

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 01-30197

Dayanne Denning,

Plaintiff-Appellant,

v.

Air Logistics, LLC, Principal Life Insurance Company, and Air
Logistics, LLC Group Benefit Plan

Defendants-Appellees.

Appeal from the United States District Court
for the Western District of Louisiana
(00-CV-1976)

March 21, 2001

Before, KING, Chief Judge, ALDISERT* and BENAVIDES, Circuit
Judges.

PER CURIAM:**

We must decide whether the district court improperly
interpreted provisions of the Air Logistics Group Benefits Plan
(the "Plan") to deny Appellant Dayanne Denning insurance coverage

* Circuit Judge of the Third Circuit, sitting by
designation.

** Pursuant to 5th Cir. R. 47.5, the court has determined
that this opinion should not be published and is not precedent
except under the limited circumstances set forth in 5th Cir. R.
47.5.4.

for an allogeneic bone marrow transplant.

The question presents itself in an appeal from the denial of a preliminary injunction by the district court. Specifically, we are required to determine whether the allogeneic transplantation for the treatment of breast cancer qualifies under the Plan's definition of "Medically Necessary Care." In the district court, Appellees successfully argued that the treatment was experimental and investigative and, therefore, it did not qualify under the Plan.

The district court had jurisdiction pursuant to the Employment Retirement Income Security Act (ERISA), 29 U.S.C. § 1001, et seq. We have jurisdiction pursuant to 28 U.S.C. § 1292.

I.

Appellant is a 41-year old woman who suffers from Stage IV metastatic breast cancer. Cancer is typically classified in terms of five stages of increasing severity from Stage I to Stage V. In connection with breast cancer, "Stage IV" signifies that the cancer cells have metastasized, i.e., spread to areas outside of the breast, the original site of the disease. Appellant was found to have metastatic disease in the liver, thoracic and lumbar spine.

Appellant is the beneficiary of a self-insured plan of her husband's employer, Air Logistics, LLC. The Claims Administrator

for the Plan is Principal Life Insurance Company ("Principal" or "Administrator"), who administers it pursuant to ERISA.

On November 23, 1999, Appellant's physician, Dr. James Gajewski, Associate Professor of Medicine, Department of Blood and Marrow Transplantation at the University of Texas M.D. Anderson Cancer Center, examined Appellant for consideration for a bone marrow transplant to treat her cancer. He informed her that she would first be treated with standard chemotherapy. If she received an optimal response, either an allogeneic or an autologous transplant would be considered. On that date, Dr. Gajewski wrote a letter to Principal asking for authorization for either the allogeneic or autologous bone marrow transplant. In the letter, Dr. Gajewski explained that metastatic breast cancer involving the bone marrow or liver has an especially poor prognosis with a median survival of less than six months after receiving standard dose chemotherapy. Record Excerpts at Tab 2.

Research regarding transplantation for breast cancer is relatively recent with few published studies in medical literature. An allogeneic transplant is when a person receives bone marrow or stem cells from a donor. The other type of transplantation that has been used in the treatment of breast cancer, autologous transplantation, is a procedure in which bone marrow or stem cells are removed from the patient and then given

back to the patient following intensive chemotherapy. Under either transplantation, the patient's bone marrow is removed and the patient is then subjected to high chemotherapy which ordinarily would destroy or severely damage the patient's bone marrow.

Appellant had to be pre-certified by the Administrator for the autologous or allogeneic transplant, but this decision was stayed pending the outcome of Appellant's standard chemotherapy treatment. On May 18, 2000, Appellant met with Dr. Gajewski for evaluation of her breast cancer and at that time, he wrote in his notes that he would try to receive urgent authorization for the allogeneic transplant procedure.

After the Administrator had received all of the clinical information necessary for completion of the pre-certification process, the materials were transmitted to Dr. James Ostiguy, Principal's Assistant Medical Director for his review. On June 20, 2000, the Administrator declined benefits for the allogeneic treatment. On June 21, 2000, Appellant requested a review by outside reviewers. The three outside experts found the procedure to be experimental and under continued scientific study. Appellant received permission to submit two unpublished articles to the outside experts, her case was then resubmitted for their review and they filed amended reports. After an evaluation of

all of the pertinent information, the Administrator again denied benefits for the allogeneic transplantation on the ground that it was not considered Generally Accepted Treatment for Stage IV metastatic breast cancer as set forth in the Plan.

II.

To prove that she has a substantial likelihood that she will succeed on the merits of her claim, Appellant must establish that the allogeneic bone marrow transplant is covered by the Plan. To consider this, we begin with the relevant portions of the Plan.

In the Booklet Rider, the "Covered Transplants" section provides that human-to-human organ or bone marrow transplant procedures are covered "when it is Medically Necessary Care." A bone marrow transplant or peripheral stem cell infusion is covered when, "a positive response to standard medical treatment or chemotherapy has been documented."

"Medically Necessary Care" is defined in the policy as follows: "Medically Necessary Care means as determined by the Claims Administrator, any confinement, treatment or service that is prescribed by a Physician and considered to be necessary and appropriate and not in conflict with Generally Accepted medical standards." Record Excerpts at Tab 11.

"Generally Accepted" is defined as follows:

Generally Accepted means Treatment or Service:

- has been accepted as the standard of practice according to the prevailing opinion among experts as shown by (or in) articles published in authoritative peer reviewed medical and scientific literature; and
- is in general use in the medical community; and
- is not under continued scientific testing or research as a therapy for the particular injury or sickness which is the subject of claim.

Id. at Tab 12.

III.

This court reviews the denial of a preliminary injunction for abuse of discretion. Bernat v. Guadalajara, Inc., 210 F.3d 439 (5th Cir. 2000); New York Life Ins. Co. v. Gillispie, 203 F.3d 384 (5th Cir. 2000).

Appellant is correct when she contends that she prevailed on the last three prongs of the formulation set forth in Canal Authority of Florida v. Callaway, 489 F.3d 567 (5th Cir. 1974). In Callaway, the court explained that four conditions must exist for a district court to issue a preliminary injunction:

(1) a substantial likelihood that plaintiff will prevail on the merits, (2) a substantial threat that the plaintiff will suffer irreparable injury if the injunction is not granted; (3) that the threatened injury to the plaintiff outweighs the threatened harm the injunction may do to the defendant; and (4) that granting the preliminary injunction will not dissolve the public interest.

489 F.3d at 574.

In the Fifth Circuit, the moving party must carry the burden of persuasion on each of the elements of the four-prong test.

See 13 JAMES W. MOORE, ET AL., MOORE'S FEDERAL PRACTICE, § 65.22[5][e] (3d ed. 2000). Unlike other circuits, which hold that no single factor is determinative, this circuit requires the moving party to persuade the court that it meets the threshold on each factor; otherwise, the court may not issue the injunction. Id. Because Appellant has met three of the four prongs, this court must resolve the issue of whether Appellant can meet the first prong, that is, whether there is a substantial likelihood that Appellant will prevail on the merits of her claim.

IV.

To prove that Appellant has a substantial likelihood of succeeding on the merits, she must prove that the Administrator's interpretation is not legally correct and that the Administrator abused its discretion in denying her claim. See Wildbur v. Arco Chemical Co., 974 F.2d 631 (5th Cir. 1992). This standard is utilized by this court to determine whether a claim for benefits pursuant to an ERISA plan was properly denied when a plan administrator has discretionary authority to determine eligibility for benefits and to construe the terms of the plan. Id. at 636.

This inquiry involves a two-step process. "First a court must determine the legally correct interpretation of the plan." Id. at 638. To do this, the court must consider: "(1) whether

the administrator has given the plan a uniform construction; (2) whether the interpretation is consistent with a fair reading of the plan; and (3) any anticipated costs resulting from different interpretations of the plan." Id.

If the court finds that the plan administrator did not correctly interpret the plan, it proceeds to the next step, which requires that it "determine whether the administrator abused its discretion." Id. If the court reaches the abuse of discretion inquiry, the three factors that the court must examine are: "(1) the internal consistency of the plan under the administrator's interpretation, (2) any relevant regulations formulated by the appropriate administrative agencies, and (3) the factual background of the determination and any inferences of lack of good faith." Id.

We begin with the language of the Plan which is set forth Part II supra. These definitions are not models of clarity and lack the precision contained in other plans recorded in the case law that specifically declare that experimental or investigative medical procedures are not covered. See Holder v. Prudential Ins. Co. of America, 951 F.2d 89, 90 n.3 (5th Cir. 1992) ("To be 'reasonably necessary,' a service or supply . . . must neither be educational or experimental in nature"); see also Fuja v. Benefit Trust Life Ins. Co., 18 F.3d 1405, 1408 (7th Cir. 1994)

(requiring that the treatment must not be deemed "experimental, educational or investigational in nature" as one of the five criteria for meeting the definition of "medically necessary" under the plan); Dahl-Eimers v. Mutual Omaha Life Ins. Co., 986 F.2d 1379 (11th Cir. 1993) ("A medically necessary service or supply is defined in the contract as one that . . . (b) is not considered experimental").

Nevertheless, we must interpret the definitions set forth in the Plan and apply the language to the situation at issue here. Because this involves a bone marrow transplant, Appellant is required to show that "a positive response to standard medical treatment or chemotherapy has been documented." Dr. Gajewski's July 5, 2000 letter accompanying Appellant's appeal to the administrator stated that Appellant initially had a "great response" to standard chemotherapy, with a decrease in her tumor markers from 700 to 150. Record Excerpts at Tab 4. Dr. Gajewski's examination notes and his decision to seek authorization for the allogeneic transplant are sufficient to support the statement that a positive response to chemotherapy has been documented.

A.

We must next consider whether Appellant's request for an allogeneic transplant is "Medically Necessary Care." The first

part of the definition is met by Appellant. This procedure has been prescribed by Appellant's treating physician and is considered to be "necessary and appropriate" for the treatment of Appellant's cancer.

The second part of the definition requires that the procedure not be "in conflict with Generally Accepted medical standards." Under the definition of "Generally Accepted," there are three prongs. In the view we take of this case, we will assume that Appellant's requested procedure is not necessarily in conflict with the standard of practice according to the prevailing opinion among those limited experts who specialize in breast cancer cases or with the treatment that is in general use in those cases. The use of an allogeneic transplant for the treatment of breast cancer, however, seems to be in conflict with the third prong because the procedure is "under continued scientific testing or research as a therapy for the particular injury or sickness which is the subject of the claim." Id. at Tab 12.

The feasibility of using this procedure to treat breast cancer, and more significantly, the success rate in the use of this treatment for breast cancer, have not been established and continue to be under scientific testing. The protocol for the Phase II clinical study that Appellant would participate in at

M.D. Anderson has the following objectives:

- 1) to assess the *feasibility* of mini-allogeneic PBPC transplantation in patients with recurrent or metastatic breast cancer.
- 2) to determine the *success rate* . . . at 100 days after the transplant and long-term progression free survival rate.
- 3) to examine the graft vs. breast cancer effect of allogeneic PBPC transplantation.

Id. at Tab 8 (emphasis added).

This study comes after two previous studies by M.D. Anderson, both of which required additional investigation into the long-term survival rate and noted that allogeneic transplants for the treatment of breast cancer should only be performed in clinical trials. The first study from 1995 reported that "allogeneic transplantation should only be performed in the context of clinical trials and its ultimate role requires demonstration of progression-free survival." Id. at Tab 10. The follow-up study from 1995-2000 reported the following:

Allogeneic GVM [graft-versus-malignancy] effects may act to prevent or delay progression of the malignancy [breast cancer]. Additional studies are required to determine if progression-free survival can be improved with allogeneic transplantation.

. . . .

At the time being, allogeneic hematopoietic transplantation should only be performed in the context of clinical trials designed to address the major outstanding issues.

Id. at Tabs 10 and 19.

It is clear from M.D. Anderson's own published studies and

the protocol for its most recent study that the use of allogeneic transplantation as a treatment for breast cancer is "under continued scientific testing or research for the injury or sickness which is the subject of [Appellant's] claim." Id. at Tab 12.

B.

Dr. Raymond Webster of Principal reviewed Appellant's claim. He wrote in a July 6, 2000 letter: "While there are a few published studies, there is not yet solid data on the efficacy of such treatment for breast cancer . . . the studies also conclude that further investigation is needed to establish the efficacy and long-term outcomes in patients with breast cancer." Id. at Tab 15. Similarly, the outside reviewers noted the lack of studies regarding the feasibility and efficacy of allogeneic transplantation in the treatment of breast cancer. Reviewer V003 stated:

In summary, although these few studies report the feasibility of allogeneic transplants with non-myeloablative regimens, the efficacy of this approach remains to be determined in larger studies with longer follow-up It remains highly speculative that there is a graft-versus-breast cancer effect elicited by donor transplants. The literature has been quoted above and is absolutely inconclusive. The proposed approach, while feasible and innovative has not been adequately evaluated to render an opinion on efficacy of this approach in this patient. This approach is certainly investigatory. The health benefits of the recommended treatment plan is unknown scientifically for this type of patient.

Tab 17, Record Excerpts. Reviewer C004 stated: "There is no demonstrated role for an allogeneic transplant, mini or otherwise, in the management of metastatic breast cancer." Id.

Appellant argues that the district court erred in crediting the opinions of the three outside reviewers. She argues first that these independent experts had not been furnished adequate information about her medical history, especially regarding whether she was medically able to or physically qualified to receive the transplant at that time. She contends also that the reviewers were not asked whether the procedure was "Medically Necessary" as defined in the Plan; nor were they furnished the Plan's definition of "Generally Accepted." The short answer to these complaints is that in light of the view we take in this case, the relevance of the reviewers' responses is not found in the state of Appellant's physical condition or whether the procedure was "Medically Necessary" as defined in the Plan, but whether the allogeneic transplant is under "continued scientific testing or research as a therapy for the particular injury of sickness which is the subject of [Appellant's] claim."

C.

In light of the foregoing and in accordance with the teachings of Wildbur, we conclude that the Administrator's interpretation is consistent with a fair reading of the Plan.

Because Appellant did not allege that there is a lack of uniformity in Plan construction and because there was no persuasive evidence introduced that the Administrator had granted coverage for any other allogeneic transplant in a breast cancer request, we determine that there was no of lack of uniformity in construing the Plan. To the extent that Wildbur refers to any anticipated costs resulting from different interpretations of the Plan, Appellant alleged in the trial court that there would be no unanticipated costs resulting from a different interpretation. Having agreed with the Administrator's interpretation of the Plan, we need not analyze whether its decision was an abuse of discretion. See Wildbur, 974 F.2d at 637-638.

V.

Appellant contends that Appellees breached their fiduciary duty by not disclosing information to her. She argues that she should have been told that the autologous procedure was covered and that the allogeneic procedure was not covered, that her not being told was a breach of a fiduciary duty, and that such breach should be "take[n] into account when determining [whether] they abused their discretion." Appellant's Brief at 10. She argues also that a conflict of interest on the part of the Administrator was present because "its decision to award or deny benefits impacts its own financial interests," id. at 7, that the actions

by Appellees show a clear conflict of interest in handling this claim, id. at 9, and that this, too, should be taken into account in determining whether the Administrator abused its discretion, id. at 10.

We do not believe that it is necessary to evaluate these two separate, but interrelated arguments because both bear upon evaluating whether the administrator abused its discretion. As emphasized heretofore, however, in light of the teachings of Wildbur, once we decide, as we have, that the Administrator interpreted the Plan correctly, we need not reach the abuse of discretion inquiry.

* * *

We have considered all contentions of the parties presented in this expedited, emergency appeal and conclude that no further discussion is necessary. We conclude that the district court did not err in denying the petition for a preliminary injunction.

This, too, must be said. As was the district court, we are cognizant of the agonizing ramifications of the decision we make today. Yet it must be understood that:

[T]hose who wear judicial robes are human beings, and as persons, are inspired and motivated by compassion as anyone should be. Consequently, we often must remind ourselves that in our official capacities, we have authority only to issue rulings within the narrow parameters of the law and the facts before us. The temptation to go about, doing good where we see fit, and to make things less difficult for those who come before us, regardless of the law, is strong.

But the law, without which judges are nothing, abjures such unlicensed [*sic*] formulation of unauthorized social policy by the judiciary.

Fuja v. Benefit Trust Life Ins. Co., 18 F.3d 1405, 1407 n.2 (7th Cir. 1993) (citation omitted).

The judgment of the district court is AFFIRMED.