4-21-2015

In re: Diet Drugs

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 14-3484

In re: Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Products Liability Litigation

Robert E. Staggs and Joan E. Staggs, Appellants

Appeal from the United States 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 Under Third Circuit LAR 34.1(a)
April 13, 2015

Before: AMBRO, VANASKIE, and SHWARTZ, Circuit Judges

(Opinion filed: April 21, 2015)

OPINION*

AMBRO, Circuit Judge

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

Robert and Joan Staggs appeal the District Court's order denying their challenge to the decision of the AHP Settlement Trust not to compensate Robert Staggs for the alleged injury due to his use of the diet drugs Pondimin and Redux. We affirm.

I. Background

Pondimin and Redux caused widespread injuries to tens of thousands of people. Their claims are subject to a settlement agreement pursuant to which AHP Settlement Trust pays money to those plaintiffs deemed to have suffered compensable injuries.

Staggs used Pondimin and Redux and submitted to AHP Settlement Trust a claim for what are known as "Matrix Benefits" after he was diagnosed with mild aortic regurgitation, a heart condition in which blood flows backward through the aorta and into the left ventricle rather than out of the left ventricle. His claim included a diagnosis by Dr. Robert Rosenthal based on a reading of Staggs's echocardiogram ("EKG"). AHP Settlement Trust referred the claim to Dr. Bryan Lucenta, who agreed that there was "mild aortic insufficiency." J.A. 3338.

According to the Settlement Agreement, a claimant suffered a compensable injury if an EKG demonstrates mild or greater aortic regurgitation. To measure this, a person must view an EKG and record the regurgitant jet height. If this value is 10% or more of the left ventricular outflow tract height, the subject of the EKG has at least mild aortic regurgitation. Crucially here, according to the Settlement Agreement, the person examining the EKG must use the "parasternal long-axis view" to measure regurgitant jet height unless that view is unavailable or inadequate, in which case one may use the

"apical long-axis view." Settlement Agreement § I.22. This is so because the parasternal long-axis view is less likely to over-represent regurgitant jet height.

Following Dr. Lucenta's review, Staggs's claim was audited. The purpose was to determine whether Staggs's claim had a "reasonable medical basis." Settlement Agreement § VI.E.6. Dr. Robert Gillespie, the auditing cardiologist, reviewed Staggs's claim and determined that his EKG showed only trace aortic regurgitation. He further concluded that there was no reasonable medical basis for Dr. Rosenthal's diagnosis. AHP Settlement Trust thus denied Staggs's claim via a "post-audit determination letter." As the Audit Rules allow, Staggs contested the denial and submitted declarations by Dr. Leon Franzin and Dr. Gerald Koppes.

They opined that the parasternal long-axis view was unavailable, and thus they relied on the apical long-axis view to determine that Staggs indeed suffered from mild aortic regurgitation. In response, Dr. Gillespie submitted a declaration explaining that the parasternal long-axis view was in fact available and that the EKG showed only trace aortic regurgitation. Thus, the Trust issued a final post-audit determination letter again denying Staggs's claim. Staggs objected, and the claim went through the settlement's "Show Cause" process, pursuant to which the parties could dispute the claim before the District Court.

It referred the Show Cause proceedings to a Special Master, who appointed the Technical Advisor, Dr. Sandra Abramson, to review the record of Staggs's claim, which included his EKG and the opinions of Drs. Rosenthal, Lucenta, Gillespie, Franzin and

Koppes. The Technical Advisor agreed with Dr. Gillespie that there was no reasonable medical basis for Staggs's claim and issued a report to that effect.

Staggs disagreed with the Technical Advisor and submitted a response to her report. He also tried to submit supplemental reports by Drs. Franzin and Koppes. However, the Special Master concluded that, pursuant to Audit Rule 34, these "rebuttals" could not be considered as part of the Show Cause record. J.A. 14–15 n.12. The District Court agreed, considered the whole Show Cause record (without the rebuttal reports of Drs. Franzin and Koppes), and ultimately concluded that the Technical Advisor and Dr. Gillespie were correct that there was no reasonable medical basis for Staggs's claim.

II. Discussion

Staggs raises three issues on appeal. He contends that the District Court (1) wrongly applied the "reasonable medical basis" standard by failing to defer to his physician's diagnosis; (2) erred in deciding that there was no reasonable medical basis for his claim; and (3) violated the Audit Rules and deprived him of due process of law by excluding the rebuttal reports of Drs. Franzin and Koppes.

A. Reasonable Medical Basis

Staggs argues that the auditing cardiologist's review of whether a diagnosis has a "reasonable medical basis" must defer to the claimant's attesting physician. From this premise, he concludes that the attesting physician's conclusion must be accepted if it is "not absurd, not ridiculous, not extreme, and not excessive." Appellant Br. at 23.

It is true that reasonable medical basis review commands a degree of deference: if an attesting physician declares a claimant qualifies for matrix benefits and an auditing

cardiologist or the District Court disagrees but nonetheless perceives a reasonable medical basis for the claim, the claim must be approved. But, even though those reviewing the diagnosis may only examine whether it has a reasonable medical basis and not impose their independent judgment of a claimant's medical condition without regard to the attesting physician's decision, it does not follow that the review is so deferential as to require approval of any claim unless it is patently absurd.

Rather than the standard Staggs urges, we adhere to the definition in our precedent and the Audit Training Module: a "reasonable medical basis" is a foundation for a diagnosis by an unbiased physician using "normal clinical judgment and accepted medical standards." J.A. 1489–90. A reasonable medical basis also exists when a diagnosis results from faithful application of the District Court's orders on "the requirements for reading an echocardiogram, *see* PTO 2640" and "the Auditing Cardiologist Training Course, *see* PTO 2825." *In re Diet Drugs (Phentermine/ Fenfluramine/Dexfenfluramine) Prods. Liab. Litig.*, 543 F.3d 179, 189 n.16 (3d Cir. 2008).

B. There Was No Reasonable Medical Basis

As stated above, Dr. Rosenthal attested that Staggs suffered from mild aortic regurgitation; Dr. Gillespie disagreed. This is a purely factual dispute, and we review the District Court's findings for clear error. The Court referred the parties' disagreement to a Special Master, who in turn appointed a Technical Advisor "to educate [the Special Master] in the jargon and theory disclosed by the [evidence] and to think through the critical technical problems." *Reilly v. United States*, 863 F.2d 149, 158 (1st Cir. 1988).

The core of the parties' dispute is whether the parasternal long-axis view of Staggs's echocardiogram was available and adequate to evaluate his aortic regurgitation. The Technical Advisor, the Special Master, and the District Court all agreed with Dr. Gillespie that this preferred view was available and that it showed no reasonable medical basis for Staggs's diagnosis. For his part, Staggs does not contend that the parasternal long-axis view suggests he suffers from aortic regurgitation; rather, he argues this view is unavailable and that the experts should have relied on the apical long-axis view, which, according to his experts, shows mild aortic regurgitation.

The Technical Advisor, duly assisting the Court in sorting out "the critical technical problems," *id.*, in this case—(1) whether the parasternal long-axis view was available and (2) whether it revealed aortic regurgitation—reviewed the EKG and concluded that the preferred view was available. J.A. 13. She also persuasively explained why the apical view in this case was likely to overstate aortic regurgitation. *Id.* She further concluded, based on both views, not only that Staggs did not suffer from aortic regurgitation but also that there was no reasonable medical basis for his claim. The Advisor's report explained that the parasternal long-axis view disclosed no regurgitation, and the apical long-axis view revealed exaggerated regurgitation.

Staggs gives us no reason to find clearly erroneous the District Court's factual finding that the parasternal long-axis view was available and adequate to determine whether he had aortic regurgitation. Instead, he reiterates his expert's opinion to the contrary. Staggs does not contest that the parasternal long-axis view is less likely to overestimate aortic regurgitation than the apical long-axis view, and he does not contest

that his experts used the latter, disfavored methodology for examining his EKG. At best, Staggs offers an alternative plausible way of reading the evidence, but "[w]here there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous." *Anderson v. Bessemer City*, 470 U.S. 564, 574 (1985). In the absence of convincing argument to support Staggs's position, we would "overstep[] the bounds of [our] duty" if we second-guessed the District Court's careful factual finding here. *Id.*

C. The District Court's Procedures Comport with the Audit Rules and Due Process

After the Technical Advisor issued her report, Staggs attempted to rebut it by submitting two contradictory expert reports that were not a part of the Show Cause record. While parties who disagree with the Technical Advisor are permitted to respond to the Advisor's reports, and while they may consult with experts in drafting their responses, the Audit Rules forbid them from submitting additional evidence to supplement the Show Cause record. Audit Rule 34, J.A. 1469.

Staggs also argues that the limitation on additional evidence violates the Due Process Clause of the Fifth Amendment. "The fundamental requirement of due process is the opportunity to be heard 'at a meaningful time and in a meaningful manner.'" *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976) (quoting *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965)). Staggs had this opportunity in spades. He submitted a claim for benefits to AHP Settlement Trust; he contested the auditing cardiologist's finding that his claim lacked a reasonable medical basis; he challenged the final post-audit determination

letter before the Special Master; he disputed the Technical Advisor's report; and he appealed the Special Master's decision to the District Court. At every stage of the process, he was represented by counsel. He had ample opportunity to submit evidence and argument to decisionmakers, and he took advantage of the thorough process available to him.

As Staggs "had many opportunities to respond" to the post-audit determination letter, he "did not suffer a denial of [his] due process rights." *Elliott v. Kiesewetter*, 98 F.3d 47, 60 (3d Cir. 1996). The District Court needed to close the evidentiary record at some point; otherwise the endless submissions of and responses to expert reports would "grind judicial . . . gears to a screeching halt." *Id.* Because the District Court afforded Staggs the opportunity to submit expert diagnoses before the Technical Advisor's report and as he had the opportunity to respond to the Technical Advisor's report in consultation with an expert, the District Court's decision, announced in the Audit Rules, to limit the evidentiary record to those documents produced before the Technical Advisor examined them comported with due process.

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For the foregoing reasons, we affirm.