IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ : MDL DOCKET NO. 1203

FENFLURAMINE/DEXFENFLURAMINE)

PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

AMERICAN HOME PRODUCTS

CORPORATION

NO. 99-20593

THIS DOCUMENT RELATES TO:

Claimant: Norma M. Schlager:

Claim No.:

183/00 1947282 :

2:15 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9485

Bartle, J.

March 9 , 2017

Norma M. Schlager ("Ms. Schlager or "claimant"), a Class Member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth, Inc., 1 seeks benefits from the AHP Settlement Trust ("Trust"). Before the court is her appeal from a September 19, 2016 determination by an arbitrator that she did not establish the required conditions necessary for recovery of Matrix Level III Benefits because she did not file a timely claim.

^{1.} Prior to March 11, 2002, Wyeth was American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

Under the Settlement Agreement, Matrix Compensation
Benefits ("Matrix Benefits") are awarded to compensate claimants
for medical conditions caused by Pondimin® or Redux™ ("Diet
Drugs").² A claimant who seeks Matrix Benefits may demonstrate
her eligibility for those Benefits in one of two ways. She may
be eligible if she was diagnosed by a Qualified Physician as FDA
Positive or as having mild mitral regurgitation by an
echocardiogram performed on or before January 3, 2003, provided
that she registered for Settlement Benefits by May 3, 2003.
Alternatively, she may be eligible if she was diagnosed by a
Qualified Physician on or before September 30, 2005 with
Endocardial Fibrosis, provided that she registered for benefits
by January 1, 2006.

^{2.} Matrix Benefits are paid according to two benefit matrices, (Matrix "A" or Matrix "B"), which generally classify claimants for compensation purposes based on the severity of their medical conditions, their ages when diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease. See Settlement Agreement, §§ IV.B.2.b. and IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious valvular heart disease who took the drugs for 61 days or longer and who did not have any of the alternative causes of the diseases that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious valvular heart disease who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult to prove that their heart disease was caused solely by the use of these Diet Drugs.

The Seventh Amendment to the Settlement Agreement provides that a Category One or Category Two Class Member³ can qualify to receive Seventh Amendment Matrix Level III, IV, or V Benefits from the Trust.⁴ See Seventh Amendment § IX.A.1. In order to qualify for these "High-Level Benefits," the Class Member must satisfy the deadlines set forth in § IX.A.1.a of the Seventh Amendment, which states in relevant part:

The Diet Drug Recipient whose condition forms the basis for the claim has or had High Matrix Level Qualifying Factors that were diagnosed and occurred by the earlier of: (i) December 31, 2011; or (ii) 15 years after the date of the Diet Drugs.

Seventh Amendment § IX.A.1. The Class Member is also required to submit a properly completed Green Form and accompanying documentation. Seventh Amendment §§ I.B.64, IX.A.1. In addition, she must:

(ii) qualif[y] for the payment of the benefits on Matrix Levels III, IV or V under the terms of the Settlement Agreement as it existed before the Execution Date; and (iii) qualif[y] as having the High Matrix Level Qualifying Factors on the same Matrix Level for which the Class Member qualifies for benefits under the Settlement Agreement as it existed before the Execution Date.

^{3.} The definitions of Category One and Category Two are set forth in §§ III.A.1 and III.A.2 of the Seventh Amendment to the Settlement Agreement.

^{4.} The Settlement Agreement matrices include five "levels" of possible benefits. In general, the level of benefits for which a Class Member qualifies corresponds to the type and severity of medical conditions she has experienced.

Seventh Amendment §§ IX.A.1.b(ii)-(iii). If a Class Member who was previously entitled only to Level I or Level II benefits "progress[es] to more serious levels of valvular heart disease," she has "the right to 'step up' to higher amounts of compensation" - that is Levels III, IV, or V - "as those levels occur pursuant to the settlement matrices." Pretrial Order ("PTO") No. 1415 (Aug. 28, 2000).

In April 2003, Ms. Schlager submitted to the Trust a Green Form seeking Level II Matrix Benefits. She did not opt out of the Seventh Amendment, and in March 2005 she was informed that she qualified as a Category One Class Member. In 2008, the Seventh Amendment Fund Administrator finished processing Ms. Schlager's claim and concluded that she had not established the necessary medical conditions to qualify for Category One benefits and that she was entitled to a Minimum Payment Amount of \$2,000. In a letter to Ms. Schlager dated March 5, 2008, the Fund Administrator summarized its conclusions as to her claim. The letter stated, among other things:

You will be entitled to claim Matrix Compensation Benefits at Levels III, IV or V as modified by the 7th Amendment, if your condition worsens so as to qualify at those levels before December 31, 2011 or fifteen years after the last use of the diet drugs, whichever date is earlier. The letter stated that "[t]he rights and obligations of Category
One Class Members, including restrictions regarding the
distribution of benefits, are set forth in the 7th Amendment,
which governs."

According to Ms. Schlager, her heart condition worsened following the Fund Administrator's determination. Ms. Schlager's son, Ron Schlager, an attorney who is handling her present appeal, wrote two letters to class counsel in April 2009 advising counsel that Ms. Schlager would likely require heart surgery for "covered complications" and wrote to "affirm . . . that the medical costs of this type would be covered." Ms. Schlager underwent surgery to replace her aortic valve on September 2, 2010.

Two months later, on November 8, 2010, this court approved Court Approved Procedure No. 16 ("CAP 16") in PTO 8559. In pertinent part, CAP 16 modified the deadlines applicable to Class Members seeking Matrix Benefits. It stated, in relevant part:

5. Green Form Filing Deadline. Any Class Member who wishes to seek Matrix Compensation Benefits must submit a completed and executed Green Form Part I and Green Form Part II postmarked or delivered to the Trust no later than four years from the later of (1) the entry of an Order approving this Procedure or (b) the date on which the Diet Drug Recipient was first diagnosed as having the last occurring

condition or event upon which the claim for Matrix Compensation Benefits is based.

PTO No. 8559 (Nov. 8, 2010).

In April 2014, Ms. Schlager submitted to the Trust a copy of the operative report of her aortic valve surgery and nothing more. Nine months later, in January 2015, she submitted a partially completed second Green Form to the Trust without a required doctor's certification. The Green Form sought Level III benefits for her aortic valve surgery. She has stated that this Green Form was meant "to 'notify' the Trust again of the aortic valve surgery."

The Trust informed Ms. Schlager in March 2015 that her Level III claim was tentatively being denied because she had not submitted a completed Green Form by the deadline of November 8, 2014 imposed by CAP 16 and because she had not provided adequate proof of her use of Diet Drugs. On June 17, 2015, the Trust reiterated this denial in its Final Determination.

Pursuant to the Settlement Agreement, Ms. Schlager appealed the Trust's Final Determination, and the court referred her claim to arbitration on July 7, 2015.

^{5.} The Trust no longer contests Ms. Schlager's assertion that she did indeed ingest Diet Drugs. Following the petition of Ms. Schlager on September 11, 2015 to submit new evidence, the Trust agreed to consider pharmacy receipts of Diet Drugs as new evidence and her petition was rendered moot.

On October 27, 2015, before the arbitration took place, Ms. Schlager provided the Trust with a completed Green Form seeking Level III benefits for her aortic valve surgery and materials purporting to prove her use of Diet Drugs. On November 13, 2015, she filed a motion requesting determination from this court on the timeliness of her claim. On January 27, 2016, the court entered PTO 9457, denying Ms. Schlager's "motion/petition for relief" in which she sought a determination from the court that her claim for Matrix Benefits was not time-barred by CAP 16. See PTO No. 9457

(Jan. 27, 2016). The court found that Ms. Schlager's claim for Matrix Benefits was untimely. Id.

Following the entry of PTO 9457 and before arbitration, Ms. Schlager filed three requests to submit new evidence. The first petition, filed September 11, 2015, was rendered moot when the Trust agreed to consider pharmacy receipts of Diet Drugs as new evidence. The Chair of the Arbitration Panel denied the second and third petitions on April 27, 2016 and May 6, 2016, respectively.

Ms. Schlager appealed PTO 9457 to our Court of Appeals. The appeal was dismissed for lack of jurisdiction on April 14, 2016.

On August 24, 2016, an Arbitration Hearing took place before the Arbitrator concerning Ms. Schlager's claim and the

Trust's Final Determination. Thereafter, on September 19, 2016 the Arbitrator entered an Arbitration Report and Award concluding that the findings of the Trust were not clearly erroneous, as established by Rule 5 of the Rules Governing Arbitration Process. The Arbitration Report and Award stated that Ms. Schlager did not file a timely claim. Thus she failed to establish the conditions required for recovery of Matrix Level III Benefits as described in the Settlement Agreement as modified by the Seventh Amendment. See Seventh Amendment \$IX.A.l.a.

Ms. Schlager has now appealed the Arbitrator's decision to this court as permitted under the Settlement Agreement. See Settlement Agreement § VI.C.4.i. We apply a clearly erroneous standard of review to the Arbitrator's findings of fact and conduct a plenary review of conclusions of law. First Options of Chicago, Inc. v. Kaplan, 514 U.S. 938, 947-49 (1995). The ruling of this court is final and binding. See Settlement Agreement § VI.C.4.1.

In her first determination, the Arbitrator concluded that CAP 16 was intended to apply to qualifying medical events that preceded its establishment. While Ms. Schlager disagrees with this conclusion, she is incorrect. It is clear that CAP 16 set deadlines for claimants who would experience a qualifying health event before CAP 16 went into effect but who would not

seek benefits until after it went into effect. For those who had not yet experienced a qualifying medical event, CAP 16 set the deadline of November 8, 2014 to submit the Green Form, four years after the entry of PTO 8559. In addition, it fixed the deadline for those who had yet to experience such an event as four years from "the date on which the Diet Drug Recipient was first diagnosed as having the last occurring condition or event upon which the claim . . . is based."

We turn to the second determination of the Arbitrator which addressed Ms. Schlager's contention that CAP 16 should not apply to her because she was denied adequate notice of it in violation of Rule 23 of the Federal Rules of Civil Procedure and the Due Process Clause of the Fifth Amendment. The Arbitrator

^{6.} Rule 23(c) of the Federal Rules of Civil Procedure states, in relevant part:

For any class certified under Rule 23(b)(3), the court must direct to class members the best possible notice that is practicable under the circumstances, including individual notices to all individuals who can be identified through a reasonable effort. The notice must clearly and concisely state in plain, easily understood language:

⁽i) the nature of the action;

⁽ii) the definition of the class certified;

⁽iii) the class claims, issues, or defenses;

⁽iv) that a class member may enter an appearance through an attorney if the member so desires;

⁽v) that the court will exclude from the class any member who requests exclusion;

⁽vi) the time and manner for requesting exclusion; and

made several findings. First, she determined that CAP 16 did not have a material adverse effect on the rights of Class Members. Second, she concluded that CAP 16 did not violate due process considerations.

Ms. Schlager maintains that the Arbitrator erred in finding that CAP 16 had no material adverse effect on her. In pertinent part, CAP 16 clarified the deadlines applicable to Class Members seeking Matrix Benefits. Category One Class Members, such as Ms. Schlager, who did not opt out of the Seventh Amendment are bound by the Seventh Amendment, which governs these Class Members' eligibility to progress to a higher level of Matrix Benefits if their conditions worsened. Seventh Amendment Six. A. CAP 16 did not reduce Class Members'

Rule 23(e) provides procedure with respect to a proposed settlement, voluntary dismissal, or compromise. Fed. R. Civ. P. 23(e).

^{7.} The Seventh Amendment provides that in order to qualify for Level III, IV, or V Benefits, the Category One or Two Class Member must satisfy the following deadlines and submit a properly completed Green Form and accompanying documentation:

The Diet Drug Recipient whose condition forms the basis for the claim has or had High Matrix Level Qualifying Factors that were diagnosed and occurred by the earlier of: (i) December 31, 2011; or (ii) 15 years after the date of the Diet Drugs.

See Seventh Amendment § IX.A.1.

eligibility for Matrix Benefits or create any contractual obligation concerning eligibility for Matrix Benefits under the Settlement Agreement. The Settlement Agreement had always provided deadlines for the occurrence of qualifying medical conditions that made Class Members eligible for Matrix Benefits. Rather, CAP 16 simply modified the deadlines for the submission of the Green Forms by Class Members seeking these High Level Matrix Benefits.

We note that without the imposition of CAP 16 there would have been a four year statute of limitations for Ms.

Schlager's claim for Matrix Benefits beginning from the date of her aortic valve surgery on September 10, 2010. The interpretation and enforcement of a class action settlement agreement is governed by the principles of contract law. In recendant Corp. Prides Litig., 233 F.3d 188, 193 (3d Cir. 2000). There is a four year statute of limitation period for contract claims. 42 Pa. C.S. § 5525. Ms. Schlager submitted her completed Green Form on October 27, 2015, outside of the four-year statute of limitation that would have existed without

^{8.} Ms. Schlager incorrectly asserts that absent CAP 16, the deadline for her to file for High Level Matrix Benefits under § VI.C.2 of the Settlement Agreement was December 31, 2015. Prior to the existence of CAP 16, the Seventh Amendment did not articulate a deadline to file for these benefits for Category One or Two Class Members bound by the Seventh Amendment, such as Ms. Schlager, who are eligible under § IX.A.1 of the Seventh Amendment to qualify for High Level Matrix Benefits.

CAP 16. CAP 16 did not rob Ms. Schlager of her right to seek high level Matrix Benefits. In effect, CAP 16 provided Ms. Schlager with nearly two more months to apply for compensation than she otherwise would have had without the entry of CAP 16. CAP 16 did not affect her eligibility to be entitled to High Level Matrix Benefits.

Ms. Schlager also challenges the Arbitrator's findings that CAP 16 did not violate due process considerations and that adequate notice of CAP 16 was provided. In order to protect an individual's due process rights under the Fifth Amendment, Rule 23(e) of the Federal Rules of Civil Procedure requires notice to class members of the terms of a proposed settlement agreement.

See Fed. R. Civ. P. 23(e); see also Carlough v. Amchem Products, Inc., 158 F.R.D. 314, 324 (E.D. Pa. Oct. 27, 1993) (citing Mullane v. Central Hanover Bank & Trust Co., 339 U.S. 306 (1950)). Our Court of Appeals has stated that "Federal Rule of Civil Procedure 23(e) itself makes clear that determinations about settlement notices in class actions are within the discretion of the district court." In re Diet Drugs Prod.

Liability Litig., 93 F. App'x. 338, 324 (3d Cir. 2004). "Minor

^{9.} To the extent Ms. Schlager argues that individual notice through the mail was required by Rule 23(c)(2) of the Federal Rules of Civil Procedure, that provision requires "the best notice that is practicable under the circumstances" of a settlement agreement. Fed. R. Civ. P. 23(c)(2). Ms. Schlager has already been properly notified of the Settlement Agreement under Rule 23(c)(2) and she does not dispute that here.

modifications may be necessary to a settlement agreement (indeed may be favorable to the class), and additional class notice is not always required because, e.g., the cost of the notice would take recovered money from the class." In re Remeron End-Payor Antitrust Litig., 2005 WL 2230314 at * 19 (D.N.J. Sept. 13, 2005). PTO 8559 was posted on the Trust's website, electronically posted on the docket, and it was served electronically to all persons registered to receive such service.

"Notice of [an amendment] is only required where the amendment to the settlement agreement would have a material adverse effect on the rights of class members. In re: The Prudential Ins. Co. of America Sales Practices Litig.,

962 F.Supp. 450 n. 10 (D.N.J. 1997)." PTO No. 8506

(July 2, 2010). We have affirmed the Arbitrator's determination that CAP 16 did not have a material adverse effect on Ms.

Schlager's rights. We now conclude that the Arbitrator did not err in determining that adequate notice of CAP 16 was provided to Ms. Schlager. Furthermore, we affirm the Arbitrator's determination that CAP 16 did not violate due process considerations.

Finally we review the determination of the Arbitrator that Ms. Schlager's 2014 stroke did not toll the statute of limitations set by CAP 16 as to her claim. Ms. Schlager argues

that it should have been assumed that serious complications would occur following the stroke of a 77-year-old person such as Ms. Schlager. According to her, the deadline set by CAP 16 should have been tolled due to her serious health issues. Our Court of Appeals has identified three principal, non-exclusive situations in which equitable tolling may be appropriate: "(1) where the defendant has actively misled the plaintiff respecting the plaintiff's cause of action; (2) where the plaintiff in some extraordinary way has been prevented from asserting his or her rights; or (3) where the plaintiff has timely asserted his or her rights mistakenly in the wrong forum." Oshiver v. Levin, Fishbein, Sedran & Berman, 38 F.3d 1380, 1387 (3d Cir. 1994). The plaintiff bears the burden of presenting facts necessary to justify equitable tolling. Byers v. Follmer Trucking Co., 763 F.2d 599, 600-01 (3d Cir. 1995); Smith v. Shared Medical System, 2004 WL 1656635 at * 4 (E.D. Pa. July 23, 2004). The record does not demonstrate how or why her medical condition prevented her from submitting a completed Green Form within the deadlines set forth by CAP 16.

Ms. Schlager raises several arguments in her appeal brief that were not addressed in the Arbitration Report and Award. We will not address those arguments here.

The decision of the Arbitrator is affirmed.

^{10.} Ms. Schlager has included with her reply brief a document that is not part of the Appeal Record. Arbitration Rule 9.a provides: "Absent prior approval by the Chair, no new evidence may be considered by the Arbitrator at any time during the Arbitration process. The evidentiary record shall be limited to records submitted to the Trust prior to its final determination." Arbitration Rule 9.a.