

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

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

NAPOLI KAISER BERN & ASSOCIATES, LLP
Attorneys for Class Members
3500 Sunrise Hwy., Suite T207
Great River, New York 11739
(212) 267-3700

HARITON & D'ANGELO, LLP
Attorneys for Class Members
3500 Sunrise Hwy., Suite T207
Great River, New York 11739
(800) 683-0852

APPELLANTS' CONSOLIDATED REPLY BRIEF

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

No. 03-3740 **NAPOLI, KAISER, BERN
& ASSOCIATES, LLP**
Paul J. Napoli
Denise A. Rubin
3500 Sunrise Hwy., Suite T-207
Great River, New York 11737
Telephone: (212) 267-3700
Fax: (212) 587-0031

HARITON & D'ANGELO, LLP
Mario D'Angelo
3500 Sunrise Highway, Suite T207
Great River, New York 11737
Telephone No. (631) 224-1133
Fax No. (631) 224-4774

ATTORNEYS FOR APPELLANTS

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.

Paul J. Napoli
Denise A. Rubin
NAPOLI, KAISER, BERN & ASSOCIATES, LLP
3500 Sunrise Hwy., Suite T-207
Great River, New York 11739
Telephone No. (212) 267-3700
Fax No. (212) 587-0031

Mario D'Angelo
HARITON & D'ANGELO, LLP
3500 Sunrise Highway, Suite T207
Great River, New York 11739
Telephone No. (631) 224-1133

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

Fax No. (631) 224-4774

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
Honorable Dean M. Trafelet, Chicago, Illinois

Counsel for Appellees:

a. Counsel for AHP Settlement Trust:

Andrew A. Chirls
WOLF, BLOCK, SCHORR AND SOLIS-COHEN, LLP
1650 Arch Street, 22nd Floor
Philadelphia, Pennsylvania 19103-2097
Telephone No. (215) 977-2000
Fax No. (215) 977-2334

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PRELIMINARY STATEMENT

Appellants Evelyn Vititoe, Amy Peters, Joseph Rogers, John Rodriguez, Barbara Meszaros and other similarly-situated class members respectfully offer the within Reply Brief in response to the appellees' brief in Opposition to the instant matter.

ARGUMENT

POINT I.

THE TRUST'S AUDITOR'S FINDINGS ON APPELLANTS' MESZAROS AND RODRIGUEZ'S CLAIMS RENDERED THE DISTRICT COURT'S PRIOR DETERMINATION, BASED ON DR. DENT'S TESTIMONY, INSUPPORTABLE. CONTINUED ADHERENCE TO THAT PRIOR DETERMINATION WAS ERROR AND AN ABUSE OF THE DISTRICT COURT'S DISCRETION.

Not surprisingly, appellees continue to rely on the procedural aspects of Pretrial Orders 2640 and 2662, specifically, that claims were not to be paid until they had been audited, and the procedural steps toward accomplishing that audit. In that reliance, the appellees have repeated the District Court's "shall not pay" language from PTO 2640 as a mantra, conveniently forgetting that the Court's prohibition was limited in its scope. *See* Pretrial Order ["PTO"] 2640, In re: Diet Drugs, 236 F. Supp. 2d 445 (E.D. Pa. 2002).

The District Court did not enter a wholesale prohibition against payment of the claims under any circumstance, but rather, against payment of the claims *prior to their being audited* ("The Trust has full authority to withhold payment of those claims...pending the completion of the audit process"). Simply stated, then, the goal of the entire exercise was to get these claims to the AHP Trust Auditing Cardiologists for their review, and to pay the claims only after an AHP Trust auditor agreed that the attesting physicians' findings were medically reasonable.

Contrary to the appellees' argument, ours is not a new or different interpretation of the District Court's order; it is the plain language of that order, and there is no basis upon which to determine that the District Court intended any other purpose or result from that language than that set forth in the quoted passage. The District Court intended that *no claim should be paid before it was audited*.

Concededly, the Meszaros and Rodriguez claims were selected for audit without the prior submission of new echocardiograms and additional attestations ["Green Forms"] to replace those made by Drs. Crouse or Mueller (the two physicians who the District Court deemed not credible in their testimony or in the attestations produced for the class members in this litigation). Nonetheless, upon audit by the Trust's cardiologists, those two claims – in their original format -- were deemed medically reasonable. With regard to this fact, appellees' counsel argues that "the Trust returned the Meszaros and Rodriguez claims to the auditing cardiologists to determine why they reached conclusions that differed from those of the district Court." Appellees' Brf. at 11. The reason is plain: the District Court never actually reviewed medical evidence or expert testimony about the Meszaros and Rodriguez claims. Rather, the District Court issued a blanket prohibition of *payment prior to audit* on a group of 78 claims, based on the testimony it deemed most credible during the September 2002 hearings, *i.e.*, that of Dr. John Dent.

Now the appellees argue that this Court should not consider the question of whether the District Court abused its discretion in making its decisions, outlined in its pretrial order 2640, based largely on its finding that Trust expert witness Dr. John Dent was somehow more credible than the experts who testified on behalf of the class members. Appellees contend that the question of the propriety of that determination lies within this Court's consideration of the matters on appeal from pretrial order 2640¹, and should be considered there, having nothing to do with the matters raised on the instant appeal. They are mistaken.

The question of whether the District Court abused its discretion when it summarily denied the claims of seventy-eight class members, including the five appellants here, is a core issue to both appeals; they cannot be separated without deleting essential information and arguments from each. It is *precisely* for that reason that appellants moved for consolidation of the two appeals, the consolidation having been granted by this Court. Similarly, the propriety of the District Court's actions in both pretrial order 2640 and pretrial order 2952 affects every subsequent order by the District Court and supports each and every abuse the class members have suffered at the hands of the Trust, Class Counsel and the defendants.

¹ Now pending before this Court on 03-4378, and consolidated with the instant appeal.

Unlike the District Court, the auditors' decisions on the Meszaros and Rodriguez claims were not based on a subjective belief that one witness was more credible than another. Rather, the Trust's own auditing cardiologists had both the medical expertise and the opportunity to actually review the echocardiogram films for these claimants before reaching their determination that the claims of Meszaros and Rodriguez were medically reasonable. They based their opinions on the original films, reports, and physicians' attestations, rather than on the testimony of Dr. Dent, as had the District Court. The auditors deemed the two claims medically reasonable – indeed, appellees expressly concede as much in their Opposition Brief on Appeal, at p. 10:

The Trust's cardiologists who audited the Meszaros and Rodriguez claims determined that the issues presented for review were supported by a reasonable medical basis. See J.A. II. 254; J.A. II. 263 (auditors' worksheets).

This outcome certainly raises the question – since the auditor's findings directly controverted Dr. Dent's opinions as stated during his testimony at the September 2002 hearings, is there an ongoing basis to affirm the District Court's adoption of Dr. Dent's opinions in its PTO 2640 with regard to these claimants' submissions? The paradox suggested here is highlighted in the appellees' brief, at 16-17, where the District Court's decision, here appealed, is cited:

Interpreting PTO 2640, its own order, the district court rejected the motions to compel, stating that "paragraph 1 of PTO 2640 explicitly precludes the Trust from paying movants' claims, which continue to be based on

medically unreasonable echocardiograms and Green Forms.”

See Pretrial Order [“PTO”] 2640, In re: Diet Drugs, 236 F. Supp. 2d 445 (E.D. Pa. 2002). The point raised in the language cited, *supra*, is the crux of the issue presented to this Court in its review of the District Court’s PTO 2952. It was an abuse of the District Court’s discretion to write, in PTO 2952, that the Meszaros and Rodriguez submissions “continue to be based on medically unreasonable echocardiograms and Green Forms” ***where the Trust’s own auditors had, upon audit, deemed them both medically reasonable.*** The District Court abused its discretion in wholly accepting Dr. John Dent’s September 2002 testimony as gospel, while simultaneously disregarding the testimony of every other physician who disagrees with Dr. Dent, including the Trust’s Auditing Cardiologists.

Appellants’ argument on this issue relies on wholly circular reasoning: they claim that the District Court’s interpretation, in pretrial order 2952, of its intent as set forth in the prior order (2640) should override any questions raised by ambiguity in the language of pretrial order 2640. That contention undermines the entire purpose of appellate review. Here, the District Court continues to rely in pretrial order 2952 on Dr. Dent’s finding that the seventy-eight claims addressed by pretrial order 2640 were “medically unreasonable.” The District Court adopted that finding despite the uncontested showing that the attesting physicians followed the standards set in the Settlement Agreement for obtaining the echocardiograms in each of those claims. Here, at least two of those claims have been reviewed by the

Trust's own Auditors, and both were found "medically reasonable." Those findings should overcome the District Court's adoption of Dr. Dent's testimony.

Similarly, the appellees argue that new attestations supporting the Meszaros and Rodriguez claims (submitted by Dr. Bruce Charash) are insufficient to overcome the District Court's directive that new echocardiograms and Green Forms be submitted for each of the seventy-eight claims summarily deemed medically unreasonable. The revised "Court-Approved Notice" disseminated to the class members includes an updated section on the processing of Matrix Claims, stating in relevant part:

Each Auditing Cardiologist has been retained by the Trust to review complete Matrix claims to determine if there was a reasonable medical basis for the representations made by the physician who completed Part II of the GREEN Form. The Auditing Cardiologist will review the Echocardiogram tape or disk to determine if the Echocardiogram study was conducted in accordance with the standards specified in the Settlement Agreement, and where possible, will confirm the presence or absence of certain medical conditions relevant to the Matrix claim. The Auditing Cardiologist will also review the medical records filed in support of the claim. If the Auditing Cardiologist finds a reasonable medical basis for the claim, the Trust will process the claim further in accordance with the requirements of the Settlement Agreement. ...

Official Court-Approved Notice of May 3, 2003 Deadline, at §C.4, "Processing of Matrix Claims" p. 12. There is no notice to the class members that new echocardiograms will be required, or that their claims, if deemed legitimate by the Trust Auditors, will be submitted to repeated courses of review. Nor, moreover, is

there a requirement that the auditing cardiologist find the same disease diagnosed by the attesting cardiologist. The language of the notice states only that the Auditing Cardiologist will “review the Echocardiogram tape or disk *to determine if the Echocardiogram study was conducted in accordance with the standards specified in the Settlement Agreement,*” and *where possible,* will confirm the presence or absence of certain medical conditions relevant to the Matrix claim.”

Notably, each and every one of the echocardiograms submitted with the seventy-eight claims summarily denied by the District Court were “conducted in accordance with the standards specified in the Settlement Agreement.” The Trust argued only that the levels of valvular regurgitation measured were different than those estimated by Dr. Dent upon his “eyeball” review of these films. The District Court’s subsequent support of the Trust’s contention that an Auditor must find the same levels of disease as that diagnosed by the attesting physicians is an abuse of the Court’s discretion, adding new requirements to the Settlement Agreement without providing notice or an opportunity for class members to opt out before being bound by those findings.

Where, as here, the Auditors found that the claims of appellants Meszaros and Rodriguez were medically reasonable, the fact that the Trust accidentally accelerated several cases through that audit process should not render the Auditor’s ultimate findings meaningless. Nor, moreover, should the Auditors’ opinions be dismissed summarily on the basis that they were reviewing Dr. Crouse or Dr.

Mueller's attestations. If the Auditors read those films, and the attesting statements related to those films, *and upon those readings*, agreed that the measurements were correct and the diagnoses medically reasonable, it is reasonable to accept those opinions without new films and reports.

More to the point, upon receiving notification that the Trust intended to pay their claims, both Mr. Rodriguez and Ms. Meszaros complied with the additional submissions required by Medical Court Approved Procedure No. 4 ["MED CAP 4"], thus submitting additional attestations by Dr. Bruce Charash to support their claims in place of Dr. Crouse and Dr. Mueller's prior-submitted attestations.

Hence, even to the point that it could be argued that the additional attestations were needed before the claims could be sent to audit or before the Trust could issue payment on the auditors' findings, these class members have complied with that aspect of the District Court's amendments to the Settlement Agreement.

The lengths to which the Trust went to deny payment to these legitimate beneficiaries is alarming. The claims having been audited and deemed legitimate, there is no authority in the Settlement Agreement or the Orders of the District Court to submit the claims to repeated audit until the Trust obtains the answer it wants. This represents a breach of fiduciary duty and was not permissible under the Settlement.

These events and the disparate opinions that resulted demonstrate, in graphic fashion, the subjective nature of this diagnostic modality and why a reasonable

medical basis standard that recognizes the probability of disparate opinions must be followed. To do otherwise would eviscerate one of the fundamental concepts of this Settlement, *i.e.*, that deference would be given to the diagnosing physician's opinion.

John Rodriguez and Barbara Meszaros' claims comply with every aspect of the District Court's requirements for payment of a claim; they have submitted alternative supporting physician's attestations, they have passed the Trust's audit with the Trust auditor – prior to further consultation with the Trust – finding the claims medically reasonable, and they have been advised of the Trust's intention to pay their claims, and thereupon, have responded that they accept the proposed payment. Aside from the technical aspects of their divergence from *the path and order of the steps* contemplated by Pretrial orders 2640 and 2662, *i.e.*, submission of new attestations, audit, finding of medical reasonability, and offer of payment, these class members claims have wholly complied with each hurdle set for them by the District Court and the appellees. Moreover, the auditors' findings that both claims were medically reasonable should be sufficient basis upon which this Court can set aside the District Court's finding that the claims were medically unreasonable. Their claims should be paid without further delay.

POINT II.

**WHILE THE VITITOE, ROGERS AND PETERS
CLAIMS WERE DENIED ON AUDIT, THEY
SHOULD ALSO HAVE BEEN PERMITTED TO
PROCEED THROUGH THE STEPS CREATED BY
THE DISTRICT COURT'S ORDERS.**

Like the Rodriguez and Meszaros claims, the AHP Settlement Trust forwarded the Vititoe, Rogers and Peters claims to audit despite the fact that the class members had not submitted additional attestations as required in PTO 2640. As the appellees have noted in their Brief, all three claims were chosen for audit prior to the November 14, 2002 entry of Pretrial Order 2640, hence there was nothing inappropriate in the Trust's having directed the claims to the audit process in October of that year. *See* Appellees' Brf. at p. 9, note 11. When the audit was complete, and resulted in denial of the three claims, the Trust submitted them to the show cause proceeding, but withdrew the application after realizing that the three claimants had not submitted new attestations and Green Forms.

Although the outcome of the audits was negative, the point on this appeal is the same for these claimants as for Ms. Meszaros and Mr. Rodriguez, *i.e.*, their claims, rightly or wrongly, have been audited and have progressed through the contest procedure. The Trust had already filed its application for the next step in the process, the "Show Cause" proceeding, when it unilaterally and summarily withdrew that application. Sending these three claimants back to the beginning of the process at this late date and despite the fact that all of the steps leading up to

the Show Cause proceeding have been completed on their behalf, serves no utility. Indeed, doing so deprives the three claimants of their due process rights because, given the bottleneck in the Trust's claims processing, new submissions to the Trust, as the District Court seemed to intend for these three claimants, would virtually guarantee that their claims would disappear into the ether of backlog. Forcing that outcome, and the resultant waste of the Trust's funds and the claimants' time and expenses, demonstrates another abuse of the District Court's discretion.

CONCLUSION

For all of the foregoing reasons, and because the Settlement Agreement has been wholly emasculated and the class members denied their rights to due process by the Trust's impermissible manipulation of their experts to obtain opinions they deem acceptable, this Court should reverse the District Court's Pretrial Order 2952, direct that the Trust pay the claims of John Rodriguez and Barbara Mezaros without delay, and that the Trust should submit the claims of Appellants Vititoe, Peters and Rogers to the "show cause" proceedings.

Dated: Great River, New York
February 23, 2004

Respectfully submitted,

Napoli Kaiser Bern & Associates, LLP
Attorneys for Appellants

By: 
Denise A. Rubin (DR-5591)


On the brief:
Paul J. Napoli
Napoli Kaiser Bern & Associates, LLP
Attorneys for Appellants

Mario D'Angelo
Hariton & D'Angelo, LLP
Attorneys for Appellants

CERTIFICATE OF COMPLIANCE

1. The undersigned certifies that this brief complies with the type-volume limitations of FED. R. APP. P. 32(a)(7)(B) because the brief contains less than 14,000 words, exclusive of the exempted portions in FED. R. APP. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface and typestyle requirements FED. R. APP. P. 32(a)(5) and 32(a)(6) because the brief has been prepared in proportionally spaced typeface using Microsoft Word 2000 in Times New Roman 14-point type for text and footnotes.


Denise A. Rubin (DR-5591)
Attorney for Appellants

CERTIFICATE OF ADMISSION

Pursuant to Third Circuit LAR 28(3)(d), the undersigned certifies that at least one of the attorneys whose names appear on the brief is a member of the bar of this Court.

A handwritten signature in black ink, appearing to read "Denise A. Rubin", written over a horizontal line.

Denise A. Rubin (DR-5591)

Attorney for Appellants

CERTIFICATE OF SERVICE

I, Denise A. Rubin, hereby certify that on the 23rd of February, 2004, I caused two true and correct copies of the Appellants' Reply Brief to be served on the following counsel by email and via first class mail.

Gregory P. Miller, Esq.
Miller Alfano & Raspanti Pc
1818 Market Street, Suite 3402
Philadelphia, PA 19103

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

Robert D. Rosenbaum Esq.
Arnold & Porter
555 Twelfth Street, NW
Washington, DC 20004-1206

Michael T. Scott Esq.
REED SMITH, LLP
1650 Market Street, Suite 2500
Philadelphia, PA 19103

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


Denise A. Rubin (DR-5591)