Wilson v. Office of the Civilian Health & Medical Program of the Uniformed Servs. (CHAMPUS)

United States District Court for the Eastern District of Virginia, Newport News Division

October 21, 1994, Filed

Civil Action No. 4:94cv130

Reporter
866 F. Supp. 931 *; 1994 U.S. Dist. LEXIS 15476 **; 18 Employee Benefits Cas. (BNA) 2466

Gail Ann Wilson, Plaintiff, v. The Office of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), a subdivision of the Department of Defense of the United States of America, and William Perry, in his official capacity as the Secretary of Defense for the United States, Defendants.

Core Terms

experimental, cells, stem, coverage, arbitrary and capricious, breast cancer, bone marrow, Transplantation, investigational, Autologous, patients, chemotherapy, procedures, Rescue, Harden, administrative record, Peripheral, oncologist, clinical trial, technology, blood, preliminary injunction, permanent injunction, board certified, news release, high dose, administered, Phase

Case Summary

Procedural Posture
Plaintiff insured brought an action against defendant government insurer for a permanent injunction and declaration enjoining the insurer from denying the insured payment for certain medical procedures. The insurer moved for summary judgment.

Overview
The court considered the issue of whether the insurer acted arbitrarily and capriciously in determining that the treatment sought by the insured was not a covered benefit under the insurer's policy. The Court found that even given the very narrow standard of review, the insurer's conclusions regarding the experimental or investigational nature of the treatment being sought by Plaintiff were arbitrary and contrary to the evidence as set forth in the administrative record. The Court, having reviewed the administrative record and the additional filings, concluded that the insurer's denial based on the assertion that the procedure was investigational and experimental, was arbitrary and capricious because the insurer relied on material that was not up-to-date and a current news release about a report that had not been established as authoritative; while at the same time ignoring the views of board certified oncologists. The court further found that the procedure was not analogous to an excluded bone marrow transplant procedure and that the insurer could not deny coverage due to the lack of phase III clinical trials.

Outcome
The court granted the insured's motion for a permanent injunction, enjoined the insurer from denying coverage for the insured's medical procedure, and deemed the insurer's motion for summary judgment to be moot.

LexisNexis® Headnotes

Administrative Law > Judicial Review > Standards of Review > Arbitrary & Capricious Standard of Review

Administrative Law > Judicial Review > Standards of Review > General Overview

HN1[] **Standards of Review, Arbitrary & Capricious Standard of Review**

The scope of review under the arbitrary and capricious standard is narrow and a court is not to substitute its judgment for that of the agency. Nevertheless, the agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made. Agency action is arbitrary and capricious if the

agency relies on factors that Congress did not intend for it to consider, entirely ignores important aspects of the problem, explains its decision in a manner contrary to the evidence before it, or reaches a decision that is so implausible that it cannot be ascribed to a difference in view.

Counsel: **[**1]** For GAIL ANN WILSON, plaintiff: Timothy Gerard Clancy, Cummings, Hatchett, Moschel & Patrick, Hampton, VA. Robert E. Hoskins, Foster & Foster, Greenville, SC. Suzanne E. Coe, Greenville, SC.

For THE OFFICE OF CIVILIAN HEALTH AND MEDICAL PROGRAMS OF THE UNIFORMED SERVICES (CHAMPUS), A SUBDIVISION OF THE DEPARTMENT OF DEFENSE OF THE UNITED STATES OF AMERICA, WILLIAM PERRY, in his official capacity as the Secretary of Defense for the United States, defendants: Lawrence R. Leonard, Office of United States Attorney, Norfolk, VA.

Judges: Clarke, Jr.

Opinion by: J. CALVITT CLARKE, JR.

Opinion

[*931] ***ORDER***

This matter comes before the Court on Plaintiff's Motion for Declaratory and Injunctive **[*932]** Relief. Gail Ann Wilson ("the Plaintiff"), brings this action for a permanent injunction and declaration enjoining the Office of Civilian Health and Medical Program of the Uniformed Services, ("CHAMPUS") and William Perry, Secretary of Defense for the United States, (collectively the "Defendants") from denying Plaintiff payment for certain medical procedures. Defendants have moved for summary judgment. These claims are governed by ERISA, *29 U.S.C. § 1001 et. seq.*. For the reasons stated **[**2]** below, Plaintiff's motion is **GRANTED,** making Defendant's motion for surtimary judgment moot.

FACTS/BACKGROUND

Plaintiff is a forty-seven year old married female residing in Newport News, Virginia. The Plaintiff's husband, Jim Wilson, is retired Navy. As retired personnel, Mr. Wilson and his dependent wife maintain health benefits coverage with CHAMPUS, which is a subdivision of the Department of Defense of the United States Government.

In June 1994, Plaintiff was diagnosed with having Stage II breast cancer. [1] Plaintiff's treating physician, Dr. Elizabeth Harden, M.D. told the Plaintiff that her cancer was very aggressive and she recommended high-dose chemotherapy ("HDC") with peripheral stem cell rescue ("PSCR"). Dr. Harden is a board certified oncologist with experience in administering HDC to patients with breast cancer and other types of cancer. According to Dr. Harden, Plaintiff was to begin treatment as soon as possible, that was by September 26, 1994. Dr. Harden also stated that if Plaintiff did not begin treatment as soon as was possible, her condition would likely deteriorate to the point that she may not be able to receive the treatment or that her health would suffer **[**3]** from the lack of timely care. Dr. Harden states that HDC/PSCR represents the Plaintiff's best opportunity for long-term survival and sustained remission.

HDC/PSCR as it is to be administered to Plaintiff includes several stages. Currently, the Plaintiff is in the middle of the treatment. The first stage consists of the administration of low doses of chemotherapeutic agents, and Plaintiff has already undergone 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 the stage, Plaintiff will have the extra stem cells removed by a procedure known as leukapheresis. The stem cells will then be quickly frozen **[**4]** and stored in liquid nitrogen. Plaintiff is schedule to complete this stage of treatment the week of October 16, 1994.

Subsequent to the leukapheresis stage, Plaintiff will receive high doses of standard chemotherapeutic agents. Following the administration of the chemotherapeutic agents, Plaintiff's cancer cells should have been killed along with the healthy white blood stem cells. After the infusion of the above chemotherapy, Plaintiff will have her previously collected stem cells reinfused into her system so that her body will begin to rebuild the depleted stem cell count. Subsequent to re-administration of the stem cells, Plaintiff will likely be hospitalized for a short period for observation. Plaintiff is

[1] Currently, Plaintiff's cancer had advanced to stage III breast cancer; however, on July 15, 1994, the date CHAMPUS denied Plaintiff's pre-treatment coverage request, she had Stage II breast cancer.

scheduled to begin this stage of the treatment the week of October 31, 1994.

Plaintiff made a claim for a pre-treatment coverage commitment from the Defendant CHAMPUS which was denied on July 15, 1994. CHAMPUS denial was based on two grounds. First, CHAMPUS denied coverage stating that the treatment Plaintiff sought, the HDC/PSCR procedure, is analogous to the autologous bone marrow transplant procedure [2] and is therefore excluded from coverage **[*933]** pursuant to the CHAMPUS policy **[**5]** manual. Second, CHAMPUS stated that the HDC/PSCR procedure is "experimental" and "investigational" under the terms of its plan and is, therefore, excluded.

On September 23, 1994 the Court granted Plaintiff's Motion for Preliminary Injunction. The matter now comes before this Court in Plaintiff's Motion for a Permanent Injunction and Declaratory Judgment.

STANDARD OF REVIEW/PROCEDURAL POSTURE

The scope of review of the action against CHAMPUS is the arbitrary and capricious standard as established by the Administrative Procedures Act ("APA"). *5 U.S.C. § 706 (2)(A)*. (YEAR). *See also* Woods Psychiatric Institute v. United States, 925 F.2d 1454 (Fed. Cir. 1991). **[**6]** Generally, under the APA this Court must find the decision of the Department of Defense denying coverage for HDC/PSCR to be arbitrary, capricious, or not in accordance with the law. The Supreme Court has stated the appropriate standard for courts to apply in determining whether an action was arbitrary and capricious:

> HN1[↑] The scope of review under the "arbitrary and capricious" standard is narrow and a court is not to substitute its judgment for that of the agency. Nevertheless, the agency must examine the relevant data and articulate a satisfactory explanation for its action including a "rational connection between the facts found and the choice made." Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168, 9 L. Ed. 2d 207, 83 S. Ct. 239 (1962).

Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 77 L. Ed. 2d 443, 103 S. Ct. 2856 (1983). "Agency action is arbitrary and capricious if the agency relies on factors that Congress did not intend for it to consider, entirely ignores important aspects of the problem, explains its decision **[**7]** in a manner contrary to the evidence before it, or reaches a decision that is so implausible that it cannot be ascribed to a difference in view." Bedford County Memorial Hospital v. Health and Human Services, et. al., 769 F.2d 1017, 1022 (4th Cir. 1985) quoting Motor Vehicle, 463 U.S. at 43.

ANALYSIS

The issue in this case is whether the Defendants acted arbitrarily and capriciously in determining that the treatment sought by Plaintiff was not a covered benefit under the CHAMPUS policy. For the following reasons, the Court finds that the Defendants did act in an arbitrary and capricious manner in denying Plaintiff coverage.

1. CHAMPUS' Determination that HDC/PSCR Is an Experimental and Investigational Procedure Within the Meaning of CHAMPUS and Is Therefore Excluded.

Defendant argues that CHAMPUS' denial of Plaintiff's claim for pre-certification arose from language in its policy manual that precludes coverage for "experimental and investigational procedures or treatment regiments." In order for the Court to determine whether or not it was arbitrary and capricious for the Agency to **[**8]** contend that HDC/PSCR qualifies as an experimental or investigational procedure under the CHAMPUS policy, the Court must first look to the specific language of the regulations.

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.

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[2] Autologous Bone marrow Transplantation is a support procedure for HDC. This procedure is similar to PSCR in that they both provide a support means for an individual who is receiving HDC, yet it is important to note that they are different procedures. In ABMT, bone marrow is collected from a patient; whereas during the PSCR treatment white blood cells are collected.

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:

> medical 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 **[*934]** of usual professional medical practice in the general medical community.

In support of its denial of medical coverage, CHAMPUS **[**9]** submits to the Court the following list of materials from the administrative record that the agency relied on in making the initial determination that HDC/PSCR was an investigatory procedure:

1. The American Medical Association Diagnostic and Therapeutic Technology Assessment (AMA DATTA) evaluation of January 1990 entitled "Autologous Bone Marrow Transplantation - Reassessment" by Elizabeth Brown, M.D.;
2. The 1988 study entitled "Public Health Service Reassessment: Autologous Bone Marrow Transplantation" prepared by the Office of Health Technology Assessment, Agency for Health Care Policy and Research (OHTA/AHCPR) of the Public Health Service, and authored by Harry Handelsman, D.O.;
3. The June 1993 study entitled "autologous Bone Marrow Transplant and Peripheral Blood Stem Cell Rescue for the Treatment of Breast Cancer" copyright by ECRI, 5200 Butler Pike, Plymouth Meeting, PA 19462;
4. News releases concerning the most recent ECRI assessment of "Autologous Bone Marrow Transplant and Peripheral Blood Stem Cell Rescue for the Treatment of Breast Cancer."

Further, Dr. David Bogner, Medical Director of CHAMPUS, stated in an affidavit that since the time these reports were **[**10]** initially prepared, the Office of CHAMPUS has performed a continuous review of the referred medical literature and has had numerous confirming discussions with the OHTA regarding their position.

The Court, however, finds that in light of the factors set out below that even given the very narrow standard of review, CHAMPUS' conclusions regarding the experimental or investigational nature of the HDC/PSCR treatment being sought by Plaintiff were arbitrary and contrary to the evidence as set forth in the administrative record.

First, as Chief Judge Voorhees stated in *Hawkins v. Mail Handlers & CHAMPUS,* after reviewing both the 1990 evaluation prepared by the American Medical Association and 1988 study conducted by the OHTA, most of the evidence submitted by CHAMPUS on this issue is based on information which is no more recent than 1990. *Hawkins v. Mail Handlers & CHAMPUS,* No. 1:94cv6, slip. op. at 8-9 (W.D.N.C. Jan. 28, 1994). 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 **[**11]** protocol, this case may have turned out differently.

Holder v. Prudential Ins. Co. of America, 951 F.2d 89, 91 (5th Cir. 1992); *see also Gripkey v. Mail Handlers & CHAMPUS,* No. 3:94-378-0 (D.S.C. Feb. 14, 1994).

Second, CHAMPUS argued at the Preliminary Injunction Hearing that the new report by ECRI made this case distinguishable from the prior cases because, in making the determination to not cover the Plaintiff's desired treatment, Dr. Bogner considered a new piece of research which purports to be an extensive technology assessment of high-dose chemotherapy and stem cell rescue for metastatic breast cancer. [3] However, as candidly stated by the counsel for CHAMPUS during the Permanent Injunction Hearing, at the time that CHAMPUS issued the denial letter, on July 15, 1994, CHAMPUS did not have the actual ECRI Report, but rather relied on a two page news release about the **[*935]** ECRI Report. The Court finds reliance on this news summary unreasonable, arbitrary and capricious. In addition, after the 1994 ECRI Report was submitted

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[3] The study, published by ECRI, a nonprofit agency operating out of Plymouth Meeting, Pennsylvania, concluded that for patients with metastatic breast cancer HDC and Stem Cell Rescue has not shown itself to be better than conventional chemotherapy and that some previous studies finding otherwise were flawed by a biased design. *See Health Technology Assessment Report: Autologous Bone Marrow Transplantation and Peripheral Blood Stem Cell Rescue for the Treatment of Breast Cancer,* ECRI (May 1994) (the "ECRI Report"). However, as noted above, the Defendants did not even have the benefit of the full report but rather relied on a news release covering the Report.

to the Court at the Preliminary Injunction, the Court reviewed the report in its entirety and the Court has grave concerns **[**12]** about the ECRI Report.

During the Preliminary Injunction Hearing CHAMPUS introduced the entire ECRI Report and stated that Dr. Bogner relied upon the report in making his decision; yet, the record does not establish that Dr. Bogner is himself an oncologist and thus qualified to assess the persuasive value of the specialized ECRI Report. It was not until the **[**13]** Permanent Injunction Hearing that Defendant's counsel candidly admitted that the medical director was not relying on the entire report; but rather was looking only at a news release. Furthermore, although given numerous opportunities to do so, CHAMPUS expressly declined to present any evidence establishing the ECRI Report as independently reliable. [4] Lastly, the Court notes the following disclaimer which is stamped in red letters throughout the ECRI Report:

> NOTICE
> This is a preliminary draft and the property of ECRI. It is for your own use and should not be reproduced or transmitted to third parties. This draft will be changed upon receipt of information from our reviewers. The final published document may have significant changes.

By its own terms, the ECRI report is still under review and should be considered only a "preliminary draft" which is subject to "significant change." Therefore, this Court finds that in the light of previously decided cases, the submission of the 1994 ECRI Report does not cure the unreasonableness of CHAMPUS' decision.

[14]** Furthermore, the Court notes that in *Mashburn v. Mail Handlers & CHAMPUS,* the Middle District of Tennessee did consider an earlier draft of the ECRI Report, which is the third item listed by the CHAMPUS medical director in the instant case, and nevertheless found CHAMPUS' decision arbitrary and capricious. *Mashburn v. Mail Handlers & CHAMPUS, 1994 U.S. Dist. LEXIS 19779*, No. Civ.94-0549 (M.D.Tenn Aug. 4, 1994). opposition to Defendants' position, Plaintiff submitted a voluminous amount of material as part of the administrative record. Recent affidavits from two board certified oncologists, Dr. William H. West and Dr. Elizabeth Harden, indicate that the HDC/PSCR is in no way experimental or investigatory, but rather an accepted and established medical treatment for the Plaintiff's condition.

Dr. West, a board certified and practicing oncologist, stated in an affidavit "that it has been clearly established that the net health outcome for patients receiving HDC has improved just as much if not more than for patients receiving the alternative, standard dose chemotherapy, and the prospects of the patient obtaining a complete response with HDC as opposed to standard dose chemotherapy are significantly greater." **[**15]** April 1, 1994 Affidavit of Dr. William H. West. While Dr. West indicated that refinements to the HDC/PSCR procedure were still necessary, he also indicated that the treatment could neither be described as investigational nor experimental. He further stated that the treatment had been in existence for nearly ten years and had been generally accepted as a private community based treatment. Dr. West described how the prevalence of the treatment was rapidly increasing in the United States and was viewed optimistically by the majority of the oncology community.

Dr. Elizabeth Harden, Plaintiff's treating physician, also Board Certified in Internal Medicine and Oncology, has experience in **[*936]** administering high dose chemotherapy to patients with breast cancer and practices primarily in Hampton, Virginia. Dr. Harden testified that HDC is a widely accepted procedure in Virginia. Dr. harden stated in her affidavit that she did not feel there was any way the Plaintiff's treatment could said to be experimental or investigational, as the same has established efficacy, and the Plaintiff is an ideal candidate. She further stated that the treatment offered the Plaintiff her best chance for long term **[**16]** survival and sustained remission.

Also in the administrative record is the affidavit of Dr. Lee Schwartzberg, a practicing board certified oncologist in Memphis, Tennessee. Dr. Schwartzberg's affidavit indicates that his general opinion is that HDC/PSCR cannot reasonably be said to be experimental or investigational under any criteria. Furthermore, he states that he regards high dose chemotherapy treatment regimens as standard of care in his practice.

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[4] CHAMPUS did submit the affidavit of Jeffrey Lerner, Ph.D., ECRI's Vice President for Strategic Planning to show that ECRI is a nonprofit, tax-exempt health services research agency committed to the assessment, evaluation, and continued improvement of healthcare technology. The affidavit went on to state that the technology assessment reports, like the instant report, are prepared by full-time staff composed of doctoral-level clinicians and research scientist. However, the Court finds this affidavit insufficient to establish the reliability of the report. Mr. Lerner is not an oncologist or even a medical doctor nor does he state that any oncologists are involved in the health technology assessment program.

Plaintiff also made part of the administrative record the testimony from CHAMPUS' own expert witness, Dr. Bruce Cheson, that under clinical trials the procedure is non-investigational and non-experimental. See also *Wheeler v. Dynamic Engineering & CHAMPUS, 850 F. Supp. 459, 469 (E.D.Va. 1994)* ("In his deposition, Dr. Cheson admits that he accepts HDC/PSCR when administered in a clinical trial. The reasons he wants the procedure carried out within a clinical trial is so that proper records will be kept to improve the administration of the procedure to patients.").

The Court, having reviewed the administrative record and the additional filings, [5] concludes that CHAMPUS' denial based on the assertion that **[**17]** the HDC/PSCR procedure is investigational and experimental, is arbitrary and capricious. [6] Defendants' relied on material that was not up-to-date and a current news release about a report that has not been established as authoritative; while at the same time ignoring the views of board certified oncologists.

[18]** 2. CHAMPUS' Decision to Equate Peripheral Stem Cell Rescue Treatment with Autologous Bone Marrow Transplant Treatment.

The denial letter also states that the HDC/PSCR procedure is analogous to the autologous bone marrow transplant procedure and is therefore excluded from coverage pursuant to the CHAMPUS policy manual. The CHAMPUS policy excludes ABMT to support high dose cytoxic therapy for Stage IV breast cancer. *See* Volume I, Chapter III, Section 6.38245.1(d). Defendant argues **[*937]** that bone marrow transplantation and peripheral stem cell rescue accomplish the same thing, namely to provide the patient with stem cells capable of producing the various blood cell lines. Therefore, according to the government, the provisions of Chapter Three on marrow transplantation also apply to peripheral stem cell rescue. However, the Court finds such an extension arbitrary and capricious. As stated in *Wheeler,* "although the two procedures are similar in that they both provide support for a patient receiving high dose chemotherapy, the two are distinct procedures . . . . The section cited by CHAMPUS excluding coverage for autologous bone marrow transplantation does not apply to Plaintiff's **[**19]** case." *Wheeler, 850 F. Supp. at 468*. Furthermore, this argument, while appearing in the denial letter, was not raised by the Defendants in any briefs or arguments.

3. CHAMPUS' Denial of Coverage Due to Lack of Phase III Clinical Trials.

CHAMPUS, although not in a separately stated reason, also relied on the fact that the proscribed treatment is not conducted in a Phase III clinical trial setting. In arguing that the agency was rational in determining that the HDC/PSCR is still experimental, stated that the agency denies coverage of such treatment because it is not conducted in a Stage III clinical trial setting. [7]

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[5] According to cases such as *Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 28 L. Ed. 2d 136, 91 S. Ct. 814*; and *1902* ***Atlantic Ltd. v. Hudson, 574 F. Supp. 1381 (E.D. Va. 1983)***, although the Court is limited in an APA review to considering only the administrative record, there can be an exception permitting the Court to ask for and consider evidence (such as affidavits) outside the record to clarify matters which require additional information.

[6] The Court finds that four out of the five previously decided cases did indeed find that the denial of coverage by CHAMPUS was arbitrary and capricious. See *Hawkins v. Mail Handlers Benefit Plan & CHAMPUS,* No. 1:94cv6 (W.D.N.C. Jan. 28, 1994) ("the Court finds that, whether it conducts its examination under the standards for preliminary injunction or under the more deferential standards for administrative review, the results would be identical."); *Gripkey v. Mail Handlers Benefit Plan & CHAMPUS,* No. 3:94-378-0, (D.S.C. Feb. 14, 1994) ("The per se application of these rules to all decisions to decide whether or not a procedure is experimental is clearly arbitrary and capricious."); *Wheeler v. Dynamic Engineering and CHAMPUS, 850 F. Supp. 459 (E.D. Va. 1994)* ("The proper standard of review in the action against CHAMPUS is the arbitrary and capricious standard. . . . The Court, having heard the testimony of the expert witnesses, and having thoroughly reviewed all of the exhibits, concludes that CHAMPUS' denial of coverage for HDC/PSCR for the treatment of Stage IV breast cancer is unreasonable, arbitrary and capricious.") *Mashburn v. Mail Handlers Benefit Plan & CHAMPUS,* No. 3:94-0549 (M.D.Tenn. Aug. 4, 1994) (In a Motion for Permanent Injunction, the Court held "upon reviewing the administrative record and the filings, the Court finds that the denial of coverage by CHAMPUS was arbitrary and capricious and not supported by substantial evidence.") Furthermore, in *Gardner v. Mail Handlers Benefit Plan, et. al.,* United States District Court for the District of New Mexico, No. Civ. 94-0652 the one court that did not expressly mention the likelihood of success on the merits, did state that the factor was satisfied, noting that the Court was persuaded by the reasoning in *Wheeler, Gripkey* and *Hawkins.*

[7] The general argument concerning the absence of Phase III Clinical Trials applies to both CHAMPUS' reasons for excluding the HDC/PSCR treatment: the experimental and investigatory nature of the treatment argument and the analogous to ABMT argument.

However, defendant concedes that this policy is not in writing. In *Gripkey,* in issuing a preliminary injunction, the District of South Carolina was faced with this same argument. It held, "these criteria are no where set forth in the agency's official rule making. The per se application of these rules to all decisions to decide whether or not a procedure is experimental is clearly arbitrary and capricious." *Gripkey,* slip. op. at 6. Furthermore, in *Pirozzi v. Blue Cross-Blue Shield of Virginia,* Blue Cross relied heavily on the **[**20]** absence of phase III studies relating to the efficacy of HDCT-ABMT, [8] and the Court held that such reliance was misplaced. "The absence of extensive data comparing HDCT-ABMT treatment with a control group is relevant, but neither determinative nor ultimately persuasive of the treatment's status as an experimental medical practice." *Pirozzi v. Blue Cross-Blue Shield of Virginia, 741 F. Supp. 586, 593-94 (E.D. Va. 1990)*.

CONCLUSION

[21]** For the reasons stated above, Plaintiff's motion for permanent injunction is **GRANTED.** Defendants are hereby enjoined from denying coverage for Plaintiff's high-dose chemotherapy with peripheral stem cell rescue as treatment for her breast cancer. Defendant's motion for summary judgment is deemed to be moot and denied.

IT IS SO ORDERED.

J. Calvitt Clarke, Jr.

United States District Judge

Norfolk, Virginia

October , 1994.

End of Document

[8] Autologous Bone Marrow Transplantation is a support procedure for HDC. The purpose of this procedure is similar to PSCR in that they both provide a support means for an individual who is receiving HDC. It is important to note that they are different procedures. In ABMT, marrow is collected from a patient.