2-10-2015

In Re: Diet Drugs

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

_____

No. 14-3082

_____

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

Patrick J. Venetz and Nancy E. Venetz,
Appellants

_____

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA
(D.C. Nos. 2:99-cv-20593; MDL No. 2-16-md-1203; MDL No. 2-11-md-01203)
District Judge: Hon. Harvey Bartle, III

_____

Submitted Under Third Circuit LAR 34.1(a)
February 10, 2015

_____

Before: CHAGARES, VANASKIE, and SHWARTZ, Circuit Judges.

(Filed: February 10, 2015)

_____

OPINION*

_____

SHWARTZ, Circuit Judge.

Patrick J. Venetz ("Venetz") and Nancy E. Venetz appeal from the District Court's order denying Venetz's claim for benefits under the Diet Drug Nationwide Class Action

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

Settlement Agreement (the "Settlement Agreement"). For the following reasons, we will affirm.

I

Venetz's appeal arises from the multi-district class action litigation regarding the diet drugs Pondimin® (fenfluramine) and Redux® (dexfenfluramine), previously sold by American Home Products ("AHP")[1]. See In re Diet Drugs Prods. Liab. Litig., 543 F.3d 179, 181 (3d Cir. 2008) ("Patterson"). AHP settled the litigation, placed funds in a trust for claim payments, and established the "Settlement Trust" (the "Trust") to review and administer benefit claims by Pondimin® and Redux® users who suffer from "severe heart-valve regurgitation" or other "less severe heart-valve conditions that progress to the more serious levels" during the fifteen-year period following execution of the Settlement Agreement. In re Diet Drugs Prods. Liab. Litig., 385 F.3d 386, 390–92 (3d Cir. 2004).[2]

To obtain benefits under the Settlement Agreement, a claimant must complete and submit to the Trust a multi-part "Green Form." Patterson, 543 F.3d at 182. In Part I of the Green Form, the claimant provides personal background information, including the level of benefits for which he believes he is qualified. Part II of the Green Form is completed by a board-certified cardiologist or cardiothoracic surgeon (an "attesting

[1] AHP changed its name to Wyeth in 2002. See In re Diet Drugs Prods. Liab. Litig., 385 F.3d 386, 388 n.1 (3d Cir. 2004). Pfizer, Inc. acquired Wyeth in 2009.

[2] We have detailed the diet drugs litigation (commonly known as the "Fen-Phen litigation") and the settlement in several opinions. See, e.g., Patterson, 543 F.3d at 180–81; In re Briscoe, 448 F.3d 201, 206–08 (3d Cir. 2006); In re Diet Drugs Prods. Liab. Litig., 401 F.3d 143, 145–48 (3d Cir. 2005); In re Diet Drugs Prods. Liab. Litig., 282 F.3d 220, 225–29 (3d Cir. 2002).

physician") who has reviewed the claimant's echocardiogram and attests to the medical conditions underlying the claimant's benefits request.

Venetz submitted a "Green Form" for Trust benefits. In it, Robert L. Rosenthal, M.D. attested that, based on his review of Venetz's September 29, 2002 echocardiogram, Venetz had "[m]oderate mitral regurgitation." JA 3339. Dr. Rosenthal also attested that Venetz underwent surgery "to repair or replace the aortic and/or mitral valve(s)" due to his use of Pondimin® or Redux®, JA 3313, and had "[v]entricular fibrillation or sustained ventricular tachycardia" resulting in "hemodynamic compromise," JA 3315. In combination, such conditions would entitle a claimant to benefits at severity "Level V" of the Settlement Agreement Matrix A-1.[3]

Waleed N. Irani, M.D., one of the Trust's auditing cardiologists, evaluated Venetz's claim and applied a "reasonable medical basis" standard to determine the validity of the moderate mitral regurgitation diagnosis. See Patterson, 543 F.3d at 183–84. Dr. Irani found that Venetz had only mild mitral regurgitation[4] and, contrary to Dr. Rosenthal, concluded that there "was no reasonable medical basis" to find moderate

[3] A claimant's benefits are determined by a pair of "matrices," Matrix A and Matrix B, which classify claimants based on factors such as the severity of their medical condition, age, length of illness, and the presence of other medical conditions that may impact their valvular heart disease. Patterson, 543 F.3d at 181. In general, the longer the claimant took the drug(s) and the more severe the injury, the greater the monetary compensation. The gross value of Venetz's claim under Level V of Matrix A-1 is approximately $1,289,418.

[4] The District Court has previously noted that measuring the severity of regurgitation is critical because "not all levels of mitral regurgitation are medically significant." In re Diet Drugs Prods. Liab. Litig., 236 F. Supp. 2d 445, 450 (E.D. Pa. 2002) ("PTO 2640") (stating that mild and trace mitral regurgitation exists in approximately ninety percent of the population but moderate levels of mitral regurgitation can "become[] a serious medical condition").

mitral regurgitation entitling Venetz to Matrix A-1, Level V benefits. JA 3399. As a result, the Trust denied Venetz's request for such benefits.

Venetz contested the Trust's determination and provided declarations by Drs. Rosenthal and Paul W. Dlabal attesting that Venetz suffered from "at least" moderate mitral regurgitation. JA 3407, 3413. The Trust forwarded Venetz's submission to Dr. Irani. In response, Dr. Irani submitted a declaration again concluding that there was no reasonable medical basis for the Green Form's attestation that Venetz's echocardiogram showed moderate mitral regurgitation.[5] Based on this declaration, the Trust denied Venetz's benefits claim.

---

[5] Specifically, Dr. Irani's declaration explained:

> Only mild mitral regurgitation is present in real time. The Nyquist setting at those points identified by Drs. Rosenthal and Dlabal is very low, at 41cm/sec, resulting in an increased color signal and falsely inflated jet size to a[] [regurgitant jet area/left atrial area] ratio of 20% . . . . However, these still frames do not reflect the actual degree of mitral regurgitation and do not reasonably support a finding of moderate mitral regurgitation. These sill [sic] frames reflect inflated jet size due to very low Nyquist setting resulting in increased color signal. The still frames identified by Drs. Rosenthal and Dlabal are not representative of mitral regurgitation seen in real time. Mitral regurgitation is mild in real time.

JA 3460 (emphasis in original). The "Nyquist" limit setting is "particularly important to the image displayed on the echocardiogram machine." PTO 2640, 236 F. Supp. 2d at 452. It represents "the highest velocity of blood flow that an echocardiogram machine can accurately measure." Id. "For example, if the Nyquist limit is set [to] 70 cm/second, the machine can only accurately calculate and display the velocity of blood that is moving slower than 70 cm/second." Id. As the District Court has explained:

> Although medical literature does not propose an optimal Nyquist limit for echocardiograms, the generally accepted practice is the higher the better. Accordingly, a Nyquist limit in the 30's or 40's may not be as ideal for

Venetz disputed this determination and requested that his claim proceed through the "Show Cause process" set forth in the Settlement Agreement and the Audit Rules. Accordingly, the Trust applied for and the District Court issued an order (PTO 8986) requiring Venetz to show cause why his claim for benefits should be paid at the level stated in his Green Form. The District Court referred the claim to the Special Master for further proceedings.

In accordance with the Audit Rules, the Special Master appointed a "Technical Advisor," Gary J. Vigilante, M.D., to review Venetz's claim and the parties' submissions. Vigilante issued a "Technical Advisor Report" finding no reasonable medical basis for Dr. Rosenthal's Green Form attestation that Venetz had moderate mitral regurgitation because "the echocardiogram of September 29, 2002 was of poor quality and an accurate [regurgitant jet area] could not be determined." JA 3604. Although the Report noted evidence of mitral regurgitation, it "most likely was mild," with the echocardiogram's poor quality rendering it "impossible to quantify [its] severity." JA 3599.

The District Court affirmed the Trust's denial of Venetz's claim, crediting the opinions of Drs. Irani and Vigilante that Venetz "failed to establish a reasonable medical basis for finding that he was not diagnosed 'as having Mild Mitral Regurgitation.'" JA 19 (citing Settlement Agreement § IV.B.2.d.(2)(a), 893–94.). Venetz appeals.

> identifying and measuring a mitral regurgitant jet as would a limit in the 60's or 70's.

Id.

II[6]

Venetz raises two issues on appeal. First, he asserts that "there is no rule of law" for determining, nor does the Settlement Agreement define, what constitutes a "reasonable medical basis" under the Settlement Agreement. Appellant Br. 16–17. As a result, he argues that deference should be given to his physician, and that the claimant should be required to show only that his physician's opinions are not "absurd, ridiculous, extreme, or irrational." Reply Br. 26. He further asserts that "the Trust [should be required to] put forth evidence to show that the attesting physician and any physician in support of the claim failed to act as ordinary and prudent physicians." Appellant Br. 24. Second, he argues that the District Court misapplied that standard in affirming the Trust's denial of his benefits claim.

We disagree with both arguments. Although the Settlement Agreement does not define the term "reasonable medical basis," JA 964–66, the standard is articulated in, among other things: (i) the practices identified by the District Court in In re Diet Drugs

[6] The District Court had jurisdiction under 28 U.S.C. § 1332. We exercise 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." Patterson, 543 F.3d at 184 n.10. This abuse of discretion standard applies because implementation of a settlement usually involves contract interpretation, which concerns the process by which a court "seeks to ascertain the intent of the parties [that is] embodied in the language that the parties chose to memorialize their agreement." Williams v. Metzler, 132 F.3d 937, 946 (3d Cir. 1997). An abuse of discretion may be found if the District Court's decision "rest[s] on a clearly erroneous finding of fact, an errant conclusion of law or an improper application of law to fact." Patterson, 543 F.3d at 184 n.10 (internal quotation marks omitted); see also In re Cendant Corp. Prides Litig., 233 F.3d 188, 193 (3d Cir. 2000) (noting that unlike contract construction, "contract interpretation is a question of fact" subject to review under "the clearly erroneous standard").

Prods. Liab. Litig., 236 F. Supp. 2d 445 (E.D. Pa. 2002) ("PTO 2640"); (ii) other orders of the District Court, Patterson, 543 F.3d at 186; and (iii) the "Auditing Cardiologist Training Course," see id. at 185–86 & 187 n.16 (rejecting argument that "the District Court has not concretely defined 'reasonable medical basis'"). As such, the standard exists and "[Venetz] and h[is] attorneys had sufficient notice" of it. Id. at 187 n.16.

In PTO 2640, the District Court explained that a diagnosis lacks a "reasonable medical basis" if it is "beyond the bounds of medical reason," PTO 2640, 236 F. Supp. 2d at 458, and provided the following examples:

> (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation.

JA 16 (citing PTO 2640). Thus, a diagnosis predicated upon any of these facts would lack a reasonable medical basis.

The Audit Rules also address who bears the burden of showing the existence of a reasonable medical basis. For instance, under Audit Rule 24, the auditing cardiologist's findings are essentially viewed as correct, unless the claimant can show his attesting physician's opinion has a reasonable medical basis. Thus, "[o]nce the Trust denies a claim and the claim advances to a show cause proceeding, the claimant has the burden of proving there was a reasonable medical basis for the attesting physician's representations." Patterson, 543 F.3d at 189. To carry this burden, the claimant must

present evidence rebutting the auditing cardiologist and/or the Technical Advisor's conclusion that the attesting physician lacked a reasonable medical basis for his opinion. See id. at 190. Therefore, Venetz's assertion that his doctor's views should be deemed presumptively correct and rejected only if they are absurd, ridiculous, extreme, or excessive, is inconsistent with the factors used to determine whether a reasonable medical basis exists and the Audit Rules governing the Settlement Trust, which require him to show why the auditing cardiologist and Technical Advisor are wrong and that his physicians had a reasonable medical basis for their opinion. We will not disturb the agreed-upon and court-approved burdens of proof nor read new definitions into the Settlement Agreement and thus we reject his first argument.

We also reject his second argument, as the District Court did not clearly err in affirming the Trust's denial of Venetz's benefits claim. See In re Orthopedic Bone Screw Prods. Liab. Litig., 246 F.3d 315, 320 (3d Cir. 2001) ("The test is not what this court would have done under the same circumstances; that is not enough. [We] must feel that only one order could have been entered on the facts." (citation and internal quotation marks omitted)). Here, the District Court evaluated the medical opinions presented to it and determined that Venetz failed to rebut the findings of the auditing cardiologist, Dr. Irani, and the Technical Advisor, Dr. Vigilante. For example, the District Court credited the Technical Advisor's finding that Venetz's "level of regurgitation was inflated 'due to inclusion of low velocity nonturbulent flow' and an "'inappropriately' low" Nyquist limit, and as a result, his echocardiogram "'was performed significantly below the appropriate standard of care.'" JA 16–17 (quoting Technical Advisor Report at 7–8, JA

3599–3600). Notably, Dr. Dlabal, one of Venetz's attesting physicians, even conceded that "'[t]he Nyquist Limit on this study is set at a somewhat low level.'" JA 16 n.16 (quoting Declaration of Dr. Dlabal at 2, JA 3413). This deficiency shows that that there is a basis for concluding that Venetz's doctors' opinions lacked a reasonable medical basis. As a result, Venetz has failed to demonstrate that the only conclusion that may be drawn from the record is that his echocardiogram showed moderate mitral regurgitation. Thus, the District Court did not abuse its discretion in holding that Venetz failed to meet his burden of proving that there was a reasonable medical basis for his attesting physician's finding of moderate mitral regurgitation.[7]

III

For these reasons, we will affirm the District Court's Order affirming the Trust's denial of Venetz's claim for benefits.

[7] Venetz's assertion that "a report based on more than a single frame will rebut the auditing cardiologist's assessment of the entire echocardiogram, provided that the report includes some indication of the maximum jet's representativeness," Appellant Br. 31 (emphasis added) (citing Patterson, 543 F.3d at 185), is without basis. The case upon which he relies, Patterson, held that an unrepresentative, single frame will never meet a claimant's burden, as "the Settlement Agreement requires a cardiologist to review the echocardiogram for a regurgitant jet that is representative of the severity of the claimant's medical condition," 543 F.3d at 185. Thus, the District Court also did not err in crediting Dr. Ilani's conclusion that the "still frames" identified by Drs. Rosenthal and Dlabal "do not reflect the actual degree of mitral regurgitation and do not reasonably support a finding of moderate mitral regurgitation." JA 16.