

NO. 03-3740

**IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT**

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

On Appeal from the United States District Court
for the Eastern District of Pennsylvania

MDL DOCKET NO. 1203

Sheila Brown, et al. v. American Home Products Corporation
Civil Action No. 99-20593
Hon. Harvey Bartle, III

**BRIEF OF NAPOLI KAISER BERN & ASSOCIATES, L.L.P.,
AND HARITON & D'ANGELO, LLP, ON BEHALF OF THEIR
CLIENTS SUBJECT TO PRETRIAL ORDER 2952**

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APPELLANTS' CONSOLIDATED BRIEF

(CONCERNING CLAIMS OF EVETTE VITITOE, JOSEPH ROGERS AND
AMY PETERS AND CLAIMS OF JOHN RODRIGUEZ AND BARBARA
MESZAROS)

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CERTIFICATE OF INTERESTED PERSONS

1. *In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Products Liability Litigation*; MDL Docket No. 1203; in the United States District Court for the Eastern District of Pennsylvania, Philadelphia Division.

2. The undersigned counsel of record certifies that the following listed persons have an interest in the outcome of this case. These representations are made in order that the Judges of this Court may evaluate possible disqualification or recusal.

* Appellants:

a. No. 03-3740: Hariton & D'Angelo, LLP, and Napoli, Kaiser, Bern & Associates, LLP on behalf of their clients affected by Pretrial Order 2952. Those claimants are Amy Peters, Joseph Rogers, Evette Vititoe, John Rodriguez and Barbara Meszaros.

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* All individuals and entities listed below will be referred to as Appellants and/or class members throughout this brief.

Appellees:

Wyeth, f/k/a American Home Products Corporation

The AHP Settlement Trust, governed by the following Trustees:

Joseph L. Castle, II, Radnor, Pennsylvania
George A. Beller, M.D., Charlottesville, Virginia
Honorable Richard S. Cohen, New Brunswick, New Jersey
Senator Chris Harris, Arlington, Texas
Alison Overseth, New York, New York
Rose-Marie Robertson, M.D., Nashville, Tennessee
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STATEMENT OF RELATED CASES

Pursuant to Third Circuit LAR 28.1(a)(ii), Appellants state that the appeal docketed as 02-4378, arising out of the District Court's Pretrial Order 2640 is related to this matter. The Appendix Record and Briefs for 02-4378 are already on file with this Court and this Court granted appellants' motion to consolidate the instant appeal with 02-4378 for disposition by its order dated October 1, 2003.

TABLE OF CONTENTS

CERTIFICATE OF INTERESTED PERSONS	i
STATEMENT OF RELATED CASES	iii
TABLE OF CONTENTS	iv
TABLE OF AUTHORITIES	v
JURISDICTIONAL STATEMENT	1
STATEMENT OF THE ISSUES	2
STATEMENT OF THE CASE	2
The Diet Drug Litigation.....	3
The September 2002 Hearings and Pretrial Order 2640	4
Appellant John Rodriguez.....	7
Appellant Barbara Meszaros.....	11
Appellants Evette Vitito, Amy Peters and Joseph Rogers	16
ARGUMENT	18
POINT I.	
THE TRUST’S AUDITORS’ REVIEW OF THE MESZAROS AND RODRIGUEZ CLAIMS, FINDING THEM MERITORIOUS, SHOULD HAVE BEEN UNDISTURBED AND THE CLAIMS PAID ACCORDING TO THE COURT’S AND THE TRUST’S FIDUCIARY OBLIGATIONS TO THE TRUST’S BENEFICIARIES.	18
POINT II.	
THE APPELLANTS ENTERED A VALID CONTRACT WITH THE TRUST UPON RETURNING THEIR ACCEPTANCES OF THE POST-AUDIT DETERMINATIONS AND THE TRUST’S REFUSAL TO PAY THEIR BENEFITS CONSTITUTES A BREACH OF ITS OBLIGATIONS UNDER THE CONTRACT.....	29
CONCLUSION.....	32

TABLE OF AUTHORITIES

CASES

<i>Christianson v. Colt Indus. Operating Corp.</i> , 486 U.S. 800 (1988).....	26
<i>Cohen v. Beneficial Indus. Loan Corp.</i> , 337 U.S. 541 (1949).....	1
<i>Evans v. Marks</i> , 421 Pa. 146, 218 A.2d 802 (1966)	30
<i>Georgine v. Amchem Products</i> , 1995 WL 251402 (ED Pa. 1995)	29
<i>Hillcrest Found. v. McFeaters</i> , 332 Pa. 497, 2 A.2d 775 (Pa.1938).....	30
<i>Iman v. Hausman</i> , 354 Pa.Super. 458, 512 A.2d 41 (Pa. Super 1986)	31
<i>In re Bodnar's Estate</i> , 472 Pa. 383, 372 A.2d 746 (1977)	30
<i>In re City of Philadelphia Litigation</i> , 158 F.3d 711 (3d Cir. 1998).....	26
<i>In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.</i> , 990 F. Supp. 834 (J.P.M.L. 1998).....	3
<i>In re Jones & Laughlin Steel Corp.</i> , 328 Pa.Super. 442, 477 A.2d 527 (Pa. Super 1984)	31
<i>In Re: Cendant Corp.</i> , 233 F.3d 188 (3d Cir. 2000).....	29
<i>In re: Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Products Liability Litigation</i> , 236 F. Supp. 2d 445 (ED Pa. 2002)	23
<i>Jenkins v. County of Schuylkill</i> , 441 Pa.Super. 642, 658 A.2d 380 (Pa.Super.Ct. 1995)	30

<i>Lanci v. Metropolitan Insurance Company,</i> 388 Pa.Super. 1, 564 A.2d 972 (Pa. Super 1989)	31
<i>Price v. Ross,</i> 339 Pa.Super. 461, 489 A.2d 252 (Pa. Super 1985)	31
<i>Public Interest Research Group of New Jersey, Inc. v. Magnesium Elektron, Inc.,</i> 123 F. 3d 111 (3d Cir. 1997).....	27
<i>Rice v. United States of America, Department of Alcohol, Tobacco and Firearms,</i> 1996 WL 494138 (ED Pa. 1996)	26
<i>Sparler v. Fireman’s Insurance Co. of Newark, N.J.,</i> 521 A.2d 433 (Pa. Super 1987).....	30
<i>Three Rivers Motors Co. v. Ford Motor Co.,</i> 522 F.2d 885 (3d Cir. 1975).....	30
<i>United Artists Theatre Circuit, Inc. v. Township of Warrington, PA.,</i> 316 F.3d 392 (3d Cir. 2003).....	26, 27
<i>Washner v. American Motor Sales Corp.,</i> 597 F.Supp. 991 (E.D.Pa.1984)	31
<i>Wolbach v. Fay,</i> 488 Pa. 239, 412 A.2d 487 (1980)	31
STATUTES	
28 U.S.C. § 1291	1
28 U.S.C. § 1332	1
28 U.S.C. § 1407	1

JURISDICTIONAL STATEMENT

The National Class Action Settlement Agreement With American Home Products, Inc. [“Settlement Agreement”] settled pending state court Class Actions from seven separate states, including New York, Pennsylvania, Texas, New Jersey, West Virginia, Illinois and Washington. The independent basis of the District Court’s jurisdiction over class members is the District Court’s status as the court assigned to preside over the MDL 1203 diet drug litigation. *See* 28 U.S.C. §§ 1332 and 1407.

This Court’s jurisdiction is proper under 28 U.S.C. § 1291 and the collateral order doctrine. *See Cohen v. Beneficial Indus. Loan Corp.*, 337 U.S. 541 (1949).¹ The appeals are all timely. PTO 2952 was entered on August 11, 2003, the Notice of Appeal was filed on or about September 8, 2003.

¹ All *Cohen* elements are satisfied in this consolidated appeal. PTO 2952 (1) conclusively determines the disputed issue of audits of the subject claims; (2) is separate from the merits of the class members’ claims for benefits; and (3) is effectively unreviewable on appeal from final judgment because benefits claims will already have been decided under the audit process changed by PTOs 2640 and 2662. Additionally, class members will be irreparably harmed because their due process rights and Federal Rule 23 have been violated, and they will suffer by any further delay in appellate review. *See Firestone Tire & Rubber v. Risjord*, 449 U.S. 368, 376 (1981).

STATEMENT OF THE ISSUES

Pursuant to FED. R. APP. P. 30(b)(1), Appellants Barbara Meszaros and John Rodriguez, Evelyn Vititoe, Amy Peters and Joseph Rogers the following issues for consideration by this Court on Appeal 03-3740:

1. Did the District Court violate Fed. R. Civ. P. 23 and/or otherwise err by denying claimants' motions to compel the AHP Settlement Trust, once the claims at issue in the motion below had been submitted to the audit procedure, to pay those claims the Trust's auditors deemed meritorious?
2. Did the District Court violate Fed. R. Civ. P. 23 and/or otherwise err by denying claimants' motions to compel the AHP Settlement Trust, once the claims at issue in the motions below had been submitted to the audit procedure, to follow through with the remaining aspects of the Settlement Agreement including, but not limited to, the show cause proceedings for those claims denied?
3. Such other and further issues as may become apparent during the preparation of the appellate brief and Appendix Record on Appeal.

STATEMENT OF THE CASE

The present consolidated appeal arises from the MDL 1203 Diet Drug litigation. Specifically, this appeal arises from Pretrial Order 2952 entered by the United States District Court for the Eastern District of Pennsylvania (Bartle, J.) in multidistrict litigation ["MDL"] 1203, the products liability action arising from the claimants' use of defendant's diet drugs fenfluramine (trade name "Pondimin", and half of the diet drug litigation colloquially known as "fen-phen") and dexfenfluramine (trade name "Redux). The long and tortured history of this

litigation and the Settlement Agreement entered therein (the NATIONAL CLASS ACTION SETTLEMENT AGREEMENT WITH AMERICAN HOME PRODUCTS, INC.) is well known to this Court from other appeals pending *sub judice*.

The Diet Drug Litigation

After Wyeth's products Pondimin and Redux were withdrawn from the market in 1997, persons who had taken fen-phen (and/or their derivative claimants) filed some 18,000 individual lawsuits and more than 100 class actions in U.S. state and federal courts. Some lawsuits advanced various types of personal injury and consumer claims against Wyeth, certain Wyeth personnel and physicians. Others consisted of requests for medical monitoring and reimbursement for medical and prescription expenditures.

Because of the large number of similar cases, on December 10, 1997, all pending federal actions were transferred to the U.S. District Court for the Eastern District of Pennsylvania for coordinated and/or consolidated pretrial proceedings. *See In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, 990 F. Supp. 834 (J.P.M.L. 1998). The Hon. Louis C. Bechtel was the MDL transferee judge until his retirement. The Hon. Harvey Bartle, III took his place in July 2001, and presently presides over MDL 1203.

The AHP Settlement Trust was created as a part of the "*Nationwide Class Action Settlement Agreement with American Home Products Corporation*"

["Settlement Agreement"]. That agreement arises out of the diet drugs ["fen-phen" for fenfluramine, dexfenfluramine and phentermine] product liability multi-district litigation.

To prevent fraud in the submission of medical claims, the Settlement Agreement included an audit requirement. Under the Agreement, the Trust was required to audit 5% of all claims, and Wyeth was permitted to designate for additional audits up to 10% of filed claims within a quarter for a combined total of 15% of claims for compensation from Fund B, one of the two fen-phen settlement funds. The audits were to confirm whether the attesting physician had a "medically reasonable basis" to conclude a class member was entitled to benefits. Subsequent to the final judicial approval of the Settlement Trust, after all appeals from the settlement class were exhausted, appellees collectively determined that there were substantially more claimants than anticipated.

The September 2002 Hearings and Pretrial Order 2640

Following six days of hearings in September 2002, the District Court ordered (*In re: Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Products Liability Litigation*, 236 F. Supp. 2d 445, 449 at note 2 [ED Pa. 2002]) that the AHP Settlement Trust "shall not pay the claims of the following class members submitted by the law firms of Hariton & D'Angelo, LLP and/or Napoli Kaiser, Bern & Associates, LLP without prejudice to the right of said claimants to

submit new echocardiograms and Green Forms signed by a certifying cardiologist other than Linda J. Crouse, M.D. or Richard L. Mueller, M.D.,” and listed thereafter the names of 78 plaintiffs. Appellants John Rodriguez and Barbara Meszaros were listed among the 78 plaintiffs this Court included in that order, as were appellants Evette Vittoe, Amy Peters and Joseph Rogers.

Shortly thereafter, on November 26, 2003, the District Court issued its PTO 2662, expanding the 100% audit to all of the claims submitted for Matrix B benefits. (A. 564-565).²

Notably, however, the language of PTO 2640 does not preclude the audit of the claims addressed in PTO 2640. PTO 2640 specifically states that the “Trust has full authority to audit under the Settlement Agreement *each and every* echocardiogram and Green Form *already submitted* or to be submitted in the future on behalf of a class member wherein Linda Crouse, M.D. or Richard Mueller, M.D. is the certifying cardiologist.” (*emphasis added*) The Trust took this very same position when it decided to audit the claims of claimants Ruth Enloe and Linda Morales,³ despite the fact that the District Court had directed that those

²Hereinafter, all citations designated as “(A. ____)” refer to pages so enumerated in the Appendix Record on Appeal.

³ Linda Morales and Ruth Enloe’s claims were deemed meritorious by the District Court at footnote 2 of Pretrial Order 2640, upon Trust expert Dr. John Dent’s testimony, during the September 2002 hearings, that both claimants’ echocardiograms demonstrated the moderate mitral valve regurgitation attested to by their physicians. The District Court directed that both claims be paid.

two claimants were to be paid their benefits upon Wyeth's expert Dr. John Dent's testimony.

PTO 2640 is wholly consistent with the Court's prior rulings and anticipated that the 78 claims denied payment by PTO 2640 would be audited. The carefully chosen language of the paragraph is explicit. PTO 2640 states:

The Trust has full authority to withhold payment of those claims identified in *paragraphs (1), (2) and (3) pending the completion of the audit process.* (Emphasis added).

Consistent with this reading of PTO 2640 and the subsequent PTO 2662, the Trust audited the claims of Appellants Rodriguez and Meszaros, and favorable determinations were issued. PTO 2640 plainly directed that the Trust pay these claims if the Trust auditor concluded that there was a reasonable medical basis to support the claim. Further, in accordance with Trust policies and procedure, the appellants received valid offers of settlement. Appellants Meszaros and Rodriguez accepted the Trust's offers of settlement and both signed and returned the post audit acceptances to the Trust. Appellants also incurred additional expenses for consultations with qualified physicians to comply with the new District court-approved procedure regarding medical histories ["MED CAP 4"]. Given all of

Notwithstanding that fact, and citing the directive in PTO 2640 to audit "each and every claim," the Trust submitted both claims thereafter to audit, and upon completion of the audit, denied both claims. When claimants moved the District Court to compel payment of their claims based on its determination that the claims should be paid in PTO 2640, the Trust ultimately stipulated to pay the claims.

these facts, pursuant to the law of this case and basic tenets of contract law, the Trust had no right to unilaterally deny payment of appellants' claims.

By refusing to pay claims that it has deemed meritorious upon audit, the Trust has taken a position that is inconsistent with its role as a fiduciary. The Trust's unilateral decision to suspend processing and payment of these claims is inconsistent with the actions taken by the Trust to date and with the explicit language of PTO 2640.

Appellant John Rodriguez

Appellant John Rodriguez is a male police officer, born August 12, 1955. Mr. Rodriguez had a transthoracic echocardiogram 2-D and M-Mode combination, Spectral Analysis Doppler and Color Flow Doppler was performed by sonographer Audrey Loeb, RDCS, RVT on March 25, 2002. Those tests were read by Linda J. Crouse, M.D., FACC on March 25, 2002. Dr. Crouse reported that Mr. Rodriguez had ***demonstrated 31% or moderate mitral valve regurgitation, verified using the RJA/LAA method, and left atrial enlargement.*** See Dr. Linda Crouse's evaluation of Mr. Rodriguez's test results, a true copy of which was annexed to the motion papers below as Exhibit "A," and which now appear in the Appendix Record for this Appeal at (A. 150-151).

Subsequently, a Matrix claim was filed on or about April 19, 2002. A true copy of that claim appears at (A. 152). On or about October 23, 2002 the claimant

received notice that Wyeth had designated his claim for Audit. A true copy of that notice is appears at (A. 153). Wyeth's contention was that Mr. Rodriguez's March 25, 2002 echo study showed physiologic to mild mitral valve leaking.

Trust expert Dr. John Dent read Mr. Rodriguez's echocardiogram and determined that it *had* been conducted "in accordance with the standards and criteria as outlined in Feigenbaum (1994) or Weyman (1994)," *See*, Dr. Dent's 5-page evaluation form, a true copy of which appears at (A. 161).

The Trust's auditing cardiologist, John Gottdiener, M.D., determined that claimant John Rodriguez is entitled to matrix benefits. The Trust refused appellants' requests for the auditor's worksheet on this case.

Subsequently, on or about April 1, 2003, Mr. Rodriguez received an Initial Post-Audit Determination, a true copy of which appears at Exhibit "E" to the motion papers below. (A. 162-165). That Initial Post-Audit Determination stated:

The audit was concluded and was utilized by the Trust to determine that *the claimant is entitled to Matrix Compensation Benefits at Level 2.* (Emphasis added).

The determination indicated, however, that, based on PTO 2805 and PTO 2807, all Matrix claims would be subject to a complete medical audit in order to determine if his claim should be paid on the A-1 Matrix or on the B-1 Matrix. In any case, the Trust issued its determination on the B-1 Matrix without prejudicing Mr. Rodriguez's right to establish that he was entitled to A-1 Matrix Benefits.

On April 8, 2003, Mr. Rodriguez's original executed Acceptance of the aforementioned Initial Post Audit Determination was forwarded to the Trust for payment in the amount of \$66,872.54. A true copy of that document was annexed to the motion papers below at Exhibit "F." (A. 168).

While waiting for the B-matrix benefit check, Mr. Rodriguez pursued his right to establish his eligibility for the A-matrix compensation. To that end, on April 14, 2003, Mr. Rodriguez met with Dr. Bruce Charash, a Board Certified Cardiologist, qualified to complete the Physician Verification Form necessary to establish that there were no pre-existing or existing conditions that would prevent Mr. Rodriguez from obtaining the A-matrix benefits he had initially claimed on April 19, 2002. *See* Dr. Bruce Charash's Affidavit, a true copy of which appears at (A. 172). *See also* Dr. Charash's report of Mr. Rodriguez (A. 170).

Hence, contrary to the Court's Pretrial Order 2952, the claims do not "continue to be based on medically unreasonable echocardiograms and Green Forms." As the District Court contemplated in PTO 2640, the Green form and echocardiogram report it deemed unreasonable on the appellants' first submission has been replaced by the attestation and Green Form submitted by Dr. Charash. Hence, the underlying intent and purpose of PTO 2640 has been fulfilled on the appellants' claims.

On April 15, 2003, appellants' counsel Hariton & D'Angelo, LLP, had a phone conversation regarding entering Post-Submission Costs for adjusted attorneys' fees with Trust attorney Chaz Groshon, Esq. Mr. Groshon stated that there would be monthly deadlines for submitting Acceptances, and that, if Acceptances were sent to the Trust before the end of one month, the claimant could expect that the benefits check would be issued at the end of the following month.

On April 18, 2003, appellant Rodriguez's completed Physician Verification Form and DDR Acknowledgement, the Green Form Part II.E and a transcribed medical history report was forwarded to the Trust via fax and overnight mail. *See Charash Aff.*, at Exhibit "G" to the motion papers below. (A. 172). Accordingly, on May 15, 2003, a Revised Determination was issued after the Trust's receipt of the medical audit materials and Mr. Rodriguez was approved for A-Matrix Benefits. *See Revised audit determination*, annexed to the motion papers below as Exhibit "H". (A. 181). On May 22, 2003, the executed Revised Determination was forwarded to the Trust via fax and overnight mail. *See signed Revised Determination annexed to the papers below as Exhibit "I"* (A. 181).

No B-Matrix check was issued to Mr. Rodriguez on May 30, 2003. The law office of Hariton& D'Angelo, LLP called the Trust to see when a check could be expected, leaving a message for Chaz Groshon, Esq., explaining that Mr. Rodriguez had been calling twice a day for the past two weeks inquiring as to

whether his Matrix B benefits had been received. The message further indicated that a response as to when payment could be expected would be appreciated.

On or about June 5, 2003, an email received from Mr. Groshon stated that the check for Mr. Rodriguez's claim was "not forthcoming" for reasons that would later be set forth in Mr. Henshell's letter to Paul Napoli. *See* Henshell letter, a true copy of which was annexed to the papers below at Exhibit "J" (A. 181).

The same day, Hariton & D'Angelo attorney Mario D'Angelo responded to Mr. Henshell. A true copy of Mario D'Angelo's letter to the Trust, responding to Mr. Henshell, was annexed to the motion papers below as Exhibit "K" (A. 188-189).

Appellant Barbara Meszaros

Appellant Barbara Meszaros, a female, 51 years of age, underwent transthoracic echocardiogram, 2-D and M-Mode combination, spectral analysis doppler and color flow doppler, performed by Richard L. Mueller, MD, FACC, FACP, on October 29, 2001. *See* Echocardiogram test results and evaluation annexed to the motion papers below at Exhibit "L," (A. 190). Dr. Mueller read those test results the same day. Dr. Mueller determined that Ms. Meszaros demonstrated 38% *or moderate* mitral valve regurgitation, low moderate aortic regurgitation (29%) and verified, by showing the RJA/LAA measurements on his report, a left atrial enlargement shown in the apical view as 5.4cm.

Subsequently, a Matrix claim was filed for Ms. Meszaros on or about February 15, 2002. *See* Exhibit “M,” (A. 191).

Trust expert Dr. Dent reviewed Ms. Meszaros’ echocardiogram results on or about August 3, 2002. *See* Dr. Dent’s review forms, annexed to the motion papers below at Exhibit “N,” (A. 192-196). Dr. Dent described the views as good (“Diagnostic images in all views for all cardiac structures that need to be assessed”) *and Dr. Dent agreed that* the echocardiogram submitted by Dr. Mueller was conducted in accordance with the standards and criteria as outlined in Feigenbaum (1994) or Weyman (1994). *See* Exhibit “N,” at p. 4.⁴ (A. 195). Dr. Dent read the echocardiogram as demonstrating -- and Dr. Dent’s summary form (A. 193) also indicates his determination that Ms. Meszaros’ echocardiogram revealed -- “mild” mitral regurgitation.

On or about August 1, 2002, Ms. Meszaros received a tentative determination for Matrix A, Level II benefits compensation in the amount of \$473,032.00. That determination stated that if no one contested the determination

⁴ Dr. Dent and the Trust auditors have disagreed in the past. That is the nature of the test of a “medically reasonable basis”. Dr. Dent said several times that he had reviewed Linda Morales’ echocardiogram, and that he deemed the results of that echocardiogram to reveal a “moderate” level of valvular disease according to the standards set for this litigation. This was contrary to the auditors’ findings in both *Enloe* and *Morales* and continues to form the basis of claimants’ arguments running throughout each of our briefs that different qualified doctors can have different opinions and both can be “reasonable”.

within thirty (30) days, the letter would automatically become the Trust's final determination. *See* Exhibit "O" to the motion papers below, (A. 197-199).

On August 4, 2002, Ms. Meszaros signed the Trust's Determination and the form was forwarded to the Trust on or about August 6, 2002. *See* Exhibit "P" to the motion papers below (A. 201). On or about October 16, 2002, Ms. Meszaros received notice that Wyeth had designated her claim for Audit (A. 202). Wyeth's contention was that Ms. Meszaros' October 29, 2001 echo study did not show left atrial enlargement, as Dr. Mueller's Green Form and report had indicated. *See* Exhibit "Q", (A. 205).

For almost six months, Ms. Meszaros waited. Finally, a letter from the Trust arrived January 16, 2003 stating that her claim was being sent to an Auditing Cardiologist. (A. 206). Her claim was audited by a Trust auditing cardiologist, and several months later, on or about April 3, 2003, Ms. Meszaros received an Initial Post-Audit Determination stating:

The audit was concluded and was utilized by the Trust to determine that *the claimant is entitled to Matrix Compensation Benefits at Level 2. (Emphasis added).*

However, based on PTO No. 2805 and 2807, all Matrix claims would be subject to a complete medical audit in order to determine if the valid claim should be paid on the A-1 Matrix or on the B-1 Matrix. In any case, the Trust issued its

Determination on the B-1 Matrix without prejudicing Mrs. Meszaros' right to establish that she was entitled to A-1 Matrix Benefits.

On April 8, 2003, the original executed Acceptance of Ms. Meszaros' Initial Post Audit Determination was forwarded to the Trust for payment in the amount of \$63,304.77. A true copy was annexed to the motion papers below at Exhibit "S" (A. 209).

While waiting for the B-Matrix benefit check, Mrs. Meszaros pursued her right to establish her eligibility for the A-matrix compensation. On April 14, 2003, Mrs. Meszaros met with Dr. Bruce Charash, a Board Certified Cardiologist, qualified to complete the Physician Verification Form necessary to establish that there were no pre-existing or existing conditions that would prevent Ms. Meszaros from obtaining the A-matrix benefits she had initially claimed on February 15, 2002. *See* Med-Cap 4 papers including Dr. Charash's report, annexed to the motion papers below as Exhibit "T" (A. 210-221).

On April 15, 2003 the law office of Hariton & D'Angelo, LLP had a phone conversation regarding entering Post-Submission Costs for adjustment of attorneys' fees with Trust attorney Chaz Groshon, Esq. Mr. Groshon stated that there would be monthly deadlines for submitting Acceptances and that if Acceptances were sent to the Trust before the end of one month than the claimant could expect that the benefits check would be issued at the end of the following

month. On April 18, 2003, the completed Physician Verification Form and DDR Acknowledgement, the Green Form Part II.E and a transcribed medical history report was forwarded to the Trust via fax and overnight mail.

Accordingly, on May 16, 2003, a Revised Determination was issued after the Trust's receipt of the medical audit materials and Ms. Meszaros was *again* approved for A-Matrix Benefits.

On May 21, 2003 Ms. Meszaros came to her counsel's office to personally deliver her signed Acceptance of the Revised Determination and discussed with her counsel her concern regarding the Trust's broken promises. On May 22, 2003, the executed Revised Determination was forwarded to the Trust via fax and overnight mail. *See* Exhibit "U" to the underlying motion papers (A. 222).

No B-Matrix check was issued to Ms. Meszaros on May 30, 2003 or thereafter. An employee from the law office of Hariton & D'Angelo LLP, called the trust regarding Ms. Meszaros' claim. Once again a message was left for Chaz Groshon, Esq., requesting a response. On or about June 5, 2003 an email from Mr. Groshon stated that the check for Ms. Meszaros' claim was "not forthcoming" for reasons that would later be stated in Mr. Henshell's letter to Paul Napoli.

Mario D'Angelo responded by his letter of June 5, 2003. *See* Correspondence (Exhibit K to the papers below) (A. 188-189).

Appellants Evette Vitito, Amy Peters and Joseph Rogers

Appellants Evelyn Vittoe, Amy Peters and Joseph Rogers, each received unfavorable determinations following audit of their claims. Each exercised their rights under the Settlement Agreement and implementing PTOs issued by the District Court, demanding Show Cause proceedings.⁵ See Correspondence to Jules Henshell dated April 18, 2003, true copies of which were attached to the motion papers below at Exhibit “A” (A. 288-289). In response, the Trust initiated the Show Cause procedures as required. Thereafter, however, the Trust applied to the Court to withdraw the Show Cause applications, without claimants’ consent and in derogation of its duty to move the claims through the claim process to a swift completion. In the case of these appellants, despite the law of this case and the basic tenets of contract law, the Trust unilaterally interrupted the audit and review processes it initiated, the end result being that the claimants have been denied their right to pursuing their claims through the procedures enacted by the District Court *at the Trust’s behest*.

By refusing to process these claims as required, the Trust took a position wholly inconsistent with its role as a fiduciary. Consistent with PTO 2640, the

⁵ The procedure for appeal of unfavorable determinations has since been amended to include an intermediate step where the claimant files a “contest letter” that is first reviewed by the Trust. Only upon the contest letter receiving a further unfavorable response by the Trust will the show cause proceeding go forward. This intermediate step of the contest letter did not exist at the time of the Vittoe, Rogers and Peters appeals.

Trust audited these class members' submissions and issued final determination letters denying their claims. The class members, as the Settlement Agreement provided, each demanded that their claims be submitted to a show cause proceeding. There is no authority in the Trust Agreement or the Settlement Agreement, nor in PTO 2640, for the Trust to unilaterally interrupt and end the appeals procedure contemplated by the District Court's orders.

On June 10, 2003, appellants' counsel Paul J. Napoli wrote to MDL-1203 Special Master Gregory Miller, objecting to the Trust's decision to suspend the show cause proceedings. Mr. Napoli requested that the Show Cause proceedings go forward. *See* June 10, 2003 Correspondence to MDL-1203 Special Master Gregory Miller, a true copy of which was annexed to the papers below at Exhibit "B" (A. 291-292). Mr. Napoli was advised that the issues raised in his correspondence would have to be resolved by the District Court on formal application. Such an application was made, and the District Court denied the motion as part of its Pretrial Order 2952, here appealed.

ARGUMENT

POINT I.

**THE TRUST’S AUDITORS’ REVIEW OF THE
MESZAROS AND RODRIGUEZ CLAIMS,
FINDING THEM MERITORIOUS, SHOULD HAVE
BEEN UNDISTURBED AND THE CLAIMS PAID
ACCORDING TO THE COURT’S AND THE
TRUST’S FIDUCIARY OBLIGATIONS TO THE
TRUST’S BENEFICIARIES.**

The District Court held in PTO 2640 that 78 claims listed therein were medically unreasonable and could not be paid unless those claimants submitted further medical attestations by different physicians. *See* Pretrial Order 2640, at (A. 293-294). For reasons unknown, without waiting for the further medical submissions by the claimants, the American Home Products [“AHP”] Settlement Trust submitted both claimants’ submission to medical audit. Upon completion of the audit, John Rodriguez’s claim by Dr. John Gottdiener⁶ and Barbara Meszaros’ claim by Dr. Andrew D. Sumner, both were deemed medically reasonable, and the Trust’s auditing physicians each confirmed the appellants’ attesting physicians’ diagnosis of moderate mitral regurgitation. (A. 181 and A. 197-199). Rather than

⁶ Notably, Dr. Gottdiener has since been removed as an auditor for the Trust due to revelations of evidence found by appellants’ counsel that Dr. Gottdiener was in fact ineligible to serve as an auditor due to financial affiliations with defendant Wyeth. This fact was recently confirmed by the District Court’s Pretrial Order 3164, directing that any claimant whose submission was audited by Dr. Gottdiener could request that their submission be re-audited.

pay those claims upon the finding that the attesting physicians' diagnoses had been upheld by the Trust auditors, however, the Trust proceeded, inexplicably, to deny both appellants' claims. *See* Denial letters at A. 187, 249 and A. 248.

The Trust's duties and obligations are well known to all of the parties who have been before this Court in the proceedings connected with MDL 1203. In its PTO 2881, the District Court clearly stated:

We reiterate, as we did in PTO 2663, that we are distressed that benefits due and owing to rightful claimants who have been injured by fen-phen have not and are not being paid on a timely basis. Legitimate claimants should be paid as promptly as possible consistent with the sound administration of the Trust.

Notwithstanding that fact, and despite the fact that the Trust determined through audit that both Barbara Meszaros and John Rodriguez are rightful claimants who have been injured by fen-phen, and that both deserve compensation, the Trust failed to pay those claims, consistent with PTO 2640(4) and the results of their own audit. In so doing, the Trust demonstrated utter disregard for its duties and obligations in addressing these claimants' rights.

The Trust tendered offers of settlement that the claimants accepted, and thereupon encouraged these claimants to take the steps necessary to comply with

MED-CAP (4).⁷ Given the Trust's subsequent conduct with regard to these claimants, however, it is clear that the Trust never intended to pay the claims, regardless of whether or not the claimants fulfilled the requirements of the Settlement Agreement. That conclusion is unavoidable in light of the totality of the Trust's conduct following the initial Trust audit of the Meszaros and Rodriguez claims. Importantly, this was not a situation where the Trust failed to review Mr. Rodriguez's and Ms. Meszaros' claims; rather, it is a situation *where the Trust's auditors expressly found upon a review of those claims* and the echocardiograms that they were based on, that both claimants' test results demonstrated moderate mitral regurgitation, and, more importantly, an entitlement to Matrix compensation.

Opposing the appellants' motion to the District Court to compel payment of the appellants' claims, the Trust submitted the two claims to further review by the auditing physicians. Dr. Gottdiener, whose anti-claimant bias in these matters has been revealed by appellants' counsel and confirmed by the District Court's Pretrial Order 3164, recanted his initial audit conclusions. Dr. Gottdiener stated, in opposition to the motion to compel payment, that he had not correctly reviewed Mr. Rodriguez's submission prior to releasing the results of his audit, due in part to

⁷ Medical Court Approved Procedure ["Med-CAP"] 4 requires that claimants submit extensive medical records and further medical attestations to the Trust prior to being compensated on medically-approved claims.

the fact that he had not at that time completed the auditor's training course. (A. 259-260). He thereupon stated that, following the correct protocol in the auditor's training course, he now found that Mr. Rodriguez's echocardiogram only demonstrated a mild mitral valve regurgitation, thus rendering his claim ineligible for Matrix benefits. Even more notably, Dr. Sumner's further statement in response to the motion in the District Court never expressly states that his initial findings were incorrect as to Ms. Meszaros' echocardiogram. (A. 250-251). Rather, Dr. Sumner confirms his reading of moderate mitral regurgitation but adds a waffling statement that, due to an allegedly low "aliasing velocity" setting on the echocardiogram machine, the machine "may falsely increase the regurgitant jet area." (A. 251 at ¶ 5).

Deciding the motion in its Pretrial Order 2952, the District Court held that the Trust had been directed not to pay any of the seventy-eight claimants addressed therein, so long as their claims were based on the echocardiograms and Green Forms that the Court determined to be medically unreasonable. *See* PTO 2952 (Memorandum at p. 3, [A. 1-5]) and PTO 2460 (Memorandum at [A. 293-312]). The Court agreed that the Trust's submitting all of these appellants' claims to audit (including appellants Amy Peters, Joseph Rogers and Evette Vititoe as well as John Rodriguez and Barbara Meszaros) was the result of the Trust "disregarding our PTO 2640 and its accompanying Memorandum." PTO 2952 at p. 3 (A. 3).

Having done so, the Court conceded, the Trust audits thereupon determined that their medically unreasonable claims qualified for settlement benefits, and the Trust notified the claimants of that fact and issued tentative and then revised post-audit determination letters. PTO 2952 at p. 4 (A. 4). The District Court further noted that “[o]nly after the claimants *accepted these determinations and purportedly waived certain rights* did the Trust realize its error. On June 5, 2003, the Trust informed both Meszaros and Rodriguez that it could not pay them pursuant to the terms of PTO 2640.” PTO 2952 at p. 4 (A. 4).

It cannot be understated: the District Court heard six days of testimony in September 2002 regarding a number of the claims filed, *but of the 78 claims that were deemed medically unreasonable and directed not to be paid absent further medical submissions, the District Court only heard medical testimony and evidence concerning a very limited number.* Those limited number of cases actually considered by the Court *did not include the Meszaros and Rodriguez claims.* Hence, the Court never had a basis to rule the Meszaros and Rodriguez claims “medically unreasonable” and did so on no more than its *sua sponte* determination that the attesting physicians on those claims were not credible witnesses.

Instead the District Court should have allowed the auditor’s initial findings to stand, and should have ordered the claims paid without continued delay. PTO 2640 did not preclude the Trust from auditing the claims, nor did it direct the Trust

not to audit the claims. In fact, PTO 2640 directs the opposite. Consistent with PTO 2640(2) the “Trust has full authority to audit under the Settlement Agreement *each and every* echocardiogram and Green Form *already submitted* or to be submitted in the future on behalf of a class member wherein Linda Crouse, M.D. or Richard Mueller, M.D. is the certifying cardiologist.” (*emphasis added*) The Trust took the same position when it decided to audit the *Enloe* and *Morales* claims. *See* (A. 558-559).

Indeed PTO 2640 directs that, once the *Rodriguez* and *Meszaros* claims were audited and found to be meritorious, both claims were to be paid. PTO 2640(4) is wholly consistent with the other sections of the Court’s ruling, and authorizes that the claims addressed in 2640(1) be audited. There can be no other interpretation. PTO 2640(4)states:

(4) The Trust has full authority to withhold payment of those claims identified in *paragraphs (1), (2) and (3)* pending the completion of the audit process. (*emphasis added*).

In re: Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Products Liability Litigation, 236 F. Supp. 2d 445 (ED Pa. 2002).

It cannot be overstated: the AHP Settlement Trustees stand in a fiduciary relationship with the beneficiaries of the AHP Settlement Trust. That Trust was created to assure that legitimate claims are paid in an expeditious fashion. In that capacity, it is not the Trust’s purpose, nor its auditor’s job, to go out of their way to

deny all comers. Moreover, the Trust's ongoing efforts to discredit and deny class members and their counsel are not justified just because the medical audit may return an unfavorable finding. The class members remain beneficiaries of the Trust under the Settlement Agreement, which contemplates that the injuries caused by the defendants' diet drugs are progressive in nature, and that class members deemed ineligible for Matrix-level benefits now may become eligible at a later date as their illness progresses and their injuries become more severe.

Having now denied rightful claims that were deemed so by their own auditors, the Trust has now, without any authority to do so in the Settlement Agreement or in the Pretrial Orders issued by this Court, subjected those claims to repeated scrutiny and review until the auditor returns a finding that meets with the Trust's approval. Whether that finding reflects the claimant's true medical condition is of no concern or interest to the Trust. Whether the increasingly burdensome audit and re-audit process resembles the procedure set forth in the Settlement Agreement and the District Court's orders is apparently of little moment.

Given the plain language of the prior order, the findings of the Trust's auditors should not have been disturbed, either by the Trust's further inquiries or by the District Court. The audits had been completed, and although they were done before new medical reports or a new echocardiogram were submitted

following PTO 2640, the ultimate aim of PTO 2640 had been fulfilled: a Trust auditor had reviewed the appellants' claims and determined that those claims were meritorious and deserving of payment under the terms of the Settlement Agreement.

The District Court heard testimony and argument directly related to the issue of whether or not John Rodriguez and Barbara Meszaros' echocardiograms were performed under the Settlement Agreement guidelines in the September 2002 hearings.⁸ Not only their certifying physicians, but also the Trust's auditing cardiologists agreed that both claimants had moderate mitral regurgitation, and the District Court held (and has since repeated) that claims deemed medically reasonable by the Trust auditors should be expeditiously paid.

Once the District Court made that determination, only the extraordinary circumstances described in case law relating to the Law of the Case Doctrine should have permitted even another court to disturb that finding. But that is not what happened here; it was not *another court* that essentially set aside the District Court's direction that cases deemed meritorious, such as Rodriguez and Meszaros, should be paid upon completion of audit. It is not another *court's* subsequent decision that was at issue before the District Court on the Meszaros and Rodriguez

⁸ Both of the appellants' attesting physicians testified as to their methods and office procedures in obtaining echocardiograms and interpreting those test results during the September 2002 hearings.

motion. Rather, the subsequent determination that was at odds with the District Court's holding and thus, with the law of *this* case was reached by the AHP Settlement Trust unilaterally when the Trust determined to ignore the findings of its own auditing physicians and deny the Meszaros and Rodriguez claims.

The law of the case doctrine provides that a court will generally not reconsider questions already decided by another court in the same case. *United Artists Theatre Circuit, Inc. v. Township of Warrington, PA.*, 316 F.3d 392 (3d Cir. 2003). The doctrine is designed to protect traditional ideals such as finality, judicial economy and jurisprudential integrity. *In re City of Philadelphia Litigation*, 158 F.3d 711, 717-718 (3d Cir. 1998); *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 816 (1988). The District Court recognized as much in *Rice v. United States of America, Department of Alcohol, Tobacco and Firearms*, 1996 WL 494138 (ED Pa. 1996) (“the doctrine posits that when a court ‘decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages of the same case.’”).

The law of the case doctrine precludes review of those legal issues that the court previously actually decided, *either expressly or by implication*. *In re City of Philadelphia Litigation*, 158 F.3d at 718. The doctrine applies “as much to the decisions of a coordinate court in the same case as to a court’s own decisions.” *Public Interest Research Group of New Jersey, Inc. v. Magnesium Elektron, Inc.*,

123 F.3d 111, 116 (3d Cir. 1997). The doctrine does not apply to dicta and only allows for reconsideration of previously decided issues

in extraordinary circumstances such as where (1) new evidence is available; (2) a supervening new law has been announced; or (3) the earlier decision was clearly erroneous and would create manifest injustice.

See United Artists, 316 F.3d at 397, note 4.

More troubling, the District Court found the Trust's decision appropriate, the Court continuing to refer, in its PTO 2952, to the claims as being "medically unreasonable" despite the fact that Trust auditors had determined both were meritorious, and that the attesting physicians' diagnosis of moderate mitral regurgitation had been correct. (A. 4-5). There was no basis for the Trust to have denied paying these claims after audit deemed them meritorious; there was certainly no authority for the Trust to submit those claims, after being found meritorious by their own auditors, to repeated scrutiny. The District Court should have set aside the Trust's unilateral decision to deny these claimants, a decision that wholly violated the Settlement Agreement in spirit and letter, as well as the District Court's subsequent Pretrial Orders. Meritorious claims must be paid.

The District Court, sitting in oversight of the Settlement Agreement, is in a fiduciary relationship with the beneficiaries of the Trust and the claimants under the Settlement Agreement. Where, despite its prior order that the audits should not commence absent further medical review, the Trust nonetheless submitted a claim

to audit and received, as in the case of appellants, determinations that the claims are medically reasonable and the claimants thus entitled to Matrix benefits, the District Court should have ordered those claims paid in the interest of justice and also in the interest of protecting the assets of the Trust from unnecessary waste on repeated reviews and pointless administrative activity.

Opposing the motion in the District Court, the Trust's counsel asserted that, while the Trust *may have been negligent* in processing these meritorious claims, that error was insignificant, and was somehow cured by one auditor's subsequent recantation of his opinions upon his *prior error* being discovered. As appellants noted on Reply to the District Court, the Trust's position, and the District Court's upholding the Trust's decision, demonstrates the underlying problem that appellants have raised in multiple motion arguments; there appears to be no entity, whether court or Trust, looking out for the claimants' rights as beneficiaries of this trust. Both the Meszaros and Rodriguez claims, as the underlying motion demonstrated, had long and tortuous histories. Both claims followed a path through the claims process that is, sadly, wholly representative of how the Matrix claims have been handled by this Trust to date, and how the District Court has assisted the Trust in denying claimants their due benefits at all costs.

In a class action settlement such as the Settlement at issue in these appeals, the District Court essentially "retains a special responsibility to see to the

administration of justice.” *In Re: Cendant Corp.*, 233 F.3d 188, 194 (3d Cir. 2000). Here, the Settlement Agreement was approved so that all parties could “achieve finality regarding their liability” and to “deny them...this benefit would discourage class action settlements in the future.” *Georgine v. Amchem Products*, 1995 WL 251402 (ED Pa. 1995).

POINT II.

THE APPELLANTS ENTERED A VALID CONTRACT WITH THE TRUST UPON RETURNING THEIR ACCEPTANCES OF THE POST-AUDIT DETERMINATIONS AND THE TRUST’S REFUSAL TO PAY THEIR BENEFITS CONSTITUTES A BREACH OF ITS OBLIGATIONS UNDER THE CONTRACT.

As the District Court also alluded to in its order, moreover, the Determination letters sent to the appellants, and their signed acceptances of same, constituted a valid contract between the claimants and the Trust. There is no more basic principle of contract law than that of offer and acceptance. Each of these claimants received *two* Post Audit Determinations *approving* their benefits. Barbara Meszaros received a Post Audit Determination approving her for Matrix “B” benefits on April 3, 2003. Pursuant to the instructions contained in that letter, and relying upon the Trust’s promise of payment, Mrs. Meszaros was scheduled, at additional cost to be born by her, for a follow-up consultation to meet the requirements of Med CAP 4. A physician then met with her, took a complete

medical history and completed the required forms, which were then forwarded to the Trust. Thereafter, on May 15, 2003 the Trust issued a Revised Post Audit Determination approving her for Matrix “A” benefits. As was noted in the motion papers below, Mr. Rodriguez’s claim has a similar history.

By executing the “Acceptance of Revised Post-Audit Determination and Waiver” both Barbara Meszaros and John Rodriguez were, in fact, signing a general release. In Pennsylvania, the general rule for construction of releases is that the intention of the parties must govern, but this intention must be gathered from the language of the release." *Three Rivers Motors Co. v. Ford Motor Co.*, 522 F.2d 885, 892 (3d Cir. 1975), *citing Evans v. Marks*, 421 Pa. 146, 218 A.2d 802 (1966). "It is black letter law that in order to form an enforceable contract, there must be an offer, acceptance, consideration or mutual meeting of the minds." *Jenkins v. County of Schuylkill*, 441 Pa. Super. 642, 658 A.2d 380, 383 (Pa. Super. Ct.1995). “Consideration is defined as a benefit to the party promising, or a loss or detriment to the party to whom the promise is made.' " *Hillcrest Found. v. McFeaters*, 332 Pa. 497, 503, 2 A.2d 775 (Pa.1938).

A release covers only such matters as can fairly be said to have been within the contemplation of the parties when given. *In re Bodnar's Estate*, 472 Pa. 383, 387, 372 A.2d 746, 748 (1977); *Sparler v. Fireman’s Insurance Co. of Newark, N.J.*, 521 A.2d 433, 434-35 (Pa. Super 1987); *In re Jones & Laughlin Steel Corp.*,

328 Pa.Super. 442, 456-57, 477 A.2d 527, 534 (Pa. Super 1984). The effect of a release must be determined from the ordinary meaning of its language. *Washner v. American Motor Sales Corp.*, 597 F. Supp. 991, 997 (E.D.Pa.1984); *Wolbach v. Fay*, 488 Pa. 239, 412 A.2d 487 (1980); *In re Jones & Laughlin Steel Corp.*, 328 Pa.Super. at 456, 477 A.2d at 534.

Once accepted a release is binding on the parties thereto, unless executed under fraud, duress or mutual mistake. *Iman v. Hausman*, 354 Pa.Super. 458, 512 A.2d 41 (Pa. Super 1986); *Price v. Ross*, 339 Pa.Super. 461, 489 A.2d 252 (Pa. Super 1985). A release not procured by fraud, duress, or mutual mistake is binding between the parties. *Lanci v. Metropolitan Insurance Company*, 388 Pa.Super. 1, 4-6, 564 A.2d 972, 974 (Pa. Super 1989).

Here, there was no fraud nor any other wrongdoing involved in obtaining the offers of settlement. The Trust, exercising its right to audit these claims, determined unequivocally that these claimants had meritorious claims. Similarly, there can be no claim for duress, and the Trust can not claim mutual mistake. The Trust entered into a binding contract to pay Matrix benefits to these claimants; the Trust cannot now be allowed to deny these rightful claimants their benefits.

CONCLUSION

The underlying purposes of the Settlement Agreement have been wholly subverted by the biased and unwarranted treatment of these appellants; where the audit of the claims was the underlying purpose of the Court's Pretrial Order 2640, the favorable completion of those audits and the submission of other claims to the appeals proceedings, even if done prematurely by the Trust, should be affirmed by this Court as an expedient and just result that, in both cases, achieves the ultimate purpose of the District Court's orders.

Dated: Great River, New York
December 15, 2003

Respectfully submitted,

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