IN THE DISTRICT COURT OF THE UNITED STATES
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
ASHEVILLE DIVISION

CIVIL NO. 1:94CV6

HELGA A. HAWKINS,

Plaintiff,

vs.

MAIL HANDLERS BENEFIT PLAN, and CIVILIAN HEALTH AND MEDICAL PROGRAMS OF THE UNIFORMED SERVICES (CHAMPUS),

Defendants.

MEMORANDUM OF OPINION AND ORDER

THIS MATTER comes before the Court on Plaintiff's Motion for Preliminary Injunction, filed January 14, 1994, in connection with her Complaint filed contemporaneously, as to Defendants Mail Handlers Benefit Plan ("Mail Handlers") and Civilian Health and Medical Programs of the Uniform Services ("CHAMPUS"). Upon proper notice and a hearing attended by all parties on January 20, 1994, and after due consideration of the pleadings and memoranda filed herein, the Court will deny the Motion as to Defendant Mail Handlers and grant the Motion as to Defendant CHAMPUS.

I. BACKGROUND

Plaintiff is a 61-year-old woman residing in Buncombe County, North Carolina. In May, 1993, she was diagnosed with Stage IV breast cancer which had metastasized to other

parts of her body. Plaintiff's treating physician, Dr. James B. Puckett of Asheville, North Carolina, has recommended high dose chemotherapy (HDC) with peripheral stem cell rescue (PSCR) as her best chance for survival. Plaintiff has been undergoing standard dose chemotherapy and is scheduled to begin the HDC/PSCR treatment on January 31, 1994.

Plaintiff maintains primary health coverage with Defendant Mail Handlers, with whom she filed an initial claim for pre-certification on November 14, 1993. After receiving an oral denial from said Defendant, Plaintiff renewed her request by letter dated December 24, 1993, which she also forwarded to the United States Office of Personnel Management (OPM) for expedited review. In her renewed request, Plaintiff alleged that while Defendant Mail Handlers' 1993 Plan by its terms excluded coverage for HDC/PSCR, the language of Mail Handlers' 1994 Plan had been amended so as to provide such coverage. Plaintiff further asserted in her December 24 letter that she had specifically waited until 1994 to receive treatment in order to take advantage of the amended coverage. By letter dated January 6, 1994, Defendant Mail Handlers again denied Plaintiff's claim as expressly excluded under its 1994 Plan and submitted the matter to OPM for review.

In the meantime, by letter dated November 11, 1993, Plaintiff filed a claim for pre-certification with Defendant CHAMPUS, who provides secondary health coverage to the Plaintiff. CHAMPUS subsequently denied Plaintiff's claim by letter dated November 16, 1993, on the grounds that HDC/PSCR was considered investigational and experimental and therefore excluded from coverage under the terms of its Plan. Plaintiff renewed her request on January 6, 1994, to which the Department of Defense, the appropriate reviewing agency, has not yet responded.

Pending review of her requests, Plaintiff filed her Complaint and Motion for Preliminary Injunction in this Court on January 14, 1994, pursuant to which a hearing was held on January 20, 1994, which all parties attended. At that time, the Court took the Plaintiff's Motion under advisement and allowed the parties to file supplemental pleadings up to and including January 24, 1994. At the time of the hearing, the Court was further informed that as of January 13, 1994, OPM had denied pre-certification for Plaintiff's HDC/PSCR treatment for the same reasons expressed by Defendant Mail Handlers, namely, that such treatment was explicitly excluded from coverage under Mail Handlers' 1994 Plan.

Although the matter comes before this Court after the conclusion of OPM's review, the matter was initially presented to the Court as a Motion for Preliminary Injunction, not (as Defendant Mail Handlers asserts) as an appeal of OPM's decision to deny coverage. The Court will conduct its analysis accordingly.[1] The Court would also like to commend all of the parties involved for their efforts in preparing this case for expedited resolution given the obvious import of the case to the Plaintiff.

II. ANALYSIS

A. Standard for Preliminary Injunction Generally

The Fourth Circuit has enumerated four factors for courts to consider in exercising their discretion under Fed. R. Civ. P. 65(a) to enter a preliminary injunction:

1. likelihood of irreparable harm to the plaintiff without the injunction;

---

[1] In any event, the Court finds that, whether it conducts its examination under the standards for a preliminary injunction or under the more deferential standards for administrative review, the results would be identical.

2. likelihood of harm to the defendant as a result of the injunction;

3. likelihood that plaintiff will succeed on the merits; and

4. the public interest.

Blackwelder Furniture Co. v. Seilig Mfg. Co., Inc., 550 F.2d 189, 195 (4th Cir. 1977).

Citing *Blackwelder*, Plaintiff's counsel asserts that where the likelihood of irreparable harm to the Plaintiff is great enough in light of the relatively insignificant financial harm incurred by the Defendants, the Court need not even consider the Plaintiff's likelihood of success on the merits. The Court recognizes the immense harm faced by the Plaintiff here, even with the benefit of the treatment currently sought, and Defendants' financial risks indeed pale in comparison. However, the Court is unwilling and unable to disregard completely the merits of Plaintiff's case and the likelihood of success thereof, especially in light of subsequent language in *Blackwelder* which states that:

> [I]t will ordinarily be enough that the plaintiff has raised questions going to the merits so serious, substantial, difficult and doubtful, as to make them fair ground for litigation and thus more deliberate investigation.

Id. (quoting *Hamilton Watch Co. v. Benrus Watch Co.*, 206 F.2d 738, 740, 743 (2d Cir. 1953)). In order to make such a determination, therefore, the Court must inquire into the merits of Plaintiff's case against each Defendant respectively.

B. Plaintiff's Coverage Under Mail Handlers' 1994 Plan

Ordinary rules of contract construction require an examination first of the natural or plain meaning of the policy language. *Landress Auto Wrecking Co. v. United States Fidelity*

& Guaranty Co., 696 F.2d 1290, 1292 (11th Cir. 1983). Unless there exists some ambiguity in the language of the policy, the Court must give effect to the plain meaning thereof. *Id.*

Here, the Court finds that Defendant Mail Handlers' 1994 Plan, while not a model of clarity, nevertheless expressly excludes from coverage the HDC/PSCR treatment being sought by Plaintiff. At page 16 of the 1994 Plan, under the heading "Inpatient Hospital Benefits" and following the subheading "Limited Benefits," the policy provides as follows:

> Chemotherapy when supported by bone marrow transplant or autologous stem cell support is covered only for specific diagnoses listed on page 19.

Under the general heading "Surgical Benefits" on page 19, following the subheading "What Is Covered," the Plan states:

> Benefits will be provided for the following transplants, subject to the limitations shown:
>
> * * *
>
> Bone marrow and stem cell support as follows:
>
> * * *
>
> Autologous bone marrow transplants (autologous stem cell and peripheral stem cell support) for: Leukemia in remission, resistant non-Hodgkins lymphomas, resistant or recurrent neuroblastoma, or advanced Hodgkins disease.

This subsection concludes on page 19 with the following statement:

> Chemotherapy when supported by a bone marrow transplant or autologous stem cell support is covered only for the specific diagnoses listed below.[2]

---

[2] As Defendant Mail Handlers concedes, this sentence was inadvertently carried forward from prior year brochures, in which the "specific diagnoses" for which HDC/PSCR was covered were, in fact, listed below the quoted language, as opposed to the present policy which now lists the qualifying diagnoses above the quoted language. Plaintiff points to this inconsistency as creating sufficient ambiguity in the policy so as to provide coverage where Plaintiff herself admits there was no such coverage previously. For the reason stated *infra*, the Court finds little merit in this contention.

Immediately thereafter on page 19, following the heading entitled "What Is Not Covered," the Plan lists the following:

> Services or supplies for or related to surgical transplant procedures for artificial or human organ/tissue transplants not specifically listed as covered, such as autologous bone marrow transplants for breast cancer. Related services or supplies include administration of chemotherapy when supported by transplant procedures.

Finally, on page 26 under the general heading "Other Medical Benefits" and following the subheading "What Is Not Covered," the policy lists the following:

> Chemotherapy supported by a bone marrow transplant, or with stem cell support, for any diagnosis not listed as covered on page 19.

As the language of the 1994 Plan clearly states, unless the patient's particular diagnosis is specifically listed on page 19, HDC/PSCR treatment in connection therewith is simply not covered. Significantly, breast cancer of any form is not among those enumerated diagnoses. Plaintiff points to the inconsistency created by the provision on page 19 that refers to diagnoses "listed below" as an ambiguity sufficient to warrant coverage for the HDC/PSCR treatment being sought here. She cites two instances in the policy "below" the language at issue that presumably provide for the coverage in question. First, on page 24 under the general heading "Hospital Outpatient Care," the Plan states that it "pays . . . [f]or chemotherapy and radiation therapy for the treatment of cancer . . . ." Furthermore, on page 25 under the heading of "Chemotherapy," the Plan states that it pays "[f]or doctors' outpatient services . . . rendered for chemotherapy . . . for treatment of cancer . . . ."

However, the Court finds that these provisions regarding chemotherapy generally are not inconsistent with an exclusion from coverage elsewhere in the policy of high dose chemotherapy in connection with bone marrow transplant or peripheral stem cell support.

See Nesseim v. Mail Handlers Ben. Plan, 995 F.2d 804, 807 (8th Cir. 1993). Plaintiff conceded at the hearing that absent the stray sentence on page 19 concerning diagnoses "listed below," the 1994 Plan would not otherwise provide for the coverage at issue here. This Court finds that such a mistake, while certainly not a model example of clarity or diligence, does not amount to an implicit change in coverage or to an ambiguity in the policy sufficient to warrant judicial imposition of coverage. In fact, throughout the Plan Plaintiff is otherwise reminded that "[c]hemotherapy when supported by bone marrow transplant or autologous stem cell support is covered only for specific diagnoses listed on page 19." Furthermore, Plaintiff had no reason to believe that her coverage had changed in this respect from the 1993 Plan, which Plaintiff concedes would clearly exclude her treatment, since no such change was identified or summarized by the Defendant in any of its documentation. Therefore, the Court finds that, by virtue of the plain meaning of the Defendant Mail Handlers' 1994 Plan, the HDC/PSCR treatment currently being sought by Plaintiff is not covered thereunder.

Accordingly, since the Court hereby determines that Plaintiff's likelihood of success on the merits is relatively small in light of the plain meaning of Defendant Mail Handlers' 1994 Plan, the Court finds that Plaintiff is not entitled to a preliminary injunction in connection therewith, notwithstanding the threat of irreparable harm that she otherwise faces.

C. Plaintiff's Coverage Under the CHAMPUS Policy

CHAMPUS' denial of Plaintiff's claim for pre-certification was based on language in its policy manual that precludes coverage for "experimental and investigational procedures or treatment regimens." Affidavit of Martha M. Maxey at 1. In order for the Court to determine whether or not HDC/PSCR qualifies as an experimental or investigational procedure under the CHAMPUS policy, the Court must again look to the specific language of the contract.

The general exclusion for experimental or investigational procedures in the CHAMPUS policy is set forth in 32 C.F.R. § 199.4(g)(15):

> Not in accordance with accepted standards, experimental or investigational. Services and supplies not provided in accordance with accepted professional medical standards; or related to essentially experimental or investigational procedures or treatment regimens.

The CHAMPUS policy manual, Chapter 8, Section 14.1, provides a non-exclusive list of 69 "investigational or experimental" procedures which do not qualify for benefits under the policy. Significantly, HDC/PSCR is not listed therein. The policy elsewhere defines "experimental" as:

> [m]edical care that essentially is investigatory or an unproven procedure or treatment regimen (usually performed under controlled medicolegal conditions) that does not meet the generally accepted standards of usual professional medical practice in the general medical community.

The definition goes on to include services provided under scientific research grants and drugs not approved by the FDA for commercial marketing as "experimental."

In support of its denial of benefits to Plaintiff, Defendant CHAMPUS submits to the Court a 1988 study conducted by the Office of Health Technology Assessment and a

January, 1990, evaluation prepared by the American Medical Association, both of which essentially characterize HDC/PSCR as an experimental or investigational treatment. In addition, CHAMPUS cites ongoing clinical trials, its continuous review of the medical literature, and the parameters of other insurance carrier policies as bases on which its decision was made. *See* Affidavit of David F. Bogner, M.D., at 4.

However, as Plaintiff points out, most of the evidence submitted by Defendant CHAMPUS on this issue is based on information which is no more recent than November, 1989.[3] As the Fifth Circuit recently noted:

> it is the nature of medical research that what may one day be experimental may the next be state of the art treatment. Had [the plaintiff] undergone a similar treatment [to HDC/PSCR] more recently under an accepted protocol, this case may have turned out differently.

Holder v. Prudential Ins. Co. of America, 951 F. 2d 89, 91 (5th Cir. 1992) (citing recent cases that have found HDC/PSCR not to be experimental). Furthermore, Plaintiff has submitted recent affidavits from five practicing oncologists, whom the Court finds to be fairly representative of the "general medical community" and who maintain that HDC/PSCR is not experimental or investigational but rather an accepted and established medical treatment for the Plaintiff's condition. *See generally* Affidavits of Drs. William West, Mark O'Rourke, Lee S. Schwartzberg, Gerald King, and James B. Puckett. Therefore, the Court finds that Plaintiff has succeeded in at least casting doubt on Defendant CHAMPUS' conclusions

---

[3] Defendant also cites a 1994 Journal of Oncology conference report which disapproves of the use of HDC/PSCR treatments outside the scope of clinical trials. Affidavit of David F. Bogner, M.D., at 4. However, even that report expressed some optimism at the prospects of the treatment's ultimate success. Id.

regarding the experimental or investigational nature of the HDC/PSCR treatment being sought here.

In assessing the merits of Plaintiff's case, therefore, the Court is mindful of the Seventh Circuit's recent observation that "there is a growing and confusing body of case law that addresses whether HDC-ABMT [autologous bone marrow transplant] is an experimental procedure for purposes of insurance coverage. The courts that have struggled with the issue have reached different outcomes." *Harris v. Mutual of Omaha Companies*, 992 F.2d 706, 713 n.4 (7th Cir. 1993). In light of this observation, and in light of the cases that Plaintiff has cited holding that HDC/PSCR is no longer considered experimental or investigational,[4] the Court finds that Plaintiff's likelihood of success on the merits of this issue is at least significant, if not substantial. The Court accordingly finds that Plaintiff is entitled to a preliminary injunction as to Defendant CHAMPUS.

III. CONCLUSION

Based on the foregoing, the Court will deny Plaintiff's Motion for Preliminary Injunction as to Defendant Mail Handlers, but will grant said Motion as to Defendant CHAMPUS pending a trial on the merits. Furthermore, pursuant to Fed. R. Civ. P. 65(c),

---

[4] *See, e.g., Helman v. Plumbers & Steamfitters Local 166 Health & Welfare Trust*, 803 F. Supp. 1407, 1413 (N.D. Ind. 1992) ("recent cases have determined that a finding that ABMT [autologous bone marrow transplant] is 'experimental' cannot be sustained even under the most deferential standard of review"); *White v. Caterpillar, Inc.*, 765 F. Supp. 1418, 1421-23 (W.D. Mo.), *aff'd* 985 F.2d 564 (8th Cir. 1991) (determination that HDC/ABMT considered "investigational" held to be arbitrary and capricious); *Bucci v. Blue Cross-Blue Shield, Inc.*, 764 F. Supp. 728, 732-33 (D. Conn. 1991) (HDC/ABMT held not to be experimental); *Adams v. Blue Cross/Blue Shield, Inc.*, 757 F. Supp. 661, 669-76 (D. Conn. 1991) (HDC/ABMT held not to be experimental).

the Court will order the Plaintiff to post security in an amount equal to her ownership share of the equity in her residence, which the Court understands to be approximately $25,000, in the event that Plaintiff is unable to prevail in a trial on the merits.

IV. ORDER

IT IS, THEREFORE, ORDERED that Plaintiff's Motion for Preliminary Injunction is hereby DENIED as to Defendant Mail Handlers Benefit Plan; and

IT IS FURTHER ORDERED that Plaintiff's Motion for Preliminary Injunction is hereby GRANTED as to Defendant Civilian Health and Medical Programs of the Uniformed Services (CHAMPUS); and that said Defendant is hereby RESTRAINED from denying health care coverage and benefits to the Plaintiff for Peripheral Stem Cell Rescue and for High Dose Chemotherapy in connection therewith for the treatment of Stage IV breast cancer, under the terms of the health care policy provided to her by said Defendant; and that said Defendant shall pay for the costs of such treatment during the period pending a trial on the merits; and

IT IS FURTHER ORDERED that Plaintiff give security in the amount equal to her ownership share of the equity in her residence, which the Court finds to be approximately $25,000; and

IT IS FURTHER ORDERED that a trial on the merits of this matter be scheduled by the Clerk of Court as soon as practicable.

THIS the 28th day of January, 1994.

RICHARD L. VOORHEES, CHIEF JUDGE
UNITED STATES DISTRICT COURT