NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 14-1298

IN RE: DIET DRUGS (PHENTERMIN/FENFLURAMINE/DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

Estate of Thomas L. Harold, Deceased;
Ester A. Harold,
Appellants

On Appeal from the District Court
for the Eastern District of Pennsylvania
(D.C. Civil Action Nos. 2-99-cv-20593, 2-11-md-01203, 2-16-md-01203)
District Judge: Honorable Harvey Bartle, III

Submitted Pursuant to Third Circuit LAR 34.1(a)
November 19, 2014

Before: AMBRO, SCIRICA, and ROTH, Circuit Judges

(Filed: January 29, 2015)

OPINION[*]

SCIRICA, *Circuit Judge*

[*] This disposition is not an opinion of the full Court and pursuant to I.O.P. 5.7 does not constitute binding precedent.

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The Estate of Thomas L. Harold, a claimant under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth, and his spouse, Esther A. Harold (together, "Appellants"), appeal an order in which the District Court affirmed a decision of the AHP Settlement Trust (the "Trust") denying them benefits under the Settlement Agreement.[1] We will affirm.

I.

This case, like others that we have reviewed, is part of a multidistrict litigation concerning diet drugs previously sold by Wyeth—fenfluramine (marketed as "Pondimin"), and dexfenfluramine (marketed as "Redux"). After studies suggested that the diet drugs may have been linked to valvular heart disease, Wyeth and the representatives for plaintiffs entered into the Settlement Agreement in November 1999. The Settlement Agreement determines a claimant's recovery using damage "matrices" that assess factors such as the severity of the claimant's medical condition, age, and length of illness. Matrix Level II, relevant in this appeal, describes individuals with "moderate to severe" mitral regurgitation.[2]

In order to make a Matrix claim under the Settlement Agreement, a claimant is

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[1] The District Court's order finally resolved the particular claim at issue. Accordingly, we treat the challenged order as final and exercise appellate jurisdiction under 28 U.S.C. § 1291. We review a District Court's exercise of its equitable authority to administer and implement a class action settlement for abuse of discretion. *See In re Diet Drugs*, 543 F.3d 179, 184 n.10 (3d Cir. 2008).

[2] "Mitral regurgitation involves the backward or reverse flow of blood through a defective mitral valve which separates the left atrium of the heart from the left ventricle." *In re Diet Drugs*, 543 F.3d at 181 n.2 (alterations omitted).

required to submit a three-part "Green Form" to the Trust. Part II of the Green Form requires, among other things, a physician's certification, based on a reading of an echocardiogram videotape, of the claimant's level of valvular heart disease. At a certain point early in the administration of the settlement, a concern emerged that some claims being paid out by the Trust were illegitimate, and that the Trust's funds would be depleted before paying all claimants. The District Court therefore issued PTO 2662, which required the Trust to audit every Matrix claim, and developed a set of rules (the "Audit Rules") to govern the audit proceedings. *See In re Diet Drugs*, 226 F.R.D. 498, 506-09 (E.D. Pa. 2005). Under those Rules, an "auditing cardiologist" would review the claim to determine "whether there was a reasonable medical basis for each answer in Part II of the GREEN Form that differs from the Auditing Cardiologist's finding on that specific issue" and "whether there were any intentional material misrepresentations made in connection with the Claim." Once the Trust made its determination as to whether the claimant was eligible for Matrix benefits, it would issue a "Post-Audit Determination" informing the claimant of audit results. The claimant would then have the right to contest this "Post-Audit Determination," thereby requiring the Trust to review the contest materials and issue a "Final Post-Audit Determination." Finally, if the claimant disputed the Final Post-Audit Determination, he or she could proceed through a show cause process with the District Court.

Mr. Harold first submitted his claim to the Trust on June 17, 2002, seeking compensation under Matrix Level II. Included with his claim was an attestation from a cardiologist, Dr. Roger Evans, that Mr. Harold's echocardiogram showed severe mitral

valve regurgitation. The Trust audited Mr. Harold's claim and, on November 10, 2003, denied the claim based on the findings of an auditing cardiologist, Dr. Maged Rizk, that "there was no reasonable medical basis for" Dr. Evans's opinion that Mr. Harold had severe mitral valve regurgitation. Mr. Harold then contested the Trust's determination, and the Trust reversed its finding. It indicated in its Post-Audit Determination that Dr. Rizk had reversed his opinion as to whether there was a "reasonable medical basis for the representation that [Mr. Harold] has moderate mitral regurgitation."

After the issuance of that Post-Audit Determination, but before Mr. Harold's claim was paid, the District Court stayed further processing of Mr. Harold's claim (as well as those of other claimants) because Wyeth and Class Counsel were in the process of negotiating amendments to the Settlement Agreement that aimed to streamline the benefit-eligibility criteria. *See In re Diet Drugs*, 226 F.R.D. 498, 506-10 (E.D. Pa. 2005). Prior to entry of the stay, the Trust had determined that approximately 968 claims, including Mr. Harold's, had passed audit and were payable (the "Pre-Stay Payable Claims"), but also advised the District Court that it believed some of those claims to be fraudulent.

To address this potential fraud among the Pre-Stay Payable Claims, on August 26, 2004, the District Court issued PTO 3883. That order directed the Trust to divide the 968 Pre-Stay Payable into three categories, including, as is relevant here, the paragraph "5(a) claims." That category was designated for claims that the Trust alleged contained intentional material misrepresentations of fact. For the 5(a) claims, the Trust was required to "process and determine whether there was an intentional manipulation of the

echocardiogram tape or disk submitted in connection with the claim that was not detected by the Trust before Audit or by the Auditing Cardiologist in the Audit of the claim and that amounts to a material misrepresentation of fact in connection with such a claim." The order went on to state that "[f]or this purpose, claim 'processing' is limited to . . . investigations into whether there was such a material misrepresentation of fact in connection with the claim," and "does not include the re-Audit of a claim." (*Id.*). The Trust designated Mr. Harold's claim as a paragraph 5(a) claim.

On August 24, 2004, the Court ordered the Trust to review the paragraph 5(a) claims and issue new Post-Audit Determinations. Under the Audit Rules, if a claimant contested the new Post-Audit Determinations, the Trust would then issue a Final Post-Audit Determination. If the claimant challenged the Final Post-Audit Determination, the claim would proceed through the show cause process before the District Court.

The Trust issued a new Post-Audit Determination for Mr. Harold's claim on March 26, 2007. The Trust denied Mr. Harold's claim, finding that there was "substantial evidence of intentional material misrepresentation of fact" in connection with the claim. Mr. Harold contested the Trust's determination and, after reviewing the contest materials, the Trust affirmed its decision that Mr. Harold was not entitled to Matrix benefits. In this Final Post-Audit Determination, dated August 13, 2007, the Trust found that Mr. Harold's contest "fail[ed] to Demonstrate a Reasonable Medical Basis" for Dr. Evans's attestations that Mr. Harold's echocardiograms demonstrated severe mitral regurgitation. (*Id.*).

At that point, Mr. Harold disputed the Trust's final determination, and requested that the claim proceed through the show cause process. Pursuant to that process, the Trust applied to the Court for an order to show cause why Mr. Harold's claim should be paid, and on September 26, 2007, the Court issued said Order and referred the matter to a Special Master for further proceedings. After development of the show cause record, the Special Master appointed a Technical Advisor, Dr. Gary Vigilante, to review the show cause record and prepare a report for the Court, which he did on March 21, 2011. Finally, the show cause record, including the Technical Advisor's Report and Mr. Harold's response to that report, was referred to the District Court for review and determination pursuant to Audit Rule 35.

The District Court framed the issue for resolution as "whether the Estate has met its burden of proving that there is a reasonable medical basis for its claim." The Court noted that "[w]here the Trust's post-audit determination finds intentional material misrepresentations of fact, the representative claimant has the burden of proving that all representations of material fact in connection with its claim are true." Ultimately, the Court went on, "if we determine that there is no reasonable medical basis for the answer in the Green Form either because of an intentional material misrepresentation of fact or some other valid reason, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate." Applying those standards, the District Court denied the claim, finding that "the Estate has not established a reasonable medical basis for finding that Mr. Harold had at least moderate regurgitation." The Court expressly

declined to address whether any intentional material misrepresentation of fact had been made in connection with the claim.

II.

Harold argues that the District Court erred by affirming the Trust's denial of his claim on the basis that there was no reasonable medical basis for finding that he suffered from moderate mitral regurgitation. He argues that, under the Settlement Agreement, the only question properly before the Court was whether an intentional material misrepresentation of fact had been made in connection with his claim, a question that the District Court expressly declined to answer.

This argument is contradicted by the plain text of the Settlement Agreement, to which basic principles of contract construction apply. *See In re Cendant Corp. Prides Litig.*, 233 F.3d 188, 193 (3d Cir. 2000). Under such principles, "we ascertain and give effect to the intention of the parties as expressed in the agreement." *Gleason v. Norwest Mortg., Inc.*, 243 F.3d 130, 140 (3d Cir. 2001).

The Settlement Agreement clearly authorizes the District Court to determine, in the show cause process, whether there was "reasonable medical basis to support a material representation made by a physician in support of a Claim." If the Court determines that there was no reasonable medical basis, it may "grant such relief as may be appropriate, including . . . an order disallowing the Claim." The Audit Rules—which the parties agree apply to the show cause process—are consistent with this conclusion. Audit Rule 24 provides that "[w]here the Trust's Final Post-Audit Determination was based, in whole or in part, on the ground that no reasonable medical basis exists for a

GREEN Form Question at issue, the Claimant shall have the burden of proving that there was a reasonable medical basis for the answer(s) of the Attesting Physician." There is no question that the Trust's Final Post-Audit Determination was based, at least in part, on such a conclusion; an entire section of the letter is titled "Your Contest Fails to Demonstrate a Reasonable Medical Basis for Dr. Evans' GREEN Form Representations." For that same reason, the Court complied with Audit Rule 18(c), which limits the Show Cause process to "those issues and evidence presented by the Claimant in any submitted Contest materials and by the Trust in its Final Post-Audit Determination."

In arguing to the contrary, Harold suggests that the "no reasonable medical basis" finding should never have been before the District Court in the first place. In particular, Harold contends that by considering in the Final Post-Audit Determination whether there was a reasonable medical basis for his claim when that issue had not been raised in the initial Post-Audit Determination, the Trust violated PTO 3883, which expressly prohibited the Trust from engaging in a "re-Audit" of any 5(a) claim. But whether the Final Post-Audit Determination was indeed an impermissible "re-Audit" appears to be a factual question, and Harold has not made any suggestion that the District Court made any erroneous findings in this regard, nor has he even pointed to whether it was litigated at all. In fact, PTO 3883 expressly provides that, for paragraph 5(a) claims, the Trust was to take steps that "lead to a determination of the amount to be paid in connection with such claims," which would include issuing new Post-Audit Determinations and Final Post-Audit Determinations. *See also* PTO 5625 Memorandum, at 7 (directing the Trust to review the claim file of any claimant who disagreed with the denial of a paragraph 5(a)

claim, issue a new Post-Audit Determination, and issue a Final Post-Audit Determination for any claimant who contested the new Post-Audit Determination). In reaching a Final Post-Audit Determination, the Audit Rules required the Trust to include an "explanation of [its] assessment of the Claim." Because Harold has made no argument as to why the Trust's finding should not be considered such an explanation, we cannot conclude that the "no reasonable medical basis" was improperly before the District Court.

III.

For the foregoing reasons, we will affirm the District Court's order affirming the AHP Settlement Trust's denial of benefits.