Whitehead v. Federal Express Corp.

United States District Court for the Western District of Tennessee, Western Division

December 31, 1994, Decided ; December 31, 1994, Filed, Entered

NO. 94-3018 TUA

Reporter
878 F. Supp. 1066 *; 1994 U.S. Dist. LEXIS 19895 **

KATHERINE WHITEHEAD, Plaintiff, vs. FEDERAL EXPRESS CORPORATION, Defendant.

Core Terms

medically necessary, patient, breast cancer, chemotherapy, cancer, customarily, oncologists, effective, cells, preliminary injunction, investigational, coverage, illness, Protocol, therapy, stem, Clinical, Breast, adjuvant, provides, Injunctive, arbitrary and capricious, committee's decision, high dose, chemotherapeutic, nodes, district court, axillary, benefits, Charges

Counsel: **[**1]** For Plaintiff: Robert E. Hoskins, Foster & Foster, Greenville, SC. Glen G. Reid, Jr. & William M. Larsha, Jr., McDonnell Dyer, Memphis, Tennessee.

For Defendant: James R. Mulroy, II & Elizabeth C. Smith, Federal Express Corporation, Memphis, Tennessee.

Judges: JEROME TURNER, UNITED STATES DISTRICT JUDGE

Opinion by: JEROME TURNER

Opinion

[*1067] ORDER ON PLAINTIFF'S MOTION FOR INJUNCTIVE RELIEF

The plaintiff Katherine Whitehead brought this complaint against her employer, Federal Express Corporation, seeking a preliminary and permanent injunction compelling the defendant to pay for the plaintiff's upcoming breast cancer treatment. Jurisdiction is based on *28 U.S.C § 1331*, as the plaintiff claims the following federal statutes are involved: *29 U.S.C. § 1132*, *29 U.S.C. § 701, et seq.* and 42 U.S.C. § 2000(e)(2). Presently before the court is the plaintiff's motion for a preliminary injunction.[1] This order shall constitute the court's findings of fact and conclusions of law pursuant to *Rule 65 of the Federal Rules of Civil Procedure*.

[2]** *FACTS*

Ms. Whitehead is an employee of Federal Express, and as such is provided health benefits under the terms of the Federal Express Corporation Group Health Plan (the Plan), **[*1068]** which is administered for the defendant by Metropolitan Life Insurance Company (MetLife). In August of 1994 the plaintiff, who is thirty-six years old, was diagnosed as having breast cancer. The plaintiff's cancer was clinically staged at Stage II "T2, N1, MO";[2]

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[1] The motion has been presented on affidavits filed by both parties and on oral argument heard on December 21, 1994.

[2] Clinical staging of cancer serves as the primary method for comparing techniques of therapy. The method of clinical staging used by Response Technologies, Inc. is the "TNM" method. The TNM system is described as follows:

T (Primary Tumor)

TIS: Preinvasive carcinoma (carcinoma-in-situ).

T0: No demonstrable tumor in the breast.

T1: Tumor of 2 cm. or less; skin not involved or involved locally in Paget's disease.

T2: Tumor 2 to 5 cm. in size.

T3: Tumor greater than 5 cm. in size.

T4: Tumor of any size with any of the following: skin infiltration, ulceration, peau d'orange, skin edema, pectoral muscle or chest wall attachment.

N (Regional Lymph Nodes)

N0: No clinically palpable axillary lymph nodes.

N1: Clinically palpable but movable axillary nodes (N1a-metastasis not suspected, N1b-metastasis suspected)

she had a tumor 2.3 cm. with 7 of 17 lymph nodes positive and no distant metastasis. Plaintiff underwent a lumpectomy on August 29, 1994, which accomplished a complete resection or excision of all disease. The estrogen receptor and progesterone receptor were both positive which indicates that the cancerous cells are susceptible to hormone treatment. At this point, there is no evidence of active infection and there is no metastatic disease. **[**3]**

Since diagnosis plaintiff has been receiving adjuvant chemotherapy, the goal of which is to eliminate any micrometastases likely present in high risk patients.

She, however, has been advised by her treating physician, Dr. Tauer, that her best chance for survival and remission is to immediately receive high dose chemotherapy with peripheral stem cell rescue treatment (HDC/PSCR). The doctor states that she must begin this treatment no later than January 4, 1995.[3] The HDC/PSCR procedure and subsequent hospitalization will cost approximately $ 80,000 to $ 150,000. The plaintiff sought from the Plan a pretreatment coverage commitment as the provider of the HDC/PSCR procedure, Response Technologies, Inc. (RTI), will not provide the procedure without some guarantee of payment. MetLife, as the Claims Paying Administrator, denied Ms. Whitehead's request for high dose chemotherapy coverage on the ground that the HDC/PSCR procedure is not "medically necessary" as required for coverage under the terms of the Plan. Shortly before oral argument on the motion for a preliminary injunction, the Federal Express **[**4]** Corporation Benefit Appeal Committee (the Committee) determined on review of MetLife's denial that HDC/PSCR treatment coverage is not available under the Plan. The Committee's determination was based on its conclusion that (a) HDC is not commonly and customarily recognized among oncologists as appropriate for plaintiff's Stage II breast cancer, rather it is deemed investigational, and (b) HDC is not commonly and customarily recognized with respect to the standards of good practice as effective and appropriate in the treatment of Stage II breast cancer.

The plaintiff contends in her complaint and motion for preliminary injunction that HDC/PSCR is "medically necessary" for the treatment of her cancer under the terms of the **[*1069]** Plan and she is therefore entitled to coverage for the treatment.[4]

[5]** At the hearing on the motion for the preliminary injunction the plaintiff also asserted another ground for relief under the provisions of the Plan. The Plan states that the definition of "medically necessary" will "be satisfied if the service or supply is approved by the United States Food and Drug Administration, if applicable . . . ." (Plan at 49, 50, Ex. H to Def.'s Mem. in Opp'n). The plaintiff argues that the medical agents used in the treatment have been approved by the FDA as appropriate agents for treatment of breast cancer and that HDC/PSCR is therefore covered under the Plan.

THE TREATMENT

According to the plaintiff, HDC/PSCR is to be administered to the plaintiff in several stages.

> The first stage consists of the administration of low doses of chemotherapeutic agents, and Plaintiff has

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> N2: Clinically palpable, fixed, axillary nodes (metastasis suspected)
>
> [3]: Homolateral supra- or infraclavicular nodes considered to contain metastasis; edema of the arm.

M (Distant Metastasis, i.e., whether the cancer cells have spread to areas outside the original site of the disease -- in this case the breast)

> M0: No distant metastasis.
>
> M1: Clinical and radiographic evidence of metastasis except those to homolateral axillary or infraclavicular lymph nodes; includes skin involvement beyond the breast.

Staging

> Stage I: T1, N0 or N1a, M0.
>
> Stage II: T1, N1b, M0; T2, N0, M0; or T0, N1b, M0, T2, N1a, M0; or T2, N1b, M0.
>
> Stage III: Any T3 with any N, M0.
>
> Any T4 with any N, M0.
>
> Any T with N2 or [3], M0.
>
> Stage IV: Any T, any N, with M1.

[4] In her complaint the plaintiff also asserted various charges of discrimination against the defendant. The plaintiff alleged discrimination under the Rehabilitation Act, the Equal Pay Act and Title VII of the Civil Rights Act of 1964, since the Plan provides coverage for HDC/PSCR for testicular cancer and other types of cancer while not providing HDC/PSCR for breast cancer. In her motion for a preliminary injunction the plaintiff has not raised any of these arguments. Therefore, for purposes of this motion, the court will only consider the ERISA arguments the plaintiff made in her memorandum and at the preliminary injunction hearing.

> already undergone or is currently undergoing this stage. During the second stage, Plaintiff will be administered moderate doses of standard chemotherapeutic agents. During this phase of treatment, Plaintiff's body will produce extra amounts of components of the blood known as stem cells, and immediately subsequent to this stage, Plaintiff will have the extra stem cells removed by **[**6]** a procedure known as leukapheresis. The stem cells will then be quickly frozen and stored in liquid nitrogen.
>
> Subsequent to the leukapheresis stage, Plaintiff will receive high doses of standard chemotherapeutic agents. Subsequent to the administration of the chemotherapeutic agents, Plaintiff's cancer should have been killed along with the healthy white blood stem cells. (Stem cells produce, among other things, white blood cells which constitute the body's immune system.) Subsequent to the infusion of the above chemotherapy, Plaintiff will have her previously collected stem cells reinfused into his [sic] system so that her body will begin to rebuild the depleted stem cell count. Subsequent to readministration of the stem cells, Plaintiff will likely be hospitalized for a short period for observation.

(Pl.'s Mem. in Supp. of Mot. for Injunctive Relief at 2). For further description of the treatment *see also* Wheeler v. Dynamic Engineering, Inc., 850 F. Supp. 459, 462 (E.D. Va. 1994); Kekis v. Blue Cross and Blue Shield, 815 F. Supp. 571, 574 (N.D.N.Y. 1993); Kulakowski v. Rochester Hosp. Serv. Corp., 779 F. Supp. 710, 712 (W.D.N.Y. 1991); **[**7]** Bucci v. Blue Cross-Blue Shield, 764 F. Supp. 728, 730 (D. Conn. 1991); Adams v. Blue Cross/Blue Shield, 757 F. Supp. 661, 664 (D. Md. 1991).

PRELIMINARY INJUNCTION STANDARD

In determining whether to grant a preliminary injunction a district court must consider: (1) the likelihood that the party seeking the preliminary injunction will succeed on the merits of the claim; (2) whether the party seeking the injunction will suffer irreparable harm without the grant of the extraordinary relief; (3) the probability that granting the injunction will cause substantial harm to others; and (4) whether the public interest is advanced by the issuance of the injunction. Washington v. Reno, 35 F.3d 1093, 1099 (6th Cir. 1994) (citing Keweenaw Bay Indian Community v. Michigan, 11 F.3d 1341, 1348 (6th Cir. 1993)). In addition the Sixth Circuit has said that "'the four considerations applicable to preliminary injunction decisions are factors to be balanced, not prerequisites that must be met. Accordingly, the degree of likelihood of success required to support a grant of preliminary **[**8]** injunction may depend on the strength of the other factors considered.'" Washington, 35 F.3d at 1098 (quoting In re DeLorean Motor Co., 755 F.2d 1223, 1229 (6th Cir. 1985)).

[*1070] The Sixth Circuit has also recognized that a motion for a preliminary injunction may be granted where the moving party can show "sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardships tipping decidedly toward the party requesting the preliminary relief." Friendship Materials, Inc. v. Michigan Brick, Inc., 679 F.2d 100, 103 (6th Cir. 1982) (quoting Sonesta Int'l Hotels Corp. v. Wellington Assocs., 483 F.2d 247, 250 (2d Cir. 1973)); Hypoint Technology, Inc. v. Hewlett-Packard Co., 869 F.2d 1491, 1989 WL 20560 (6th Cir. 1989); *See also* Michigan Coalition v. Griepentrog, 945 F.2d 150, 153-54 (6th Cir. 1991).

STANDARD OF REVIEW

In order to determine the issue of whether plaintiff is likely entitled to coverage under the Plan, the court must first clarify the standard by which this court reviews the Committee's **[**9]** decision. The Plan states:

> (d) *Authority of Committee.* The committee, appointed pursuant to subsection (c), shall be empowered to interpret the Plan's provisions in its sole and exclusive discretion in accordance with its terms with respect to all matters properly brought before it pursuant to this Section 8.3, including, but not limited to, matters relating to the eligibility of a claimant for benefits under the Plan. The determination of the committee shall be made in a fair and consistent manner in accordance with its interpretation of the Plan's terms and its decision shall be final, subject only to a determination by a court of competent jurisdiction that the committee's decision was arbitrary and capricious.

(Plan at 85-86, Ex. H to Def.'s Mem. in Opp'n). Established law directs that the arbitrary and capricious standard shall apply to the court's review of decisions by Plan Administrators to deny benefits where "the benefit plan gives the administrator or fiduciary discretionary authority to determine eligibility for benefits or to construe the terms of the plan." Bartling v. Fruehauf Corp., 29 F.3d 1062, 1071 (6th Cir. 1994) (quoting **[**10]** Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101, 115, 103 L. Ed. 2d 80, 109 S. Ct. 948

(1989)). Here, the provisions of the Plan clearly convey substantial discretion to the Committee to determine eligibility for benefits and to interpret the Plan's terms. This issue is not disputed by plaintiff. This court's analysis is therefore limited to a review of whether the Committee's decision was arbitrary and capricious.

> The arbitrary and capricious standard is the least demanding form of judicial review of administrative action. When it is possible to offer a reasoned explanation, based on the evidence, for a particular outcome, that outcome is not arbitrary or capricious.

Bartling, 29 F.3d at 1071 (quoting Davis v. Kentucky Fin. Cos. Retirement Plan, 887 F.2d 689, 693 (6th Cir. 1989), cert. denied, 495 U.S. 905, 109 L. Ed. 2d 288, 110 S. Ct. 1924 (1990) (quoting Pokratz v. Jones Dairy Farm, 771 F.2d 206, 209 (7th Cir. 1985)).

The arbitrary and capricious standard **[**11]** of review asks only whether the Committee's interpretation of the Plan language is reasonable. Wells v. U.S. Steel & Carnegie Pension Fund, Inc., 950 F.2d 1244, 1249 (6th Cir. 1991) (quoting Firestone, 489 U.S. at 111).

The Committee's decision is entitled to the court's affirmance unless it is without reason, "unsupported by substantial evidence or erroneous as a matter of law." Whitworth Bros. Storage v. Cent. States S.E. Areas, 982 F.2d 1006, 1013 (6th Cir.), cert. denied, U.S. , 114 S. Ct. 67, 126 L. Ed. 2d 36 (1993) (quoting Teamsters Local 348 Health and Welfare Fund v. Kohn Beverage Co., 749 F.2d 315, 321 (6th Cir. 1984), cert. denied, 471 U.S. 1017, 105 S. Ct. 2024, 85 L. Ed. 2d 305 (1985)).

It is not required, however, that the evidence be compelling or overwhelming; it must be sufficient to conclude that the decision is rational. The fact that a contrary conclusion could have been reached on the basis of some of the evidence does not afford a basis to override the Committee's decision.

Finally, when **[**12]** operating under the arbitrary and capricious standard of review, the court is not authorized to substitute its own judgment for that of the Committee. **[*1071]** Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43, 77 L. Ed. 2d 443, 103 S. Ct. 2856 (1983).

The Committee itself must "examine the relevant data and articulate a satisfactory explanation for its action." Id. at 43.

"*MEDICALLY NECESSARY*"

The focus of the parties' arguments is on whether or not the HDC/PSCR treatment is "medically necessary." The plaintiff contends that the summary plan description (SPD) provided by Federal Express Corporation to the plaintiff as an employee is the document which controls the rights of the parties and that the court should consider the definition of "medically necessary" as set forth in the SPD. The SPD provides:

> Eligible expenses for treatment of an illness or injury must be medically necessary under all plan options. Medical necessity is determined by the claims paying administrator.
>
> Care that is medically necessary may include, but is not limited **[**13]** to, care that is:
> - Commonly and customarily recognized as standards of good practice
> - Appropriate and consistent with the diagnosis or treatment of an illness or injury
> - Appropriate supply or level of service that can safely be provided.

(Summary Plan Description at 24-25, Ex. A to Pl.'s Compl. for Injunctive Relief).

The defendant argues that the Plan is the document that governs the rights of the parties. The Plan provides:

> Section 3.4. *Generally Excluded Charges.* The following charges shall be deemed *not* to be Eligible Charges under the Plan and, therefore, ineligible for coverage by the Plan, except as provided herein:
>
> . . . .
>
> (c) *Charges for Unnecessary Services and Supplies.* Charges for any service or supply which is not "medically necessary" for the care of the patient's Illness. To be considered medically necessary, the service or supply:
> (1) must be provided by a Practitioner, Hospital, or covered provider;
> (2) must be commonly and customarily recognized with respect to the standards of good practice as appropriate and effective in the identification or treatment of a patient's diagnosed Illness;
>
> (3) must be consistent with the symptoms **[**14]** upon which the diagnosis and treatment of the Illness is based;
> (4) must be the appropriate supply or level of service which can safely be provided to a patient and with regard to a person who is an inpatient, it must mean that the patient's Illness

requires that the service or supply cannot be safely provided to that person on an outpatient basis;
(5) must not be primarily for the convenience of the patient, Practitioner, Hospital, or covered provider;
(6) must not be scholastic, vocational training, educational, or developmental in nature or experimental or investigational in nature; and
(7) must not be provided primarily for the purpose of medical or other research.

Whether or not the criteria set forth in paragraphs (1) through (7) have been met shall be made initially by the Claims Paying Administrator and ultimately by the Administrator pursuant to the procedures set forth in Section 8.3 of the Plan. Paragraphs (1) through (7) shall be satisfied if the service or supply is approved by the United States Food and Drug Administration, if applicable, or if such service or supply is commonly and customarily recognized among Practitioners within the most relevant medical **[**15]** specialty as appropriate for the diagnosis or treatment of the Illness of the Covered Participant, as determined by the Claims Paying Administrator or Administrator, as applicable.

(Plan at 49-50, Ex. H to Def.'s Mem. in Opp'n).

[*1072] The Sixth Circuit has stated that "given the SPD's important role under the ERISA framework, it is natural for courts to hold the SPD controlling *when it conflicts with the plan itself."* Flacche v. Sun Life Assur. Co., 958 F.2d 730, 736 (6th Cir. 1992) (emphasis added). In the present case, however, the definition of "medically necessary" in Federal Express's Plan does not conflict with the limited examples of medically necessary care in the SPD, but only helps to more fully explain the term. Accordingly, the Plan language controls and not the "abridged version" found in the SPD.

The defendant asserts that the reason for the Committee's decision that the HDC/PSCR treatment was not "medically necessary" is two-fold:

> Based on the Plan language, the plaintiff's medical history, and the record before it as a whole, the Committee decision was to continue covering plaintiff's standard dose chemotherapy and to deny coverage **[**16]** for high dose chemotherapy under the Plan since: (a) HDC is not commonly and customarily recognized among oncologists as appropriate for Ms. Whitehead's condition (Stage II breast cancer); rather, it is deemed by them to be investigational in nature, experimental and provided primarily for the purpose of medical or other research. (b) Further, HDC is not commonly and customarily recognized with respect to the standards of good practice as appropriate and effective in the treatment of plaintiff's Stage II high risk cancer.

(Def.'s Mem. in Opp'n at 16).

The plaintiff argues that there was ample evidence submitted to MetLife and the Committee on appeal from which it could only be concluded that the HDC/PSCR treatment was safe, effective and "medically necessary."

The following documents were part of the administrative record submitted by the plaintiff:

1. Medical records of Katherine Whitehead;
2. Two articles by Dr. Karen Antman;
3. Textbook excerpt of Dr. William Peters;
4. AMA news article entitled "Breast Study Woes Preview Reform Barriers";

5. Survey from *Journal of Clinical Oncology;*

6. Affidavits of Dr. William H. West; Dr. Lee S. Schwartzberg; Dr. Gerald **[**17]** King; and Dr. Mark O'Rourke, with attachments to all affidavits, including ASCO status letter;
7. 1993 Summer edition of Drug Compendia;
8. "Use of Drugs for Unlabeled Indications" by Stuart Nightingale, M.D.;

9. "Dose and Dose Intensity of Adjuvant Chemotherapy for Stage II Breast Carcinoma", *New England Journal of Medicine,* May 5, 1994;
10. Affidavit of Dr. Kurt Tauer;
11. Affidavit of Dr. Charles Weaver, including attachments;
12. Affidavit of Katherine Whitehead;

13. Affidavit of John R. Wingard, M.D. from case of *Reger v. Espey,* filed in the United States District Court for the Northern District of Georgia Atlanta Division, C.A. No. 1:93-CV2213;

14. Portion of the deposition testimony of Dr. Bruce Cheson from the case of *Wheeler v. Dynamic Engineering, Inc.,* United States District Court for the Eastern District of Virginia;

15. Affidavit of Dr. Roy A. Beveridge in the case of *Dodd v. Blue Cross/Blue Shield Association* filed in the United States District Court Eastern District of Virginia, C.A. No. 93-964A;

16. Testimony of Dr. Lawrence A. Lemkow from the trial of *Wheeler v. Dynamic Engineering, Inc.,* United States District Court for the **[**18]** Eastern District of Virginia;
17. Affidavit of Colleen Garvey;
18. Letter dated June 6, 1994 to James King, Director of Office of Personnel Management from Roy B. Jones, M.D., Ph.D.; William P. Peters, M.D., Ph.D., Stephanie D. Williams, M.D.; Gary Spitzer, M.D., Richard Champlin, M.D. and Nancy Davidson, M.D.;

[*1073] 19. Excerpts from the deposition of Dr. Thomas Holohan from the case of *Wheeler v. Dynamic Engineering, Inc.,* United States District Court for the Eastern District of Virginia;

20. Affidavit of Finn B. Petersen, M.D. from the case of *Lori Coleman v. OPM,* United States District Court, District of Utah, Northern Division, Case No. 94-NC-109B;

21. Copy of letter and documents from Roy B. Jones, PhD, M.D., Director; Elizabeth J. Shpall, M.D., Associate Director; Scott I. Bearman, M.D., Clinical Director; all of the Bone Marrow Transplant Program at the University of Colorado, including letters in support of high dose chemotherapy from numerous expert oncologists throughout the country, including Dr. Roger H. Herzig, Marion F. Beard Professor of Hematology at the University of Louisville; Dr. J.R. Harris, Harvard Medical School; Dr. Robert F. Ozols, Fox-Chase Cancer **[**19]** Center, Philadelphia, Pennsylvania; Dr. Gabrielle N. Hortobagyi and Dr. Gary Spitzer, M.D. Anderson Cancer Center; Dr. David Golde, University of California - Los Angeles; Dr. Brian J. Lewis, University of California at San Francisco; Dr. Gerald L. Messerschmidt, University of Michigan; Dr. Charles Vogel, South Florida Comprehensive Cancer Centers; Dr. Robert B. Livingston, Professor of Medicine, University of Washington; Dr. Bernard Fisher, National Surgical Adjuvant Project for Breast and Bowel Cancers; Dr. David Goldman, Medical College of Virginia Commonwealth University; Dr. Douglas C. Tormey, University of Wisconsin Clinical Cancer Center; Dr. Lowell E. Schnipper, Harvard Medical Center; Dr. Kent Osborne, University of Texas; Dr. Alan S. Lichter, University of Michigan; Dr. Edwin C. Cadman, Yale University; Dr. Emil Frei, III, Dana Farber Cancer Institute, Boston, Massachusetts; Dr. Lawrence E. Einhorn, Indiana University; Dr. Mark Lippman; Georgetown University;
22. DATTA Evaluation: "Autologous Bone Marrow Transplant - Reassessment" by Elizabeth Brown, M.D.

(Pl.'s Mem. in Supp. of Mot. for Injunctive Relief at 8-10).

In addition, the Committee also received and considered:

[20]**
23. Affidavit of Raymond B. Weiss, M.D.;
24. Affidavit of Robert Dreicer, M.D.;
25. Sworn Affidavit of Dr. Richard H. Watt;
26. ECRI Summary of the World Health Organization.

(Exs. A, B, C and G to Def.'s Mot. in Opp'n).

The first question for this court to consider on this motion is whether it is likely that the plaintiff will succeed on the merits of her claim; the court must inquire into whether or not the decision of the Committee to deny coverage to the plaintiff for the HDC/PSCR procedure was arbitrary and capricious, given the evidence before the Committee.

On October 6, 1994, RTI submitted a request for determination of benefits and pre-authorization of treatment for Katherine Whitehead. In it, among other things, were plaintiff's medical records, a medical summary, and a Protocol which details the plan of treatment. In the Protocol it is stated that "evidence is accumulating that the intensity of adjuvant chemotherapy has a significant impact on the likelihood of progression-free survival for women with node-positive carcinoma of the breast." (Def.'s Ex. I, Breast 94-31 Protocol at 6). The Protocol provides significant information concerning HDC/PSCR and reflects **[**21]** that there is some evidence from studies that HDC/PSCR provides longer recurrence-free survival for woman with 10 or more positive axillary lymph nodes. The Protocol reflects the conclusion that:

> It would thus appear that more intensive chemotherapy will translate into improved outcomes for patients with resectable carcinoma of the breast and metastases to axillary nodes.

[*1074] (Def.'s Ex. I, Breast 94-31 Protocol at 7). It further refers to investigators of the "current study" and

in the "Objectives" section states the objective is:

> To evaluate the effect of dose of Cyclophosphamide during mobilization of peripheral blood stem cells (PBSC) on progression-free survival of high-risk resectable carcinoma of the breast (Stage II with [greater than] 6 involved axillary nodes . . . .[5]

(Def.'s Ex. I, Breast 94-31 Protocol at 5).

[22]** In addition to this very detailed explanation of the proposed procedure, four board certified oncologists associated with RTI or its CEO, Dr. West, also submitted affidavits to MetLife which addressed the proposed treatment and their opinions of its efficacy and appropriateness in plaintiff's case. Dr. Tauer, the treating physician, states he knows of no treatment that offers plaintiff "a better chance for a response or for survival" (Aff. of Kurt Tauer P 8, Document 10 of Ex. B to Pl.'s Mem. in Supp. of Mot. for Injunctive Relief) and that treatment consists of nothing more than FDA approved standard chemotherapeutic agents which are recognized as being effective in the treatment of breast cancer which will be administered in high doses. More importantly, he states: "It is undisputed that high-dose chemotherapy in the treatment of Stage II, III, and IV is accepted as an effective treatment alternative." (Document 10 of Ex. B to Pl.'s Mem. in Supp. of Mot. for Injunctive Relief, Aff. of Kurt Tauer, P 16). Finally he opined that any lesser treatment would fail to provide Ms. Whitehead with her best opportunity for recovery and long-term health and survival.

The Tauer affidavit went **[**23]** on to say:

> That I can further state that the prevailing opinion within the oncological community in the United States is that high-dose chemotherapy with peripheral stem cell rescue is a safe and effective treatment for Stage II, high-risk breast cancer and that the treatment is an accepted treatment alternative . . . .

Id. at P 18. Tauer added that the treatment for plaintiff is not investigational.

The affidavits of Dr. Weaver, Dr. West and Dr. Schwartzberg, all highly qualified oncologists, offer substantially similar support to plaintiff's position that HDC/PSCR is medically necessary in plaintiff's case.

When MetLife received the request, Dr. Richard Watt, the Medical Director of MetLife, began the determinations process. Dr. Watt, who is also a board certified oncologist, reviewed the plaintiff's submissions and sought the opinions of two unaffiliated oncologists.

The first, Dr. Raymond B. Weiss, has been Chief of the Section of Medical Oncology at a major academic tertiary care center since 1981. He has been board certified in medical oncology since 1973. His curriculum vitae, like that of the other oncologists involved in this case, is extremely impressive. In **[**24]** answer to Dr. Watt's specific question about whether the proposed treatment was medically necessary for the treatment of Katherine Whitehead, he stated, "no. Adjuvant chemotherapy of some kind is clearly necessary, but there is no proof the proposed HDC/CSCT is." (Letter of 12/4/94 from Dr. Weiss to Dr. Watt at 4, Ex. N to Def.'s Mot. in Opp'n). He also stated that the proposed treatment was experimental. *Id.* However, Dr. Weiss stated that he "could go either way on recommending approval or disapproval of this patient for having insurance coverage for the HDC." *Id.* He therefore requested additional documentation about the protocol and other matters. When he received the full protocol, he found it to be an "apparently serious attempt to do a scientific study." (Letter of 12/6/94 from Dr. Weiss to Dr. Watt at 2, Ex. M to Def.'s Mot. in Opp'n). He recommended approval of insurance coverage. **[*1075]** He, however, concludes that the proposed treatment was "investigational." *Id.*

Dr. Watt then sent Dr. Weiss some portions of the insurance contract for review. After reviewing those documents and despite the fact that he saw no objection to plaintiff entering into this HDC/PSCR procedure **[**25]** as a trial, he concluded:

> However, when I read her insurance contract language, it is clear that such investigational therapy is excluded. HDC is yet unproven as being effective for any woman with Stage II breast cancer . . . . HDC is not 'commonly . . . recognized . . . as appropriate and effective in the . . . treatment' of this patient's illness . . . .
>
> This patient could be treated for her cancer on a

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[5] While it is apparent that Dr. Tauer and RTI intended to utilize the protocol to assist further study of the treatment, that fact *alone* is clearly not sufficient to justify the conclusion that the study is experimental or investigational. Until a cure is routinely effected in the treatment of breast cancer, proper analysis of treatments is obviously necessary in order to assure that advances in treatments continue to be made. Protocols provide the vehicle for such advancements. *Adams v. Blue Cross/Blue Shield of Maryland, Inc., 757 F. Supp. 661, 663, 675 (D. Md. 1991)*; *Pirozzi v. Blue Cross-Blue Shield of Virginia, 741 F. Supp. 586, 593 (E.D. Va. 1990)*.

> clinical trial, but doing so is not medically necessary, because the trial involves treatment unproven to be more effective than routine adjuvant chemotherapy . . . . In my opinion the insurance contract would exclude her from being treated as is being proposed.

(Letter of 12/9/94 from Dr. Weiss to Dr. Watt at 1-2, Ex. O to Def.'s Mot. in Opp'n).

Dr. Weiss also provided his affidavit to the Committee in which he stated:

> It is my opinion that the proposed treatment of HDC/SCR [6] is not "medically necessary" for Ms. Whitehead under the Federal Express Corporation Group Health Plan for the following reasons: (a) HDC/SCR is not "commonly and customarily recognized as appropriate or effective" for Ms. Whitehead's illness because there is no evidence that HDC/SCR is more effective **[**26]** than subtransplant doses of chemotherapy for Stage II breast cancer, and thus, does not meet the standard of care; and (b) the use of HDC/SCR to treat Ms. Whitehead's illness is "investigational."

(Aff. of Raymond B. Weiss at P 4, Ex. A to Def.'s Mot. in Opp'n).

Dr. Robert Dreicer, an Assistant Professor at the University of Iowa College of Medicine, was also asked for his independent evaluation. Dr. Dreicer is also a board certified medical oncologist, with an extensive history in chemotherapeutical treatment of cancer.

In answer to Dr. Watt's question about whether HDC/PSCR was medically necessary for Karen Whitehead's clinical condition, he opined that the role of high dose therapy is not the standard of care and remains an investigational approach, but he noted that if the definition of medically necessary is broader than the standard of care, and is based on promising early data, HDC/PSCR might meet this definition. Nonetheless, he further opined that the procedure **[**27]** for this patient is investigational because there has been no comparison between HDC/PSCR and standard adjuvant therapy. He ended with the statement: "There is no guarantee that efficacy in the greater than 10 node group would translate to the 4-9 node group given a difference in natural history." (Letter of 10/18/94 from Dr. Dreicer to Dr. Watt at 2, Ex. K to Def.'s Mot. in Opp'n).

Later Dr. Dreicer, after being provided copies of the applicable Plan provisions, wrote to Dr. Watt that:

> The role of high-dose therapy with stem cell rescue in patients with high risk Stage II disease is not yet commonly and customarily recognized as appropriate or effective therapy in contrast to standard adjuvant therapy.

and

> It is in the setting in which it is applied i.e. adjuvant therapy of high risk breast cancer that remains investigational.

and

> The use of high dose therapy with stem cell rescue for patients with stage II breast cancer and 7 positive nodes is not the standard approach to this patient population. . . . the majority of patients with similar presentations treated in the US would not receive high-dose therapy.

(Letter of 12/12/94 from Dr. Dreicer to Dr. Watt **[**28]** at 1-2, Ex. L to Def.'s Mem. in Opp'n).

Prior to the presentation of the issue to the Committee, Dr. Dreicer was asked to provide his independent opinion in an affidavit on whether the HDC/PSCR is medically necessary. He opined:

> **[*1076]** The role of HDC/SCR in patients with stage II breast cancer is not yet "commonly and customarily recognized as appropriate or effective" therapy in contrast to standard adjuvant therapy . . .; and (b) the use of HDC/SCR to treat stage II breast cancer is "investigational" as applied to Ms. Whitehead because a comparison of HDC/SCR with standard adjuvant therapy has not been done with a patient population similar to Ms. Whitehead's.

(Aff. of Robert Dreicer at P 4, Ex. B to Def.'s Mem. in Opp'n).

Dr. Watt, having reviewed the submission by and on behalf of the plaintiff, including the supporting affidavits of four oncologists, and having received the opinions of the two independent consultants, Drs. Weiss and Dreicer, formed the opinion and so informed the Committee in a 20 page affidavit,[7] that:

> A. It is not recognized as being commonly and customarily appropriate. And this is based on the

---

[6] HDC/SCR and HDC/PSCR are the same treatment.

[7] This opinion of necessity grossly simplifies the extensive information provided to the Committee, as for example, in Dr. Watt's 20 page affidavit. For reasons of time which has been critical in this case, the court has merely set forth the ultimate conclusions of all of the doctors whose opinions were presented to the Committee.

> fact that there is no evidence so far from medical studies **[**29]** that a lady such as Mrs. Whitehead who had seven of the lymph glands involved will benefit from high dose chemotherapy.
>
> There are studies going on, but there is no evidence whatsoever that she will be better off than with the standard chemotherapy.

(Aff. of Richard H. Watt at 6, Ex. C to Def.'s Mem. in Opp'n).

> A. It is not so medically necessary because your group health plan specifically states, for example, that the treatment must be commonly and customarily recognized with respect to the standards of good practice as appropriate and effective in the identification or treatment of a patient's diagnosed illness.
>
> We have gone on to state that it is not commonly and customarily recognized as the standard treatment for Stage II breast cancer. On that grounds, [sic] it does not meet the medical necessity requirements.

Id. at 18.

[30]** The Committee reached its decision on December 20, 1994. In a letter to plaintiff's counsel, Robert Hoskins, Gwen Owens, a manager of Employee Benefits for Federal Express, explained the Committee's decision:

> The Committee denied your request on the basis of the plan provision which specifically excludes charges for any service or supply which is not medically necessary for the care of the patient's illness as determined by the Administrator. To be considered medically necessary, the service or supply must be commonly and customarily recognized, with respect to the standards of good medical practice, as appropriate and effective in the identification or treatment of a patient's diagnosed illness. In addition, it must be the appropriate supply or level of service which can safely be provided to a patient and it must not be experimental or investigational in nature. This plan provision is also communicated in *Your Employee Benefit* book. The Committee noted the plan definition of medical necessity includes the requirement that treatments must be commonly and customarily recognized among Practitioners within the most relevant specialty as appropriate.
>
> The Committee reviewed **[**31]** and thoroughly discussed all of the medical evidence presented by you on behalf of Ms. Whitehead and by MetLife. The Committee found that the medical experts presented by MetLife made a better case that the treatment is not commonly and customarily recognized by oncologists as effective and appropriate for Ms. Whitehead's illness than was made by Dr. Tauer and the other physicians who believed that this treatment was necessary for Ms. Whitehead. The Committee based its decision on reviews by Dr. Watt, MetLife's Medical Director, and Dr. Weiss and Dr. Dreicer, the consulting oncologists, obtained by MetLife. **[*1077]** The Committee noted the MCOP oncologists used by MetLife were independent medical experts. Finally, the Committee noted that the information presented by you failed to show the treatment in question to be commonly recommended for stage II breast cancer with less than 10 positive lymph nodes.

(Letter of 12/20/94 from Gwen Owens to Robert E. Hoskins at 1, submitted as an exhibit by stipulation of the parties).

Despite the fact that the Committee was presented with diametrically differing opinions from highly qualified oncologists, it was required to make a determination as to **[**32]** coverage based on the Plan provisions and the materials submitted. It did so. It accepted the opinions of Drs. Watts, Weiss and Dreicer over that of Drs. Tauer, West, Schwartzberg and Weaver.

Given the impressive credentials of all the oncologists whose opposing views were presented to the Committee, there is no legal basis for this court to conclude that the decision of that Committee to reject coverage was without reason, unsupported by substantial evidence or erroneous as a matter of law. *Whitworth Bros. Storage, 982 F.2d at 1013*; *Daniels v. Employees, 758 F. Supp. 326, 331 (W.D. Pa. 1991)*. There is sufficient evidence for a reasonable person to agree with the Committee's decision.

There is much room for debate on the issue Placed before the Committee. The treatment is extremely expensive and in a significant percentage of patients is fatal. Yet, for a number of oncologists it is the preferred form of treatment and provides the best chance of recovery for their patients. The law, as it is now, however, does not permit the court to substitute its judgment for that of the Committee. There is no allegation in this case **[**33]** of any breach of fiduciary duty and once the determination is made that substantial evidence was offered to, and supports the decision of, the Committee, the court's obligation to

deny the request for a preliminary injunction on this issue is clear. There is no basis to conclude that the plaintiff would likely succeed on the merits upon a full trial on the issue of whether HDC/PSCR is medically necessary under the terms of the policy.

Moreover, given the established nature of the law setting forth the standard of review as "arbitrary and capricious," the court cannot hold that the plaintiff has shown a sufficiently serious question going to the merits to make it a fair ground for litigation.

"FDA APPROVED" CLAUSE

The second argument the plaintiff makes concerns the clause set out after the seven criteria listed for the definition of "medically necessary." The plaintiff points-out that the Plan states that the definition of "medically necessary" will "be satisfied if the service or supply is approved by the United States Food and Drug Administration, if applicable . . . ." (Plan at 49, 50, Ex. H to Def.' Mem. in Opp'n). The plaintiff argues that the medical agents used in the treatment **[**34]** have been approved by the FDA as appropriate agents for treatment of breast cancer, and that therefore this procedure is covered under the plan. The court now considers whether it is likely the plaintiff will succeed on the merits on this argument.

The "FDA approved" argument was not raised in the pleadings, but was initially advanced in oral argument. It has never been presented to the Committee or to the Claims Paying Administrator. The Plan provides at Section 8.3, at 84-86 (Ex. H to Def.'s Mem. in Opp'n) that every claimant with respect to whom a claim is denied shall have the right to request in writing the Committee to review the denial and to submit issues in writing for review of that Committee.

The attempt to raise the issue of "FDA approval" for the first time in open court conflicts sharply with the power of the Committee "to interpret the Plan's provisions in its sole and exclusive discretion in accordance with its terms with respect to all matters properly brought before it . . . ." (Plan at 85, § 8.3(d), Ex. H to Def.'s Mem. in Opp'n).

This court does not have the lawful authority to usurp the empowerment of the Committee to interpret the terms of the Plan, only to review **[**35]** its decisions under the arbitrary and capricious standard.

[*1078] Since the specific issue has not been presented to the Committee,[8] it has not had the opportunity to review the facts to determine the scope and effect of FDA approval, the question of FDA approval of chemotherapeutical drugs involved in this protocol, and the effect of the answers to those questions given the specific language of the Plan.

Moreover, the court itself has an insufficient record relative to this issue and no factual basis to determine the questions mentioned above. Under these circumstances there is nothing for the court to review and no basis to conclude under applicable standards **[**36]** that defendant should be ordered to pay, on motion for preliminary injunction and without trial, approximately $ 80,000 to $ 150,000 which, once paid, does not appear to be recoverable.[9] Despite the overwhelming sympathy and emotional support any person would feel for a cancer patient such as plaintiff, the court does not have a lawful basis to require payment under these circumstances.

The motion for a preliminary injunction is denied.

IT IS SO ORDERED this 31st day of December, 1994.

JEROME TURNER

UNITED STATES DISTRICT JUDGE

End of Document

[8] Under Section 8 of the Plan, it would appear that plaintiff is entitled to have the Claims Paying Administrator consider the issue of FDA approval of the chemotherapeutic drugs involved in her protocol and its effect on the medical necessity of her proposed HDC/PSCR procedure. Section 8.2(b)(3) also provides a procedure for this issue to be reviewed by the Committee.

[9] Plaintiff is understandably unable to pay for the treatment herself and is not in a financial position to post a bond to secure repayment if ordered upon trial of this case.