the audit process, you may contact the followin persons:

For AHP Settlement Trust:

Jules S. Henshell, Esquire
Director, Matrix Claim Integrity,
Review, & Disposition
AHP Settlement Trust
P.O. Box 42805
Philadelphia, PA 19101
215.923.5211

For Class Counsel:

Luke Pepper, Esquire
Class Counsel Claims Office
325 Chestnut Street, Suite 320
Philadelphia, PA 19106
215.413.2759

Sincerely,

AHP Settlement Trust

Diet Drug Recipient: Ruth Enloe
Claim No.: 183/00 8007411

ACCEPTANCE OF POST-AUDIT DETERMINATION AND WITHDRAWAL WITHOUT PREJUDICE

I hereby accept the Post-Audit Determination of the above captioned Claim contained in the letter from the AHP Settlement Trust dated January 21, 2003, and hereby withdraw my Mat Compensation Benefits Claim at this time. I understand that my withdrawal of this Claim d not prejudice my ability to submit a new claim in the event that my medical condition chang the future, meets the criteria for Matrix Compensation and I have complied with the requirements and deadline date(s) contained in the Nationwide Class Action Settlement as approved by the United States District Court.

Claimant: _____ DATE: _____

Witness: _____

AHP Settlement Trust

P.O. Box 42805, Philadelphia, PA 19101 • 215-923-5211 • Fax: 215-923-5217

February 20, 2003
VIA 2nd Day Air

Linda Morales
c/o Hariton & D'Angelo, LLP
Attn: Mario D'Angelo, Esquire
3500 Sunrise Highway, Suite T-207
Great River, NY 11739

RE: Post Audit Determination Letter
Diet Drug Recipient: Linda Morales
Claim No.: 183/00 8006806

Dear Class Member c/o Counsel:

In accordance with the requirements of the Nationwide Class Action Settlement Agreement with American Home Products Corporation (the "Settlement Agreement") your Claim for Matrix Compensation Benefits ("Claim") was selected for audit and reviewed by ar Auditing Cardiologist. Your Claim was selected and audited to determine whether there was reasonable medical basis for the answers given by the physician who completed your Green Form with respect to the question(s) identified in the enclosed Attestation of Auditing Cardiologist Form ("Attestation Form").

The Auditing Cardiologist found that there was no reasonable medical basis for the answers given by the physician who completed your Green Form with respect to the question identified in the Attestation Form. The reason(s) for the Auditing Cardiologists findings are explained in the enclosed Attestation Form. Based on the findings of the Auditing Cardiologi set forth in the enclosed Attestation Form, the Trust has determined that you do not qualify fc any Matrix Compensation Benefits under the Settlement Agreement.

Since the Auditing Cardiologist found that there is no reasonable medical basis to support the answers in the Green Form that were placed into audit, the Settlement Agreement directs the Trust to apply to the Court for an Order to Show Cause why the Claim should be p as submitted. Such an application will require you to prove to the Court why your Claim sho be paid as submitted and the relief requested by the Trust in its application should not be grar Post Audit Determinations and Show Cause Proceedings are described in Sections IV throug VIII of the Policies and Procedures for Audit and Disposition of Matrix Claims in Audit approved by the court May 31, 2002 ("Polices and Procedures"). A copy of the Policies and Procedures was previously sent to you. Pursuant to the terms of the Settlement Agreement, t Court will then determine whether there was no reasonable medical basis to support the answ in the Green Form that were placed into audit.

If you do not want your Claim to proceed through the audit process, you may withdra your Green Form without prejudicing your ability to submit a new Matrix Compensation Cla (new Green Form) in accordance with the terms of the Settlement Agreement. Submission of new Green Form will constitute a new Claim and may be based on a new echocardiogram an any other medical evidence previously submitted that you believe supports your eligibility fo Matrix Compensation Benefits at the level of severity you are requesting. Accordingly, you must complete fully all portions of the Green Form and may not rely on any answer provided a previous Green Form. You may withdraw your Matrix Compensation Claim by completing returning the enclosed Withdrawal Without Prejudice form. Withdrawal of your Claim will prejudice your ability to submit a new Claim if your condition changes in the future and mee the criteria for Matrix Compensation and you have complied with the requirements and dead date(s) contained in the Settlement Agreement for making a Matrix Compensation Claim.

If you dispute this Post Audit Determination and wish to proceed to the commenceme of show cause proceedings before the Court, you must so advise the Trust in writing. Your written notice disputing the Post Audit Determination must be postmarked or placed in the h of a delivery carrier no later than thirty (30) days from the date of this letter, addressed as follows: **AHP Settlement Trust, Post Audit Determination Dispute/Show Cause, P.O. Bo 42290, Philadelphia, PA 19101.** Pursuant to Section IV.C.3 of the Policies and Procedures Audit Disposition of Matrix Compensation Claims in Audit, failure to deliver to the Trust a written response disputing this Post Audit Determination may be deemed acceptance of the Trusts determination.

If you have any questions concerning the audit process, you may contact the followin persons:

For AHP Settlement Trust:

Jules S. Henshell, Esquire
Director, Matrix Claim Integrity,
Review, & Disposition
AHP Settlement Trust
P.O. Box 42805
Philadelphia, PA 19101
215.923.5211

For Class Counsel:

Luke Pepper, Esquire
Class Counsel Claims Office
325 Chestnut Street, Suite 320
Philadelphia, PA 19106
215.413.2759
215.701.3561

Sincerely,

AHP Settlement Trust

Diet Drug Recipient: Linda Morales
Claim No.: 183/00 8006806

ACCEPTANCE OF POST-AUDIT DETERMINATION AND WITHDRAWAL WITHOUT PREJUDICE

I hereby accept the Post-Audit Determination of the above captioned Claim contained in the letter from the AHP Settlement Trust dated February 20, 2003, and hereby withdraw my Matrix Compensation Benefits Claim at this time. I understand that my withdrawal of this Claim does not prejudice my ability to submit a new claim in the event that my medical condition changes in the future, meets the criteria for Matrix Compensation and I have complied with the requirements and deadline date(s) contained in the Nationwide Class Action Settlement as approved by the United States District Court.

Claimant: _____ DATE: _____

Witness: _____

Exhibit I

[redacted]

Claimant Name: Enloe, Ruth
Claimant Number: 8007411
Date of Echocardiogram: 03/19/02

Auditing Cardiologist: [redacted]
Date Audit Complete: [illegible] Jan 14 2003

I have reviewed the Medical Information associated with this Claim, which was forwarded to me by the AHP Settlement Trust. This Medical Information includes (check all that apply):

☑ A copy of the tape of an Echocardiogram preformed on 3/19/02 (date); (If you reviewed more than one Echo, please provide the date of each Echo.)

☑ A copy of the Claim Forms filed in support of the Claim; and,

☑ Medical records.

The Trust's audit designation was based only on the specific issues listed below. Review the issues and respond to the questions asked.

1.a. The physician completing the claimant's Claim Form answered the following question in that Form in the following manner:

C. 3. Based on your review of the Echocardiogram tape or disk, does the above-named Diet Drug Recipient have the following conditions as defined by Singh[1]? (Check each that applies):

A. For mitral regurgitation, the following determined in any apical view:

☐ Mild mitral regurgitation, defined as (1) either the regurgitant jet area/left atrial area ("RJA/LAA") ratio is more than 5% or the mitral regurgitant jet height is greater than 1 cm from the valve orifice, and (2) the RJA/LAA ratio is less than 20%.

☑ Moderate mitral regurgitation, defined as regurgitant jet area in any apical view equal to or greater than 20% of the left atrial area but less than or equal to 40% (20% - 40% RJA/LAA).

☐ Severe mitral reguration, defined as > 40% RJA/LAA.

☐ None of the above.

1.b. In your opinion, was there a reasonable medical basis for the answer given by the claimant's physician to the Claim Form question above?

☐ Yes ☑ No

Explain: The RJA includes low velocity signals. The RJA used to calculate the RJA/LAA is probably artifact, not MR. Color gain is high.

MR is mild.

[redacted]

Claimant Name: Enloe, Ruth
Claimant Number: 8007411

[redacted]

2.a. The physician completing the claimant's Claim Form answered the following question in that Form in the following manner:

F. To the best of your knowledge, has the above-named Diet Drug Recipient developed the following conditions AFTER the date on which the patient first used Pondimin® and/or Redux™:

3. Pulmonary Hypertension secondary to moderate or greater mitral regurgitation with peak systolic pulmonary artery pressure >40 mm Hg measured by cardiac catheterization or with a peak systolic pulmonary artery pressure >45 mm Hg[2] measured by Doppler Echocardiography, at rest, utilizing standard procedures assuming a right atrial pressure of 10 mm Hg?

☑ Yes ☐ No

2.b. In your opinion, was there a reasonable medical basis for the answer given by the claimant's physician to the Claim Form question above?

☐ Yes ☑ No

Explain: The TR velocity is mis-measured. It is 2.6 m/sec, which means PA systolic is 37 mmHg, assuming a RA pressure of 10 mmHg.

[redacted]

3.a. The physician completing the claimant's Claim Form answered the following question in that Form in the following manner:

F. To the best of your knowledge, has the above-named Diet Drug Recipient developed the following conditions AFTER the date on which the patient first used Pondimin® and/or Redux™:

5. Abnormal left atrial supero-inferior systolic dimension >5.3 cm[3] (apical four chamber view) or abnormal left atrial antero-posterior systolic dimension >4.0 cm (parasternal long-axis view) measured by 2-D directed M-mode or 2-D echocardiography with normal sinus rhythm using sites of measurement recommended by the American Society of Echocardiography?[4]

☑ Yes ☐ No

3.b. In your opinion, was there a reasonable medical basis for the answer given by the claimant's physician to the Claim Form question above?

☑ Yes ☐ No

Explain: LA is mildly dilated, although it's not possible to know whether this occurred before or after pondimin +/or redux use.

[redacted]

Claimant Name: Enloe, Ruth
Claimant Number: 8007411

[redacted]

By: [redacted]

Print Name: [redacted]

Date: 1/12/03

1 J. P. Singh, et al., Prevalence and Clinical Determinants of Mitral, Tricuspid and Aortic Regurgitation (The Framingham Heart Study), 83 Am. J Cardiol. 897-902 (1999).
2 Braunwald, Heart Disease: Textbook of Cardiovascular Medicine 798-98 (1997).
3 A.E. Weyman, Principles and Practice of Echocardiography 1290-1292 (2d ed. 1994).
4 Henry, W.L. et al., Report of the American Society of Echocardiography Committee on Nomenclature and Standards in Two-dimensional Echocardiography, 62 Circulation 212-17 (1980).

[redacted]

AHP Settlement Trust
Auditing Cardiologist Worksheet

Claimant Name: Ruth Enloe
Claimant Number: 8007411

Exhibit ___ to AHP Settlement Trust Echocardiogram Report dated [redacted]

Date of Echocardiogram (mm/dd/yyyy) 3 / 1 9 / 2 0 0 2

Study Type ☑ TTE ☐ TEE ☐ Stress Echo (resting portion only)

Part 1 M-Mode Quantitative Measurements (parasternal long-axis view)

Is the patient in: ☑ Sinus rhythm ☐ Atrial fibrillation / flutter ☐ Other: specify ____

Aortic Root (1 beat)	3.0 cm	Not evaluab
Left atrium (antero-posterior dimension/parasternal long-axis view/1 beat	4.1 cm	Not evaluab
Left atrium (supero-inferior dimension/apical four chamber view/1 beat)	5.1 cm	Not evaluab
Left Ventricular Internal Dimension – End Systole (2 beats)	2.9 cm	Not evaluab
Left Ventricular Internal Dimension – End Diastole (2 beats)	4.9 cm	Not evaluat

Comments: ____

Part 2 Pulmonary Artery Pressure (continuous wave doppler)

Peak tricuspid regurgitation jet velocity	2.6 meters/second	Not evalua
PASP	37 mm Hg	Not evalua

Compute from TR velocity using the following equation: $PASP = 4 \cdot TRvel^2 + 10$ mmHg

Comments ____

Part 3 Left Ventricular Systolic Function (Assessed visually integrating information from all views

Ejection Fraction

☑	>60%	If Ejection Fraction >60%, please quantify: 65-70%
☐	50% - 60%	
☐	40% - 49%	
☐	35% - 39%	

[redacted]

AHP Settlement Trust
Auditing Cardiologist Worksheet

Claimant Name: Ruth Enloe
Claimant Number: 8007411

☐ < 30%

Part 4 Valvular Regurgitation

Mitral (Assessed visually in any apical view)

☐	None	No regurgitant color flow
☐	Physiologic	Non-sustained jet immediately (within 1 cm) behind the annular plane or ≤ 5% RJA/LAA
☑	Mild	(1) Either the RJA/LAA ratio is more than 5% or the mitral regurgitant jet height is greater than 1 cm from the valve orifice, and (2) the RJA/LAA ratio is less than 20%
☐	Moderate	RJA is equal to or greater than 20% of the LAA but less than or equal to 40% (20% -40% RJA/LAA).
☐	Severe	RJA/LAA greater than 40%.
☐	Not Evaluable	

Comments:

Aortic Based on Jet Diameter (Assessed visually in the parasternal long axis view or in the apical long-axis view, if the parasternal long-axis view is unavailable)

☑	None	No regurgitant color flow.
☐	Trace	JH/LVOTH is less than 10%.
☐	Mild	JH/LVOTH is greater than or equal to 10% and less than or equal to 24% (10% - 24% JH/LVOTH).
☐	Moderate	JH/LVOTH is greater than or equal to 25% and less than or equal to 49% (25% - 49% JH/LVOTH).
☐	Severe	JH/LVOTH is greater than 49%.
☐	Not Evaluable	

Comments:

[redacted]

AHP Settlement Trust
Auditing Cardiologist Worksheet

Claimant Name: Ruth Enloe
Claimant Number: 8007411

Part 5 Other Pathology

Are echocardiographic findings observed indicative of other recognized valvular disease?

☐ Yes ☑ No

If yes, check all applicable box(es) below: *If no, proceed to Part 6.*

Aortic Valve Pathology

☐ Congenital Aortic Valve Abnormality
Please specify:

☐ Bicuspid valve ☐ Unicuspid valve ☐ Quadricuspid valve

☐ Ventricular septal defect associated with aortic regurgitation

☐ Aortic dissection involving the aortic root and /or aortic valve

☐ Aortic sclerosis

☐ Aortic root dilatation > 5.0cm

☐ Aortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation

☐ Evidence of aortic valve surgery

☐ Aortic valve pathology of a type associated with bacterial endocarditis

☐ Aortic valve lesions of the type associated with systemic lupus erythematosis

☐ Aortic valve lesions of the type associated with rheumatoid arthritis

☐ Aortic valve lesions of the type associated with carcinoid tumor

☐ Aortic valve lesions of the type associated with methysergide and/or ergotamine use

Comments on aortic valve pathology:

Mitral Valve Pathology

☐ Mitral valve prolapse (Assessed in the parasternal long axis view and defined as displacement of one or bo mitral leaflets > 2mm above the atrial-ventricular border during systole, and > 5mm leaflet thickening during diastole)

☐ Congenital Mitral Valve Abnormality
Please specify:

☐ Parachute valve ☐ Cleft of the mitral valve associated with atrial septal defect

☐ Chordae tendineae rupture

☐ Papillary muscle rupture

☐ Papillary muscle dysfunction

[redacted]

AHP Settlement Trust
Auditing Cardiologist Worksheet

Claimant Name: Ruth Enloe
Claimant Number: 8007411

- ☐ Acute myocardial infarction associated with acute mitral regurgitation

Mitral Valve Pathology

- ☐ Mitral annular calcification
- ☐ Rheumatic mitral valve
  (Defined as doming of the anterior leaflet and/or anterior motion of the posterior leaflet and/or commissural fusion)
- ☐ Evidence of mitral valve surgery
- ☐ Mitral valve lesions of a type associated with bacterial endocarditis
- ☐ Mitral valve lesions of the type associated with systemic lupus erythematosis
- ☐ Mitral valve lesions of the type associated with rheumatoid arthritis
- ☐ Mitral valve lesions of the type associated with carcinoid tumor
- ☐ Mitral valve lesions of the type associated with methysergide and/or ergotamine use

Comments on mitral valve pathology:

General Pathology

- ☐ Endocardial fibrosis
- ☐ Other: ***please specify abnormality:***

Are there findings or explanations of valvular pathology suggested but not specifically listed?

☐ Yes ***If Yes, please comment:***

☐ No

[redacted]

AHP Settlement Trust
Auditing Cardiologist Worksheet

Claimant Name: Ruth Euloe
Claimant Number: 8007411

Part 6 Echocardiogram Evaluation

Was this echocardiogram conducted in accordance with the standards and criteria as outlined in the American Society of Echocardiography Report[1] and Weyman[2]?

☑ Yes

☐ No

If No, please comment on all observed deviations:

Has this tape been edited, modified or altered in any respect?

☐ Yes *If Yes, please comment:*

☑ No

[1] H. Feigenbaum, *Echocardiography* 68-133 (5th ed. 1994).
[2] A. E. Weyman, *Principles and Practice of Echocardiography* 75-97 (2nd ed. 1994).

Part 7 Technical Quality of Echocardiogram Tape

☐	*Excellent*	Ideal image quality
☐	*Good*	Diagnostic images in all views for all cardiac structures that need to be assessed
☑	*Fair*	Image quality that allows adequate assessment of most of the cardiac structures (aortic, mitral, and tricuspid valves) but not necessarily in all views.
☐	*Poor*	Image quality is marginal to assess the aortic and/or mitral valve(s).
☐	*Non-interpretable*	Image quality is inadequate to assess the aortic and mitral valves.

Part 8 Cardiologist Signature

[redacted] Cardiologist Signature

[redacted] Initials

1/12/03 Date of Reading

[redacted] Print Name

Craig Olmer, MD

The Women's Cardiovascular Center

4320 Wornall Road Suite 240
Kansas City, MO 64111 ph# (816)531-7474

Echocardiography Report
Final Report
Printed: 03/19/2002 12:37:54 PM

Enloe, Ruth M **500-42-6171**
61 year old **Female** DOB: **04/18/1940**
Procedure Date: **Mar 19, 2002**

Procedure performed at ***Hariton & D'Angelo; Long Island, NY--Echo L. Crouse Office***
Medical Record # (LD.) No ID type Hospital Room # ABN&PAP

Procedures Performed

Transthoracic Echocardiogram
2-D and M-Mode combination.
Spectral Analysis Doppler
Color Flow Doppler

Reason for Test

Phen-Fen

Measurements

Resting			Normal Range
M-MODE	LV Diam Dias	4.80 cm	3.5 - 5.7
	LV Diam Sys	2.40 cm	2.3 - 3.9
	LVEF	70.00 (%)	45 - 84
	LV Septum	1.00 cm	0.6 - 1.1
	LV Post Wall	1.00 cm	0.6 - 1.1
	Ao Root Size	3.00 cm	2 - 3.7

Echocardiographic Interpretation

Resting

LV (left ventricle)	LVEF : 70 %
	Normal Left Ventricular Function
MV (mitral valve)	Moderate MV Regurgitation
AV (aortic valve)	Normal aortic valve
LA (left atrium)	The left atrial size is mildly increased
RV (right ventricle)	Normal right ventricle
TV (tricuspid valve)	Moderate tricuspid valve regurgitation
	PAP Based on Tricuspid Regurgitant Jet estimated at: 46 mm Hg
RA (right atrium)	Normal right atrium
PV (pulmonic valve)	Normal pulmonary valve

Conclusion

EF--70%
Normal LV function
Mild LA enlargement; 4.26 cm in the PLAX view
Moderate MR; 4.07/16.12=25% of the LA area
No AR
Moderate TR
PAP--46 mmHg

Staff

Sonographer: **Ms. Audrey Loeb RDCS,RVT** Department: Height: In

Reviewed by: Dr. Linda J. Crouse MD, FACC Tape Group: Weight: lbs
BSA: sqm

Reviewed by Linda J Crouse MD 3/19/02
Dr. Linda J. Crouse MD, FACC

Exhibit K

[redacted]

Claimant Name: Morales, Linda
Claimant Number: 8006806
Date of Echocardiogram: 03/14/02

Auditing Cardiologi[redacted]
Date Audit Complete: 9/12/13

I have reviewed the Medical Information associated with this Claim, which was forwarded to me by the AHP Settlement Trust. This Medical Information includes (check all that apply):

☐ A copy of the tape of an Echocardiogram preformed on 3/14/02 (date); (If you reviewed more than one Echo, please provide the date of each Echo.)

☑ A copy of the Claim Forms filed in support of the Claim; and,

☐ Medical records.

Wyeth's audit designation was based only on the specific issue listed below. Review the issue and respond to the question asked.

1.a. The physician completing the claimant's Claim Form answered the following question in that Form in the following manner:

C. 3. Based on your review of the Echocardiogram tape or disk, does the above-named Diet Drug Recipient have the following conditions as defined by Singh[1]? (Check each that applies):

A. For mitral regurgitation, the following determined in any apical view:

☐ Mild mitral regurgitation, defined as (1) either the regurgitant jet area/left atrial area ("RJA/LAA") ratio is more than 5% or the mitral regurgitant jet height is greater than 1 cm from the valve orifice, and (2) the RJA/LAA ratio is less than 20%.

☑ Moderate mitral regurgitation, defined as regurgitant jet area in any apical view equal to or greater than 20% of the left atrial area but less than or equal to 40% (20% - 40% RJA/LAA).

☐ Severe mitral reguration, defined as > 40% RJA/LAA.

☐ None of the above.

1.b. In your opinion, was there a reasonable medical basis for the answer given by the claimant's physician to the Claim Form question above?

☐ Yes ☑ No

Explain: mild MR if is less than 20% of the left atrium when the jet size is measured appropriately

[redacted]

Claimant Name: Morales, Linda
Claimant Number: 8006806

[redacted]

By: [redacted]

Print Name: [redacted]

Date: 2/19/13

1 J. P. Singh, et al., Prevalence and Clinical Determinants of Mitral, Tricuspid and Aortic Regurgitation (The Framingham Heart Study), 83 Am. J. Cardiol. 897-902 (1999).

[redacted]

AHP Settlement Trust
Auditing Cardiologist Worksheet

Claimant Name: Linda Morales
Claimant Number: 8006806

Exhibit I	AHP Settlement Trust Echocardiogram Report	DDR#	Tape No.

Date of Echocardiogram (mm/dd/yyyy) 3 / 17 / 02

Study Type ☒ TTE ☐ TEE ☐ Stress Echo (resting portion only)

Part 1 M-Mode Quantitative Measurements (parasternal long-axis view)

Is the patient in: ☒ Sinus rhythm ☐ Atrial fibrillation / flutter ☐ Other: specify _____

Aortic Root (1 beat)	3.0 cm	Not evaluable ☐
Left atrium (1 beat)	4.4 cm	Not evaluable ☐
Left Ventricular Internal Dimension – End Systole (2 beats)	[illegible] cm	Not evaluable ☐
Left Ventricular Internal Dimension – End Diastole (2 beats)	[illegible] cm	Not evaluable ☐

Comments: _____

Part 2 Pulmonary Artery Pressure (continuous wave doppler)

Peak tricuspid regurgitation jet velocity	2.0 meters/second	Not evaluable ☐
PASP	24 mm Hg	Not evaluable ☐

Compute from TR velocity using the following equation: PASP = 4 $TRvel^2$ + 10 mmHg

Comments _____

Part 3 Left Ventricular Systolic Function (Assessed visually integrating information from all views)

Ejection Fraction

☒	>60%	If Ejection Fraction >60%, please quantify: 65%
☐	50% - 60%	
☐	40% - 49%	
☐	35% - 39%	
☐	30% - 34%	

[redacted]

AHP Settlement Trust
Auditing Cardiologist Worksheet

Claimant Name: Linda Morales
Claimant Number: 8006806

☐ < 30%

Part 4 Valvular Regurgitation

Mitral (Assessed visually in any apical view)

☐	None	No regurgitant color flow
☐	Physiologic	Non-sustained jet immediately (within 1 cm) behind the annular plane or ≤ 5% RJA/LAA
☑	Mild	(1) Either the RJA/LAA ratio is more than 5% or the mitral regurgitant jet height is greater than 1 cm from the valve orifice, and (2) the RJA/LAA ratio is less than 20%
☐	Moderate	RJA is equal to or greater than 20% of the LAA but less than or equal to 40% (20% -40% RJA/LAA).
☐	Severe	RJA/LAA greater than 40%.
☐	Not Evaluable	

Comments:

Aortic Based on Jet Diameter (Assessed visually in the parasternal long axis view or in the apical long-axis view, if the parasternal long-axis view is unavailable)

☑	None	No regurgitant color flow.
☐	Trace	JH/LVOTH is less than 10%.
☐	Mild	JH/LVOTH is greater than or equal to 10% and less than or equal to 24% (10% - 24% JH/LVOTH).
☐	Moderate	JH/LVOTH is greater than or equal to 25% and less than or equal to 49% (25% - 49% JH/LVOTH).
☐	Severe	JH/LVOTH is greater than 49%.
☐	Not Evaluable	

Comments:

AHP Settlement Trust
Auditing Cardiologist Worksheet

Claimant Name: Linda Morales
Claimant Number: 8006806

Part 5 Other Pathology

Are echocardiographic findings observed indicative of other recognized valvular disease?

☐ Yes ☒ No

If yes, check all applicable box(es) below: *If no, proceed to Part 6 :*

Aortic Valve Pathology

- ☐ Congenital Aortic Valve Abnormality
  Please specify:
  - ☐ Bicuspid valve ☐ Unicuspid valve ☐ Quadricuspid valve
  - ☐ Ventricular septal defect associated with aortic regurgitation
- ☐ Aortic dissection involving the aortic root and /or aortic valve
- ☐ Aortic sclerosis
- ☐ Aortic root dilatation > 5.0cm
- ☐ Aortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation
- ☐ Evidence of aortic valve surgery
- ☐ Aortic valve pathology of a type associated with bacterial endocarditis
- ☐ Aortic valve lesions of the type associated with systemic lupus erythematosis
- ☐ Aortic valve lesions of the type associated with rheumatoid arthritis
- ☐ Aortic valve lesions of the type associated with carcinoid tumor
- ☐ Aortic valve lesions of the type associated with methysergide and/or ergotamine use

Comments on aortic valve pathology:

Mitral Valve Pathology

- ☐ Mitral valve prolapse (Assessed in the parasternal long axis view and defined as displacement of one or both mitral leaflets > 2mm above the atrial-ventricular border during systole, and > 5mm leaflet thickening during diastole)
- ☐ Congenital Mitral Valve Abnormality
  Please specify:
  - ☐ Parachute valve ☐ Cleft of the mitral valve associated with atrial septal defect
- ☐ Chordae tendineae rupture
- ☐ Papillary muscle rupture
- ☐ Papillary muscle dysfunction
- ☐ Acute myocardial infarction associated with acute mitral regurgitation

[redacted]

AHP Settlement Trust
Auditing Cardiologist Worksheet

Claimant Name: Linda Morales
Claimant Number: 8006806

Mitral Valve Pathology (continued)

- ☐ Mitral annular calcification
- ☐ Rheumatic mitral valve
  (Defined as doming of the anterior leaflet and/or anterior motion of the posterior leaflet and/or commissural fusion)
- ☐ Evidence of mitral valve surgery
- ☐ Mitral valve lesions of a type associated with bacterial endocarditis
- ☐ Mitral valve lesions of the type associated with systemic lupus erythematosis
- ☐ Mitral valve lesions of the type associated with rheumatoid arthritis
- ☐ Mitral valve lesions of the type associated with carcinoid tumor
- ☐ Mitral valve lesions of the type associated with methysergide and/or ergotamine use

Comments on mitral valve pathology:

General Pathology

- ☐ Endocardial fibrosis
- ☐ Other: ***please specify abnormality:***

Are any secondary causations of valvular pathology suggested but not clearly visualized?

☐ Yes ***If Yes, please comment:***

☑ No

Part 6 Echocardiogram Evaluation

Was this echocardiogram conducted in accordance with the standards and criteria as outlined in Feigenbaum (1994) or Weyman (1994)?

[redacted]

AHP Settlement Trust
Auditing Cardiologist Worksheet

Claimant Name: Linda Morales
Claimant Number: 8006806

☑ Yes

☐ No
If No, please comment on all observed deviations:

Has this tape been edited, modified or altered in any respect?

☑ Yes *If Yes, please comment:*

☑ No

[1] H. Feigenbaum, *Echocardiography* 68-133 (5th ed. 1994).
[2] A. E. Weyman, *Principles and Practice of Echocardiography* 75-97 (2nd ed. 1994).

Part 7 Technical Quality of Echocardiogram Tape

☐	*Excellent*	Ideal image quality
☐	*Good*	Diagnostic images in all views for all cardiac structures that need to be assessed
☑	*Fair*	Image quality that allows adequate assessment of most of the cardiac structures (aortic, mitral, and tricuspid valves) but not necessarily in all views.
☐	*Poor*	Image quality is marginal to assess the aortic and/or mitral valve(s).
☐	*Non-interpretable*	Image quality is inadequate to assess the aortic and mitral valves.

Part 8 Cardiologist Signature

[redacted] [redacted] 2/10/03

Cardiologist's Signature Initials Date of Reading

Print Name

The Women's Cardiovascular Center

4320 Wornall Road Suite 240
Kansas City, MO 64111 ph# (816)531-7474

Morales, Linda L **488-46-2628**
57 year old **Female** DOB: **01/10/1945**
Procedure Date: **Mar 14, 2002**

Echocardiography Report

Final Report
Printed: 03/14/2002 4:07:01 PM

Procedure performed at ***Hariton & D'Angelo; Long Island, NY--Echo L. Crouse Office***
Medical Record # (I.D.) No ID type Hospital Room # ABNORMAL

Procedures Performed

Transthoracic Echocardiogram
2-D and M-Mode combination.
Spectral Analysis Doppler
Color Flow Doppler

Reason for Test

Phen-Fen

Measurements

Resting			Normal Range
M-MODE	LV Diam Dias	4.60 cm	3.5 - 5.7
	LV Diam Sys	2.00 cm ***	2.3 - 3.9
	LVEF	70.00 (%)	45 - 84
	LV Septum	1.20 cm ***	0.6 - 1.1
	LV Post Wall	1.20 cm ***	0.6 - 1.1
	Ao Root Size	2.50 cm	2 - 3.7

Echocardiographic Interpretation

Resting

LV (left ventricle)	LVEF : 70 %
	Mild Concentric Hypertrophy
MV (mitral valve)	Moderate MV Regurgitation
AV (aortic valve)	Normal aortic valve
LA (left atrium)	The left atrial size is mildly increased
RV (right ventricle)	Normal right ventricle
TV (tricuspid valve)	Mild tricuspid valve regurgitation
	PAP Based on Tricuspid Regurgitant Jet estimated at: 33 mm Hg
RA (right atrium)	Normal right atrium
PV (pulmonic valve)	Normal pulmonary valve

Conclusion

EF--70%
Normal LV function
Mild Concentric Hypertrophy
Mild LA enlargement; 4.35 cm in the PLAX view
Moderate MR; 4.73/19.73=24% of the LA area
No AR
Mild TR
PAP--33 mmHg

Staff				
Reviewed by:	Ms. Audrey Loeb RDCS,RVT Dr. Linda J. Crouse MD, FACC	Department: Tape Group:	Height: Weight: BSA:	in lbs sqm

Reviewed by Linda J Crouse MD 3/14/02

Dr. Linda J. Crouse MD, FACC

Evaluation of Fen-Phen Cardiac Pathology
Review of Echocardiogram

LastName Morales FirstName Linda StudyDate 3-14-2002

Study Information VHS tape copy

MOdisk # _____ Tape # _____

Measurements (mm) M-Mode Ao ____ LA 44

LVEDD ____ LVIDS ____ IVSdiast ____ PWdiast ____

EF-Teicholz ____ %

2D LA2D ____ LAlength ____ RVdiam ____

EF-Simpsons ____ %

Valve Appearance

aortic normal mitral normal

pulmonic _____ tricuspid _____

Valvular Regurgitation

AI 0 MR 2-3

0=none
1=trace
2=mild
3=moderate
4=severe

AIjetdiam ____ cm AIpercent ____ % MRjetarea 4 cmsq MRpercent 20 %

AILVOTdiam ____ cm mild = <10-24% MRLAarea 20 cmsq mild = <19%
mod = 25-49% mod = 20-40%
severe = >50% severe = >40%

TR 0 TRpeakvel _____ m/s estRAP ____ mmHg estPAP ____

PI ____ mmHg

Conclusions

1. Technically adequate study quality.
2. Normal LV size and systolic function.
3. Mildly dilated left atrium.
4. No significant AI.
5. Mild to moderate MR, narrow jet but extends toward the posterior left atrium.
6. No measurable TR.

Reviewer _____
Scott L. Roth. MD. FACC

Exhibit J

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

◄ Previous Volume 339:725-732 September 10, 1998 Number 11 Next ►

An Assessment of Heart-Valve Abnormalities in Obese Patients Taking Dexfenfluramine, Sustained-Release Dexfenfluramine, or Placebo

Neil J. Weissman, M.D., John F. Tighe, M.D., John S. Gottdiener, M.D., John T. Gwynne, M.D., for The Sustained-Release Dexfenfluramine Study Group

ABSTRACT

Background The appetite-suppressant drug fenfluramine, usually given in combination with phentermine, has been reported to be associated with cardiac valvular regurgitation. Concern has been raised that the *d*-enantiomer of fenfluramine, dexfenfluramine, may also cause this problem. We were able to study the question by modifying an ongoing trial comparing sustained-release dexfenfluramine with regular dexfenfluramine and placebo.

Methods We modified our randomized, double-blind, placebo-controlled study of dexfenfluramine to include echocardiographic examinations of 1072 overweight patients within a median of one month after the discontinuation of treatment. The patients (approximately 80 percent of whom were women) had been randomly assigned to receive dexfenfluramine (366 patients), investigational sustained-release dexfenfluramine (352 patients), or placebo (354 patients). The average duration of treatment was 71 to 72 days in each of the three groups. Echocardiograms were assessed in a blinded fashion.

Results When all degrees of valvular regurgitation were considered and when the two dexfenfluramine groups were

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► Weissman, N. J.

combined, there was a higher prevalence of any degree of aortic regurgitation (17.0 percent vs. 11.8 percent, P=0.03) and any degree of mitral regurgitation (61.4 percent vs. 54.4 percent, P=0.01) in the active-treatment groups than in the placebo group. These differences were primarily due to a higher prevalence of physiologic, trace, or mild regurgitation. Analyses that used the criteria of the Food and Drug Administration for aortic regurgitation of mild or greater severity and mitral regurgitation of moderate or greater severity found no significant difference among the groups (P=0.14 to 0.75). These analyses showed that aortic regurgitation of mild or greater severity occurred in 5.0 percent of the patients in the dexfenfluramine group, 5.8 percent of those in the sustained-release dexfenfluramine group, 5.4 percent of those in the two active-treatment groups combined, and 3.6 percent of those in the placebo group. Mitral regurgitation of moderate or greater severity occurred in 1.7, 1.8, 1.8, and 1.2 percent, respectively. Aortic regurgitation of mild or greater severity, mitral regurgitation of moderate or greater severity, or both occurred in 6.5 percent, 7.3 percent, 6.9 percent, and 4.5 percent, respectively.

Conclusions We found a small increase in the prevalence of aortic and mitral regurgitation in patients treated with dexfenfluramine, and the degree of regurgitation was in most cases classified as physiologic, trace, or mild. However, the duration of therapy was short, and whether therapy of longer duration would yield the same or different results is not known.

Source Information

From the Division of Cardiology and the Cardiovascular Institute, Georgetown University Medical Center, Washington, D.C. (N.J.W., J.F.T., J.S.G.); and the Department of Clinical Research, Wyeth–Ayerst Research, Philadelphia (J.T.G.).

Address reprint requests to Dr. Weissman at the Division of Cardiology, Georgetown University Medical Center, 3800 Reservoir Rd., NW, Washington, DC 20007-2197.

Full Text of this Article

This article has been cited by other articles:

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MEDLINE

Prevalence of valvular-regurgitation associated with dexfenfluramine three to five months after discontinuation of treatment.

Weissman NJ, Tighe JF, Gottdiener JS, Gwynne JT

J Am Coll Cardiol 1999 Dec 34:2088-95

View: Full MEDLINE | Related Records

Abstract

OBJECTIVES: The goal of this study was to determine the prevalence of valvular regurgitation and abnormal valve morphology in patients three to five months after discontinuation of dexfenfluramine (Dexfen) therapy. BACKGROUND: We previously reported the results of a randomized, double-blind, placebo-controlled trial of valvular structure and function in 1,073 patients treated either with Dexfen, with an investigational sustained-release dexfenfluramine (Dexfen SR), or with a placebo, with echocardiograms performed approximately one month from the last dose. Using FDA criteria (aortic regurgitation [AR] > or =mild and/or mitral regurgitation [MR] > or =moderate) we found no statistical difference among the groups, but when all degrees of valvular regurgitation were considered and when the two Dexfen groups were combined, there was a higher prevalence of any degree of AR, any degree of MR, and restricted posterior mitral leaflet mobility. However, it was unknown whether these differences in prevalence persisted. METHODS: The double blind was maintained, and all patients were invited to return for a follow-up echocardiogram. Echocardiograms were acquired using a standardized protocol and assessed blindly to determine the degree of valvular regurgitation and valve leaflet thickness and mobility. We had an 80% power to detect a statistically significant change in paired proportions using the McNemar test (alpha = 0.05). RESULTS: Echocardiograms were obtained on 941 patients with a median of 137 days after drug discontinuation. Aortic regurgitation (of any degree) was present in 13.8% of Dexfen (p = 0.41 compared to placebo), 10.7% of Dexfen SR (p = 0.64 compared to placebo), and 11.9% of placebo patients. The minor differences between patients treated with active drug versus placebo, which were found in the previous study, were no longer significant even when the groups were combined (p = 0.83 compared to placebo). Mitral regurgitation (of any degree) was present in 71.5% (p = 0.15 compared to placebo), 69.8% (p = 0.30 compared to placebo), and 70.5%, respectively. This was also not significantly different from placebo when both Dexfen groups were combined (p = 0.16). There was no difference in the prevalence of restricted posterior mitral leaflet mobility among the three groups (p = 0.19). CONCLUSIONS: The small increase in prevalence of minor degrees of AR and MR in patients treated with two to three months of Dexfen previously reported is no longer present three to five months after discontinuation of medication. These data suggest that the degree of regurgitation observed in patients who used Dexfen for a relatively short duration does not progress over time.

Source

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Exhibit N

Journal of the American Society of Echocardiography
May 1999

Oral Abstract Session 7
Diet Drugs, Valvular Disease, and New Technology

7A **DOES THE INCREASED PREVALENCE OF REGURGITATION ASSOCIATED WITH APPETITE SUPPRESSANTS PERSIST 3-5 MONTHS AFTER DISCONTINUATION OF MEDICATION?**

Neil J Weissman MD, John F Tighe MD, John S Gottdiener MD, John T Gwynne, Georgetown Medical Center, Washington, DC and Wyeth-Ayerst, Philadelphia, PA

We previously reported the results of a randomized, double-blind, placebo controlled study of valvular structure and function in 1072 patients (pts) on dexfenfluramine (dex), investigational sustained release dexfenfluramine (dex SR) and placebo with echocardiograms performed within a median of one month from last dose. An analysis conducted using the FDA criteria (AR ≥ mild and MR ≥ moderate) found no statistical difference among the groups. When all degrees of valvular regurgitation were considered (including trace/physiologic) and when the two dex groups were combined, there was a higher prevalence of any degree of AR (p=0.03) and any degree of MR (p=0.01) and a higher prevalence of restricted posterior mitral leaflet mobility (p=0.02). To determine if the increased prevalence persist or increases after discontinuation of dex, the double blind was maintained and all patients were invited to return for a repeat 3-5 month echocardiogram. **Results:** 941 patients had a repeat echo using a standardized protocol 137 days (median) after drug discontinuation (138 placebo, 136 dex, and 136 dex SR). AR (of any degree) was present in 11.9% of placebo pts, 13.9% of dex (p=0.54), and 10.7% of dex SR (p=0.70). The difference between pts treated with active drug vs placebo were no longer significant even when the groups were combined (p=0.91). MR (of any degree) was present in 70.4%, 71.5%, and 69.9% of placebo, dex, and dex SR patients, respectively. This was also not different even when both dex groups were combined (p=0.94). Similarly, there was no longer difference in the prevalence of restricted posterior mitral leaflet mobility (p=0.19). **Conclusion:** The small increase in prevalence of mild degrees of aortic and mitral regurgitation in patients treated with 2-3 months of dexfenfluramine previously reported is no longer present 4 to 5 months after discontinuation of medication. These data suggests that the degree of regurgitation observed in patients who used dexfenfluramine does not progress over time and there may be regression.

Testing the Test: The Reliability of Echocardiography in the Sequential Assessment of Valvular Regurgitation

from American Heart Journal
Posted 09/10/2002

John S. Gottdiener, MD; Julio A. Panza, MD; Martin St John Sutton, MD; Patrick Bannon, MD; Harvey Kushner, PhD; Neil J. Weissman, MD

Abstract and Introduction

Abstract

Background and Objective: Substantial variability in serial echocardiographic qualitative assessment of valvular regurgitation may exist. Reader variability is generally well understood, but acquisition variability (portions of variability caused by equipment, sonographers, physiologic changes) has been less frequently assessed, particularly in combination with reader variability. We attempted to determine the relative contributions of acquisition and reader variability as components of total test-retest variability for aortic (AR) and mitral (MR) regurgitation.
Methods: Outpatient echocardiographic study was done at 2 clinical sites. Twenty-three predominantly obese middle-aged females had 3 echocardiograms, 2 performed 14 ± 3 days apart and the third performed within 1 to 2 hours of the second. Triplets of echocardiograms were evaluated for change in grade of AR and MR. Medical history, anthropometrics, and blood pressures were obtained.
Results: Average intrareader variability (percentage of reads for which there is within-reader disagreement) was 5.6% for AR and 16.7% for MR. The average total test-retest variability (percentage of reads for which there is disagreement between visits) was 29.0% for AR and 24.6% for MR. The acquisition variability for AR was 23.4% ± 7.7%; for MR, it was 7.9% ± 10.2%. A significant predictor of change for AR/MR was the initial grade. Change in diastolic blood pressure was positively associated with change in AR and MR.
Conclusions: Intrareader agreement was substantial for AR and MR. Components of total test-retest variability found were reader, biological (change in diastolic blood pressure), and regression to the mean. Recommendations for clinical practice include monitoring blood

pressure changes and understanding the confidence limits of the clinical test. Test-retest variability and its components should be considered in echocardiography and other diagnostic testing.

Introduction

Echocardiography is the principal diagnostic technique used for the assessment of cardiac structures and function.[1-3] In clinical practice and research, serial echocardiograms are used to assess the improvement or worsening of regurgitation.[4-6] Accurate and reproducible measurements are necessary to permit meaningful comparisons between examinations. However, variability in image acquisition and physician interpretation may be problematic for serial assessment of valvular regurgitation.[7,8]

We have previously shown that substantial variability in serial assessment of regurgitation may exist despite excellent observer reliability.[9] Test-retest variability, which is the likelihood that a repeat test shows change that actually did not occur, is pertinent to clinical practice. However, the components of test-retest variability, reader variability, and acquisition variability (nonreader variability, such as equipment variability, differences in sonographer practice, biological changes, and regression to the mean) remain undetermined. The present study was conducted to determine the relative contribution of acquisition and reader variability as components of total test-retest variability.

Section 1 of 4 Continued

John S. Gottdiener, MD, St Francis Hospital, Roslyn, NY; **Julio A. Panza, MD**, National Heart, Lung and Blood Institute, Bethesda, MD; **Martin St John Sutton, MD**, Hospital of the University of Pennsylvania, Philadelphia; **Patrick Bannon, MD**, Mercy Hospital, Pittsburgh; **Harvey Kushner, PhD**, BIOMEDICAL Computer Research Institute, Philadelphia, PA; **Neil J. Weissman, MD**, Cardiovascular Research Institute, Washington, DC.

Am Heart J 144(1):115-121, 2002.

Exhibit P

FEN-PHEN/REDUX LITIGATION

ORAL AND VIDEOTAPED DEPOSITION OF

JOSEPH J. PITTELLI, M.D.

MONDAY, DECEMBER 6, 1999

Volume 1 of 2

Pages 1 - 228

ORAL AND VIDEOTAPED DEPOSITION OF JOSEPH J. PITTELLI, M.D., produced as a witness the instance ofthe Plaintiff above-styled and numbered cause on Monday, December 6,1999, betwee before JOSEPH D. HENDRICK, Certified Shorthand ReporterNo. 947 in machine shorthand, in The Colonade Room, Ritz-CarltonHotel, 100 Oc pursuant to the Texas, Florida, Oklahoma, Mississippiand Philadelp provisions stated on the record or attached hereto.

Job No. 990013

MS. BINIS: Well, asking -- let's -- let's re-state -- let's hear the question again.

COURT REPORTER: Question "Now, do you also know that how scientific studies are reported can affect the stock market value"

MS. BINIS: Well, I think it is a misleading question. I am going to object to form.

Q. (BY MR. BLIZZARD) You can answer it.

A. Yes.

Q. Okay. Do you know that the timing of reporting of scientific studies can affect how the stock value of the company reacts?

MS. BINIS: Objection, misleading.

A. In some cases, yes.

Q. (BY MR. BLIZZARD) Okay. So that the results of clinical studies on fen-phen and whether or not fen-phen can cause people heart valve damage can affect the financial fortunes of American Home Products, right?

MS. BINIS: Objection, hypothetical.

A. Yes.

Q. (BY MR. BLIZZARD) Okay, now, part of the work of the Redux team was to be involved in the process of the design of these scientific studies, correct?

A. Yes.

Q. The Redux team was also involved in the methodology for the studies, correct?

A. Yes.

Q. The conduct of the studies?

MS. BINIS: Objection.

A. Yes.

Q. (BY MR. BLIZZARD) Were you -- was the Redux team also involved in writing the manuscripts for some of the clinical studies that we have discussed?

A. Yes.

Q. Was the Redux team also involved in -- well, was support for the Redux team also involved in issuing press releases about the reports or about the clinical study results that were being supervised by the Redux team?

A. Yes.

Q. Was there also a discussion within the Redux team meetings about the timing of the release of scientific study results?

MS. BINIS: Objection.

A. This I can't just answer yes or no, because most of the time - probably every time - it was the release was related to either a presentation, so really the timing was based mostly on when the investigator

was going to present the data.

Q. (BY MR. BLIZZARD) When the data was ready, then?

A. Yes.

Q. But in terms of assisting the investigators in presenting the data, was the Redux team involved in that?

MS. BINIS: Objection.

A. I would say that in some investigators, we were somewhat involved; in other investigators, minimally involved. But we were involved in everyone, yes.

Q. (BY MR. BLIZZARD) Involved in sometimes in helping prepare the overheads that would be used in a presentation?

A. Yes.

Q. In helping train the mediator on how -- I'm sorry. The mediator.

Helping train the investigator on how to talk to the media about the results of the study?

MS. BINIS: Objection.

A. We didn't do that.

Q. (BY MR. BLIZZARD) Do you know what media training is?

A. Yes.

Q. Were any of the investigators media trained?
A. Yes.
Q. And were they media trained in connection with the presentation of their study results?
MS. BINIS: Objection.
A. Yes, in connection with, mostly on what kind of questions would be asked.
Q. (BY MR. BLIZZARD) All right. And in fact, were there Q and A's prepared for the investigators that would assist them in answering questions that might be posed by media?
MS. BINIS: Objection.
A. There were Q and A's prepared. I'm not sure that the Q and A's that we prepared were ever seen by the investigators. They were used mostly for our PR people.
Q. (BY MR. BLIZZARD) Were they supplied to the investigators?
A. I'm sorry, I can't answer that.
Q. All right.
A. I doubt it, but I'm not -- I -- I can't be sure of that.
Q. Okay. If in fact American Home Products and the Redux team at Wyeth-Ayerst were involved in the design of the clinical studies, the methodology of the

studies and writing the manuscripts for the studies and helped prepare the overheads for some of the studies and media training some of the investigators in connection with the presentation of the results of some of these studies, would it be fair to say that these studies were not conducted independent of the influence of American Home Products and Wyeth-Ayerst?

MS. BINIS: Objection. You are mischaracterizing his testimony. I am going to direct him to not to answer the question because the way you have asked it is not what he said.

MR. SHELLER: Barbara, you can't do that.

MR. KRATHEN: You know --

MR. BLIZZARD: Please certify the question.

MR. SHELLER: Are you directing him not to answer?

MS. BINIS: Mm-hmm.

MR. SHELLER: Barbara, that is a violation of the rules in Pennsylvania.

MR. KRATHEN: It's a violation of the Florida rules. It's a violation of the rules of every state in the United States of America and I don't think you as counsel really believe that you can direct him

not to answer that question.

MS. BINIS: If Mr. Blizzard asked my client a question to say in a way that he said something he didn't say I'm going to direct him to not to answer it. If you want to rephrase the question, you can.

MR. KRATHEN: If it doesn't involve a privilege -- if it doesn't invade a privilege you shouldn't be directing him not to answer the question.

MS. BINIS: Let's read the question back.

COURT REPORTER: Question: "If in fact American Home Products and the Redux team at Wyeth-Ayerst were involved in the design of the clinical studies, the methodology of the studies and writing the manuscripts for the studies and helped prepare the overheads for some of the studies and media training some of the investigators in connection with the presentation of the results of some of these studies, would it be fair to say that these studies were not conducted independent of the influence of American Home Products and Wyeth-Ayerst?

MS. BINIS: And I think that Mr. Pittelli's testimony was clear that this team was not involved in media training. Is that correct?

A. That's correct.

MR. KRATHEN: I am going to object and move to strike that question and answer by Mr. Pittelli.

Q. (BY MR. BLIZZARD) Let me see if I can state this simply, Dr. Pittelli.

These clinical studies that were being overseen by the Redux team were not designed and conducted independent of Wyeth-Ayerst and American Home's influence, were they?

MS. BINIS: Objection.

A. They were not -- I would eliminate American Home. Wyeth-Ayerst influence.

Q. (BY MR. BLIZZARD) Okay. They were not conducted independent of Wyeth-Ayerst influence, were they?

MS. BINIS: Objection.

A. That's correct.

Q. (BY MR. BLIZZARD) And in fact, Wyeth-Ayerst and the Redux team, through you, kept American Home Products informed about the activities of the Redux team, correct?

MS. BINIS: Objection.

A. Yes.

Q. (BY MR. BLIZZARD) Through a steering

committee at American Home Products that included the top lawyer in the company, an executive vice president of the company and Dr. Levy who is involved in research issues, correct?

MS. BINIS: Objection.

A. Yes.

Q. (BY MR. BLIZZARD) Now I want to talk to you about some documents. And we will take this as slow as we have to take it to make sure you have an opportunity to review these documents. I hope by that invitation we don't end up slowing it down unnecessarily.

Let me show you what I am going to mark as the next exhibit, Dr. Pittelli.

(Marked Deposition Ex. 1268)

Q. (BY MR. BLIZZARD) This, I believe, is an AHT; is that correct?

A. Yes.

Q. And this is dated October 30th, 1997, correct?

A. Yep. Yes.

Q. And does that authorize the expenditure of approximately $140,900 additionally per year plus some telecommunications costs of $48,000 per year, plus some one-time costs that are related to moving the Redux team into a new location?

A. Yes.
Q. Has he reported any abnormal valves anywhere?
A. No, he really hasn't.
(Marked Deposition Ex. 1276)
Q. (BY MR. BLIZZARD) Let me show you exhibit number 1276. Is this also an American Home Treasury document dated in 1998?
A. Yes.
Q. Looks like May the 1st of 1998?
A. Yes.
Q. And this is a one-year follow up study for which study?
A. Neil Weissman's 300 study.
Q. Okay. So the original funding of approximately $10 million carried you through the three-month echo, correct?
A. Yes, the original study plus the three-month follow up, I think.
Q. And that was approximately $10 million, correct?
A. Yes, approximately.
Q. Now, it looks like the one-year follow up is being funded in May of 1998 and it is another $7,975,000, correct?
A. That's right.

Q. And the one-year follow up echo, as I understand, was done at approximately 11 months, is that right, 11.9 months is what I saw.

A. That's -- yes, that's --

Q. So the 11.9 months has passed, hasn't it, since the initial echo?

A. Yes.

Q. So the data is there, correct?

A. Yes.

Q. Hasn't been reported anywhere, has it?

A. Not yet.

Q. Is there any plan to report it anywhere?

A. Desperately, yes.

Q. And currently where is it planned to be presented?

MS. BINIS: Objection. I am going to direct him not to answer that.

Q. (BY MR. BLIZZARD) Is that a secret?

MS. BINIS: Objection.

Q. (BY MR. BLIZZARD) I mean, is there -- has there been a plan made to present it at a specific scientific meeting?

A. Yes, we're trying to get it presented at a specific scientific meeting.

Q. Has that been firmed up yet?

Redux team.

Q. And the Interneuron cost sharing is $891,000, correct?

A. Yes.

Q. Okay. Well, excluding those two, if you go over to the last page, I mean the last line, does it show total research costs of $88,406,400?

A. Yes.

Q. Give or take a couple of million, correct?

A. Yes.

Q. So this research project that the company has engaged in regarding the -- the clinical effects of fen-phen has been an expensive project?

A. Not -- no, it has not been an expensive project when you look at the total amount of money that we spend on a project; it's about average.

Q. All right, now, these expenses that have been incurred by the company that are about average for a project, as you indicated, are these expenses, have they been incurred for the purpose of defending the company in lawsuits?

MS. BINIS: Objection.

A. No, the original thought that I -- that I had and that my staff had and that I think the company had was we wanted to find out if Redux or fen-phen caused

the problem.

Q. (BY MR. BLIZZARD) Okay.

A. And if it caused the problem, the extent of the problem. And that was the original intent of all of these studies.

Q. All right.

A. And that's how they were set up.

Q. So you understand the distinction of using the studies to essentially find the truth, versus using the studies for advocacy purposes?

MS. BINIS: Objection.

A. Well, I -- you know, we could all hope that they could be used for both.

Q. (BY MR. BLIZZARD) Right. But at the outset, these studies, were they designed to be used for advocacy purposes?

A. No, they were not.

Q. Okay. Let me show you --

A. Not in my mind anyway.

Q. All right. I understand. And I appreciate that.

Let me show you what is marked as --

MS. BINIS: Here.

MR. BLIZZARD: Thank you.

(Marked Deposition Ex. 1283)

RULES FOR THE AUDIT OF MATRIX COMPENSATION CLAIMS

EFFECTIVE DECEMBER 1, 2002

EXHIBIT A

Rule 2. ***Qualifications of Auditing Cardiologists.*** The Trust shall maintain a pool of qualified Auditing Cardiologists for reviewing Claims in Audit. Each Auditing Cardiologist shall be an independent Board-Certified Cardiologist, or Board-Certified Cardiothoracic Surgeon, with Level 3 training in Echocardiography. When necessary to sustain the optimal number of Auditing Cardiologists, the Trust may engage Board-Certified Cardiologists and Board-Certified Cardiothoracic Surgeons who have been certified by the National Board of Echocardiography in Transthoracic Echocardiography and have completed Level 2 training in Echocardiography. Absent Court approval, no person shall serve as an Auditing Cardiologist if that person is a Trustee of the Trust, has served as an Attesting Physician in more than ten Claims, or would be disqualified from serving as a Trustee under the provisions of Section VI.A.4.b of the Settlement Agreement. If an Auditing Cardiologist has been an Attesting Physician on a Claim, he/she may not review that Claim in Audit.

AUDIT PROCESS

Rule 3. ***Claims in Audit.*** The Trust shall refer to Audit all Claims that have been completed in accordance with the terms of Section VI.C of the Settlement Agreement and any Court Approved Procedures concerning completeness criteria that, from the face of the GREEN Form submitted, allege a medical condition for which the Claimant may be entitled to Matrix Compensation Benefits.

Rule 4. ***Procedures to Initiate Audit of Claims.*** As soon as reasonably practicable after the Trust determines under Rule 3 that a Claim should be referred to Audit under Rule 3, the Trust shall forward each Claim to an Auditing Cardiologist. The Trust shall submit to the Auditing Cardiologist the Electronic Audit Application and the documentation specified in Section VI.E.6 of the Settlement Agreement.

UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (Phentermine/ Fenfluramine/ Dexfenfluramine) PRODUCTS LIABILITY LITIGATION	:	CIVIL ACTION 99-20593
THIS DOCUMENT RELATES TO: SHEILA BROWN, SHARON GADDIE, VIVIAN NAUGLE, QUINTIN LAYER, and JOBY JACKSON-REID, Individually and all others similarly situated,	:	**Hon. Harvey Bartle**
Plaintiffs,	:	**DECLARATION OF SERVICE**
-against-	:	
AMERICAN HOME PRODUCTS CORPORATION,	:	
Defendants.	:	

DENISE A. RUBIN, an attorney duly admitted to practice in the State of New York and before the United States Court of Appeals for the Third Circuit, hereby declares that on Aug 4, 2003, I caused a true copy of the **CLAIMANTS' AFFIDAVIT AND EXHIBITS IN SUPPORT OF THEIR MOTION TO REMOVE THE AHP SETTLEMENT TRUST BOARD OF TRUSTEES** to be served on the following person(s) by e-mail and electronically filed with the Court. These papers were also served via regular mail on the persons listed in the annexed Certificate of Service.

Michael D. Schissel, Esq.
Arnold & Porter, LLP
399 Park Avenue
New York, New York 10022
Email: Michael_Schissel@aporter.com

Andrew A. Chirls Esq.
Wolf, Block, Schorr & Solis-Cohen, LLP
1650 Arch Street, 22nd Floor
Philadelphia, PA 19103
Email: achirls@wolfblock.com

Michael Fishbein
Levin Fishbein Sedran & Berman
510 Walnut Street, Suite 500
Philadelphia, Pennsylvania 19106
Email: mfishbein@lfsblaw.com

Denise A. Rubin (DR-5591)

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Notice of Motion, Affidavit of Denise A. Rubin, Exhibits, and Memorandum In Support Of the Claimants' Motion To Remove Auditors Oliner, Gottdiener and Zwas, have been served on all attorneys of record, as set forth below, on the 4th day of August 2003 via Regular Mail:

Gregory P. Miller, Esq.
MILLER, ALFANO & RASPANTI
1818 Market, Suite 3402
Philadelphia, PA 19103
Ph. (215) 972-6400
Fax 215-988-1478 or 215-981-0082

Andrew A. Chirls Esq.
Wolf, Block, Schorr & Solis-Cohen, LLP
1650 Arch Street, 22nd Floor
Philadelphia, PA 19103
Ph. (215) 977-2472
Fax (215) 405-2572

Alan Klein, Esq.
Hangley Aronchick Segal & Pudlin
One Logan Square, 27th Floor
Philadelphia, PA 19103
Ph. (215) 568-6200
Fax: (215) 568-0300

J. Clayton Undercofler
Saul Ewing Remick & Saul
Centre Square West, 38th Floor
1500 Market Street
Philadelphia, PA 19102
Ph. (215) 972-7777
Fax (215) 972-7725

Mark W. Tanner
Feldman Shepherd & Wohlgelernter
1845 Walnut Street, 25th Fl.
Philadelphia, PA 19103
Ph. (215) 567-8300
Fax: (215) 567-8333

Karl E. Seib, Jr.
Patterson Belknapp Webb & Tyler
1133 Avenue of the Americas
New York, NY 10035
Ph. (212) 336-2000
Fax (212) 336-2222

Richard Lewis
Cohen Milstein Hausfeld Toll & Toll
1100 New York Avenue, NW
Washington, D.C. 20005-3934
Ph. (212) 408-4600
Fax (212) 408-4699

Richard Wayne
Strauss & Troy
The Federal Reserve Building
150 East 4th Street
Cincinnati, Oh 45202-4018
Ph. (513) 261-2120
Fax (513) 241-8259

Gene Locks
Greitzer & Locks
1500 Walnut Street, 20th Floor
Philadelphia, PA 19102
Ph. (215) 893-3434
Fax (215) 893-3415

Mr. Doug Sisk
AHP Settlement Trust
701 Market Street, Suite 5555
Philadelpha, PA 19101
Fax (215) 923-5217

Orran L. Brown
BrownGreer, PLC
Riverfront Plaza, West Tower
901 E. Byrd Street, Suite 1400
Richmond VA 23219-4052

Stanley M. Chesley, Esq.
WAITE, SCHNEIDER, BAYLESS, *ET AL*
1513 Central Trust Tower
Cincinnati, OH 45202
Ph. (513) 621-0267
Fax (513) 621-0262

Arnold Levin, Esq.
LEVIN, FISHBEIN, SEDRAN AND BERMAN
510 Walnut, Suite 500
Philadelphia, PA 19106
Ph. (215) 592-1500
Fax (215) 592-4663

Dianne M. Nast, Esq.
RODA & NAST, P.C. 801 Estelle Dr.
Lancaster, PA 17601
Ph. (717) 892-3000
Fax (717) 892-1200

John J. Cummings, III, Esq.
CUMMINGS, CUMMINGS & DUDENHEFER
416 Gravier
New Orleans, LA 70130
Ph. (504) 586-0000
Fax (504) 522-8423

Ms. Deborah A. Hyland
Plaintiffs' Management Committee
325 Chestnut, Suite 200
Philadelphia, PA 19106
Ph. (215) 629-3919
Fax (215) 629-3998

Edward W. Madeira, Jr. Esq.
PEPPER HAMILTON, L.L.P.
1717 Arch, 34th Floor
Philadelphia, PA 19103
Ph. (215) 981-4353
Fax (215) 981-4307

Edward S. Weltman, Esq.
GOODWIN PROCTER, L.L.P.
599 Lexington Avenue
New York, NY 10022
Ph. (212) 956-1500
Fax (212) 956-3252

Peter L. Resnik, Esq.
MCDERMOTT, WILL & EMERY
28 State, 34th Floor
Boston, MA 02109-1775
Ph. (617) 535-4000
Fax (617) 535-3800

Michael T. Scott, Esq.
REED SMITH, L.L.P.
1650 Market Street, Suite 2500
Philadelphia, PA 19103
Ph. (215) 851-8248
Fax (215) 851-1420

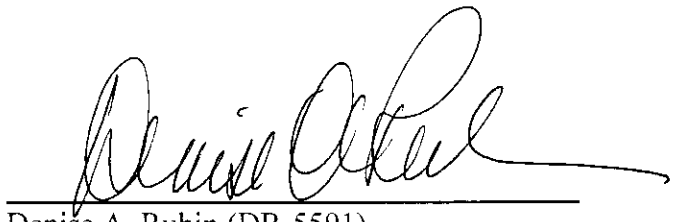
Sol H. Weiss, Esq.
ANAPOL SCHWARTZ WEISS
COHAN FELDMAN & SMALLEY, P.C.
1900 Delancey Place
Philadelphia, PA 19103
Fax (215) 735-2024

Peter L. Zimroth, Esq.
ARNOLD & PORTER
399 Park Avenue
New York, NY 10022
Fax (212) 715-1399

R. Eric Kennedy
Weisman Goldberg Weisman & Kaufman
1600 Midland Building
101 Prospect Avenue West
Cleveland, Ohio 44115
Ph. (216) 781-1111
Fax (216) 781-6747

Charles R. Parker, Esq.
HILL, PARKER & ROBERSON, L.L.P.
5300 Memorial Dr., Suite 700
Houston, TX 77007
Fax (713) 868-1275

Ellen Presby
Baron & Budd, P.C.
The Centrum
3102 Oak Lawn Ave. Ste. 1100
Dallas, Texas 75219-4241



Denise A. Rubin (DR-5591)

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS
(Phentermine/Fenfluramine/Dexfenfluramine)
PRODUCTS LIABILITY LITIGATION

MDL 1203

SHEILA BROWN, et al.

Plaintiffs,

Docket No.: 99 CV 20593

-against-

AMERICAN HOME PRODUCTS
CORPORATION, *et al,*

Defendants.

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CLAIMANTS' MOTION TO REMOVE AHP SETTLEMENT TRUST AUDITORS CRAIG OLINER, M.D., JOHN GOTTDIENER, M.D., AND DONNA ZWAS, M.D.

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NAPOLI KAISER BERN & ASSOCIATES, LLP
Attorneys for: Claimants
Office and Post Office Address, Telephone
3500 Sunrise Hwy., Suite T-207
Great River, New York 11739
(212) 267-3700

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To
Attorney(s) for

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Service of a copy of the within is hereby admitted.
Dated: July _____, 2003

_____
Attorney(s) for

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PLEASE TAKE NOTICE:

☐ NOTICE OF ENTRY
that the within is a (certified) true copy of a duly entered in the office of the clerk of the within name court on_____, 200__.

☐ NOTICE OF SETTLEMENT
that an order of which the within is a true copy will be presented for settlement to the HON. one of the judges of the within named Court, at on 20 at M.

Dated,

Yours, etc.
NAPOLI KAISER BERN & ASSOCIATES, LLP