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

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

October 23, 1994, Filed

Civil Action No. 4:94cv130

Reporter
866 F. Supp. 903 *; 1994 U.S. Dist. LEXIS 15495 **; 18 Employee Benefits Cas. (BNA) 2458

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

cells, stem, experimental, preliminary injunction, merits, breast cancer, coverage, bone marrow, Transplantation, Autologous, injunction, Rescue, Mail, arbitrary and capricious, investigational, Peripheral, procedures, chemotherapy, argues, decisions, patients, Blood, doses

Case Summary

Procedural Posture

Plaintiff insured sought a preliminary injunction pursuant to *Fed. R. Civ. P. 65* to enjoin defendants, the Office of Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) and Secretary of Defense for the United States (Secretary), from denying the insured payment for certain medical procedures.

Overview

The insured sought to enjoin CHAMPUS and the Secretary from denying to pay for high-dose chemotherapy with peripheral stem cell rescue (HDC/PSCR) to treat her Stage II breast cancer. The court ordered that the Secretary and CHAMPUS were enjoined from denying the insured payment for the HDC/PSCR, holding that the balance of hardship analysis overwhelmingly favored the insured because she was suffering from a life threatening disease, while the Secretary and CHAMPUS only stood to lose money. There was a substantial likelihood that the insured would have succeeded on the merits of her claim because the insured could cast a doubt on the Secretary's and CHAMPUS' conclusions regarding the experimental nature of the HDC/PSCR treatment. The argument of the Secretary and CHAMPUS that they considered the HDC/PSCR experimental because it was not conducted in a Stage III clinical trial setting was without merit because the policy was not in writing. The public interest favored was served by the issuance of the injunction.

Outcome

The court granted the insured's motion for a preliminary injunction to enjoin the Secretary and CHAMPUS from denying to pay for her HDC/PSCR treatment.

LexisNexis® Headnotes

Civil Procedure > Remedies > Injunctions > Preliminary & Temporary Injunctions

Civil Procedure > ... > Injunctions > Grounds for Injunctions > General Overview

Civil Procedure > ... > Injunctions > Grounds for Injunctions > Public Interest

HN1[] **Injunctions, Preliminary & Temporary Injunctions**

The four factor test for considering injunctive relief is the 1) the likelihood of irreparable harm to the plaintiff if the preliminary injunction is not granted; 2) the likelihood of harm to the defendant if the preliminary injunction is granted; 3) the likelihood that the plaintiff will succeed

on the merits; and 4) the public interest. However, these factors are not weighted equally: the "balance of hardships" inquiry is the most important determination.

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

Military & Veterans Law > Servicemembers > Enlisted Personnel

Pensions & Benefits Law > Equal Protection > Veteran Discrimination

HN2[] Standards of Review, Arbitrary & Capricious Standard of Review

The standard of review is governed by the Administrative Procedure Act, *5 U.S.C.S. § 706*. Accordingly, in a hearing on the merits, the court must find the decision by The Office of the Civilian Health and Medical Program of the Uniformed Services to deny coverage to be arbitrary, capricious, or not in accordance with the applicable law.

Civil Procedure > Remedies > Injunctions > Preliminary & Temporary Injunctions

Civil Procedure > Remedies > Injunctions > General Overview

HN3[] Injunctions, Preliminary & Temporary Injunctions

Fed. R. Civ. P. Rule 65(c) provides that no preliminary injunction shall issue except upon the giving of a security by the applicant, in such sum as the court deems proper, for the payment of such costs and damages as may be incurred or suffered by any party who is found to have been wrongfully enjoined or restrained. *Fed. R. Civ. P. 65(c)*. While the decision whether to require a bond is strictly circumscribed by *Rule 65(c)*, the computation of the bond amount is soundly within the court's discretion.

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

[*904] ***MEMORANDUM ORDER***

This matter comes before the Court on the motion of Gail Ann Wilson, (the "Plaintiff"), who seeks a preliminary injunction pursuant to *Rule 65 of the Federal Rules of Civil Procedure* 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. For the following reasons, Plaintiff's motion is **GRANTED.**

FACTS

On September 26, 1994, the Plaintiff, Gail Ann Wilson, is scheduled to receive a medical procedure **[**2]** known as high-dose chemotherapy with peripheral stem cell rescue (HDC/PSCR). The HDC/PSCR is to treat her Stage II breast cancer. [1]

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

[1] It is not entirely clear from the arguments and memoranda which stage of breast cancer plaintiff is currently suffering. At several times throughout the arguments, affidavits and motions each party has referred to the plaintiff's condition as Stage III and Stage IV as well as Stage II. The Court finds that in the majority of evidence, including the Plaintiff's own affidavit, Stage II breast cancer is identified.

States Government.

In June 1994, Plaintiff was diagnosed with having Stage II breast cancer. Plaintiff's treating physician, Dr. Elizabeth Harden, M.D. told the Plaintiff **[**3]** 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 must begin treatment as soon as possible, that is by September 26, 1994. Dr. Harden also states that if Plaintiff does not begin the treatment in a timely fashion, her condition will likely deteriorate to the point that she may not be able to receive the treatment or that her health **[*905]** will suffer 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. 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 **[**4]** immediately subsequent to this stage, Plaintiff will have the extra stem cells removed by 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. 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 made a claim for a pre-treatment coverage commitment from the Defendant CHAMPUS and CHAMPUS denied the claim stating that the subject treatment is "experimental" and "investigational" under the terms of its plan and is, therefore, excluded.

Plaintiff requested an expedited review of Defendant's denial of coverage to her. Defendant conducted an expedited review and continued to deny coverage. Thereafter, **[**5]** Plaintiff filed a motion for a preliminary injunction enjoining the defendant from denying payment of Plaintiff's medical needs. Plaintiff has also filed a Complaint in this same action seeking declaratory relief and a permanent injunction. The Plaintiff has requested expedited hearings on the declaratory judgment action and on the permanent injunction action. The defendant objects to expedited hearings on those two claims, but agreed to a hearing on September 23, 1994 on the request for preliminary injunction. At the hearing, the defendant also filed a motion for summary judgment.

On September 23, 1994 the Court heard argument on the Plaintiff's Motion for Preliminary Injunction. The issue has been thoroughly briefed and supporting documents, affidavits and excerpts from sworn testimony have been received. CHAMPUS agreed that the hearing was proper as to timing. The issue on the preliminary injunction is now ripe for decision. There was no objection from either side as to the admissibility of the supporting documents, affidavits and excerpts from testimony submitted by both parties.

ANALYSIS

I. *The Blackwelder Standard:*

This Court's path in considering a motion **[**6]** for preliminary injunctive relief has been outlined very clearly by the Fourth Circuit Court of Appeals in *Blackwelder Furniture Co. v. Seilig Mfg. Co., 550 F.2d 189 (4th Cir. 1977)*. That case establishes the following ***HN1***[↑] four factor test:

> 1.) the likelihood of irreparable harm to the Plaintiff if the preliminary injunction is not granted;
>
> 2.) the likelihood of harm to the Defendant if the preliminary injunction is granted;
>
> 3.) the likelihood that the Plaintiff will succeed on the merits; and
>
> 4.) the public interest.

Id. at 195-96.

However, these factors are not weighted equally: the "balance of hardships" inquiry is the most important determination. Therefore, if the harm to the Plaintiff by failing to grant the injunction would greatly outweigh the

harm to the Defendant in issuing the injunction, the Plaintiff's burden of proving success on the merits is materially diminished. Accordingly, if the Plaintiff meets this threshold inquiry, then it will be sufficient that she raise questions going to the merits which are "so serious, substantial, difficult **[*906]** and doubtful as to make them fair ground for litigation and **[**7]** thus for more deliberate investigation." *Id. at 195*.

HN2[↑] The standard of review is governed by the Administrative Procedure Act (APA), *5 U.S.C. § 706*. *Woods Psychiatric Inst. v. United States, 925 F.2d 1454 (Fed. Cir. 1991)*. Accordingly, in a hearing on the merits, this Court must find the decision by CHAMPUS to deny coverage for HDC/PSCR to be arbitrary, capricious, or not in accordance with the applicable law. In order to grant the Motion for Preliminary Injunction the Court must find that the Plaintiff, taking in consideration the deference and weight to be given to the decision of the Director of CHAMPUS, must have raised questions going to the merits which are "so serious, substantial, difficult and doubtful as to make them fair grounds for litigation and thus for more deliberate investigation." *Blackwelder, 550 F.2d at 195*.

A. Balance of Harms:

In the instant case, the Court finds that the balance of hardship analysis overwhelmingly favors the Plaintiff. The Plaintiff is suffering from Stage II breast cancer, a life threatening disease. Her private practitioner, **[**8]** Dr. Elizabeth Harden, a board certified oncologist, has stated by affidavit that the prescribed treatment must begin immediately or her condition may deteriorate to the point where Plaintiff's body could no longer withstand treatment.

Indeed, the Defendant cannot seriously argue against this Court's finding that the balance of harms analysis strongly favors the Plaintiff: CHAMPUS may loose some money; the Plaintiff may loose her life. In fact, the government does not even argue this point in its brief or in oral argument. Therefore, recognizing the immense harm faced by the Plaintiff, and contrasting that with the relatively minor harm before CHAMPUS, this Court moves to the second *Blackwelder* factor.

B. Substantial Question on the Merits:

Defendant CHAMPUS argues that the Plaintiff is not likely to success on the merits and therefore a preliminary injunction should not issue. As pointed out above, because the harm to the Plaintiff by failing to grant the injunction would greatly outweigh the harm to the Defendant in issuing the injunction, the Plaintiff's burden of proving success on the merits is materially diminished. *Blackwelder, 550 F.2d at 196*. **[**9]**

Defendant presented an array of arguments concerning the Plaintiff's likelihood of success on the merits; the Court reviews these arguments in turn:

1. Plain Language of the Policy

Defendant argues that under the arbitrary and capricious standard 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 regiments." 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 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.

The CHAMPUS policy manual, Chapter 8, Section 14.1, provides a non-exclusive list of 69 "investigational or experimental" procedures which **[**10]** 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 of usual professional medical practice in the general medical community.

[*907] In support of its denial of medical coverage, CHAMPUS submits to the Court the following list of materials 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 **[**11]** 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 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, the plaintiff has at least cast a doubt on CHAMPUS' conclusions regarding the experimental or investigational nature of the HDC/PSCR treatment being sought by plaintiff.

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 **[**12]** 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 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 argues that the new report by ECRI makes 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. That study, published by ECRI, a nonprofit agency operating out of Plymouth Meeting, Pennsylvania, concluded that for patients with metastatic breast cancer HDC and Stem **[**13]** 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").

Initially, the Court notes that CHAMPUS' position is not entirely precise: the Court in *Mashburn v. Mail Handlers & CHAMPUS,* did consider an earlier draft of the ECRI Report and nevertheless found CHAMPUS' decision arbitrary and capricious. *Mashburn v. Mail Handlers & CHAMPUS,* No. Civ. 94-0549 (M.D. Tenn. Aug. 4, 1994). However, even assuming that the evidence presented is entirely new, the Court nevertheless has reservations about the ECRI Report.

Although it is undisputed that Dr. Bogner relied upon the report in making his decision, **[*908]** 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. Furthermore, although given numerous opportunities to do so, CHAMPUS expressly declined to present any evidence establishing the ECRI Report as **[**14]** independently reliable. 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 displace the substantial questions which the Plaintiff has raised on the merits.

In opposition to defendants' position, Plaintiff has submitted recent affidavits from two board certified oncologists, Dr. William H. West and Dr. Elizabeth Harden, which 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. Plaintiff also relies on testimony from CHAMPUS' own expert witness, Dr. Bruce Cheson, that under **[**15]** 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.")

2. CHAMPUS Is Due Substantial Deference.

CHAMPUS asserts that this Court cannot merely find that the Plaintiff has raised a substantial question regarding the decision that HDC/PSCR is experimental or investigational. It asserts that since this determination was made by a specialized agency pursuant to the task delegated to it by Congress, its decisions is due substantial deference. Accordingly, CHAMPUS argues that its decision would have to have been arbitrary, capricious or unreasonable for this Court to overturn it. [2] While true as a matter of law regarding the Plaintiff's burden at a full trial, it is sufficient for a preliminary injunction under *Blackwelder* that the Plaintiff demonstrate that she has raised a **[**16]** serious question that, at trial, CHAMPUS' decision will be found arbitrary and capricious. *Blackwelder, 550 F.2d at 195*. Defendant further argues that no other Court has looked at the issue in this procedural light. However, 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 **[**17]** testimony of the expert witnesses, and having thoroughly reviewed all of the exhibits, concludes that CHAMPUS' **[*909]** 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.*

[18]** Defendant, 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. 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 absence of phase III studies relating to the efficacy of HDCT-ABMT, [3] 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*

[2] On September 23, 1994 CHAMPUS submitted a Memorandum in support of Motion for Summary Judgment and in Opposition to Plaintiff's Motion for Preliminary Injunction and at times it is unclear to the Court which arguments apply to each particular motion.

[3] 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, it is important to note that they are different procedures. In ABMT, marrow is collected from a patient.

Virginia, 741 F. Supp. 586, 593-94 (E.D. Va. 1990). **[**19]**

3. Prior Decisions Not Binding.

Defendant's next argument is that the prior decisions involving CHAMPUS are not binding on this Court because they do not contain precisely the same administrative record that is before the Court in the instant matter. However, CHAMPUS conceded in oral argument that the only substantial difference in the administrative record in this instance as compared to the administrative record in the *Wheeler* case is the addition of the May 1994 report by ECRI. As pointed out above, the Court gives no weight to the ECRI report based on the evidence currently before the Court.

4. Peripheral Stem Cell Rescue Is the Same as Autologous Bone Marrow Transplantation

Defendant also argues that the HDC/PSCR procedure **[**20]** 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 autologous bone marrow transplantation to support high dose cytoxic therapy for Stage IV breast cancer. *See* Volume I, Chapter III, Section 6.38245.1(d). However, as clearly stated in *Wheeler,* it is clear that Plaintiff is not having a bone marrow transplant, rather, Plaintiff is having a peripheral stem cell rescue. "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 case." *Wheeler, 850 F. Supp. at 468*.

C. The Public Interest:

Blackwelder also requires that this Court make a finding regarding the public's interest in this case. *Blackwelder, 550 F.2d at 196*. The Court finds that the public interest very much favors the meeting by the Government of its obligations to its military retirees **[*910]** and their dependents, particularly **[**21]** those dependents in life threatening situations.

II. *The Bond Requirement:*

HN3[↑] *Rule 65(c)* provides that "no . . . preliminary injunction shall issue except upon the giving of a security by the applicant, *in such sum as the court deems proper,* for the payment of such costs and damages as may be incurred or suffered by any party who is found to have been wrongfully enjoined or restrained. *Fed. R. Civ. Pro. 65(c)* (emphasis added). While the decision whether to require a bond is strictly circumscribed by *Rule 65(c)*, the computation of the bond amount is soundly within the Court's discretion. *Id.; see also Maryland Dep't of Human Resources v. United States Dep't of Agriculture, 976 F.2d 1462, 1483 (4th Cir. 1992)*.

In this case, the Court finds that the Plaintiff is without adequate resources to post a bond in any meaningful amount. CHAMPUS has offered no evidence to the contrary, and did not address this issue at either oral argument or in its brief. Furthermore, this Court notes the extreme urgency with which this injunction must be issued, the dire circumstances surrounding the Plaintiff's health, and the substantial likelihood that the Plaintiff **[**22]** will prevail on the merits of her claim.

It is apparent that to require a bond would not only defeat the Plaintiff's otherwise meritorious claim, it may also cost the Plaintiff her life. However, while no Fourth Circuit case is directly on point, the Court believes that the permissive language of *Rule 65(c)* provides it with the discretion necessary to avoid this unspeakably harsh result. Accordingly, in its discretion, and in accordance with the express language of *Rule 65(c)*, the Court finds that the Plaintiff shall be required to post a bond of zero dollars. *See Warner v. Ryobi Motor Products Corp., 818 F. Supp. 907, 909 (D.S.C. 1992)*(requiring bond of only $ 250 where Plaintiff had limited financial resources); *Kulakowski v. Rochester Hosp. Serv. Corp., 779 F. Supp. 710, 717 (W.D.N.Y. 1991)*(requiring no bond amount where Plaintiff showed inability to pay).

CONCLUSION

Therefore, under the analysis set forth in Blackwelder, this Court finds that the Plaintiff has met her dual burden: first, she has demonstrated that the balance of the harms strongly favors the Plaintiff's position; second, she has shown that there **[**23]** is a substantial likelihood that Plaintiff will succeed on the merits of this case. Accordingly, it is hereby ORDERED that the Office of the Civilian Health and Medical Program of the Uniformed Services and the Secretary of Defense for the United States, William Perry, are preliminarily enjoined from denying payment to Gail Ann Wilson for high-dose chemotherapy with peripheral stem cell

rescue until a hearing is conducted on the merits of this case and the issues which have been presented are decided. The Court notes that this matter has been set for hearing on October, 17 1994 on the Complaint for Declaratory Judgment and Permanent Injunction, at which time the Court will consider any new evidence and argument presented by either party.

The Clerk is directed to mail a copy of this Order to all counsel of record.

IT IS SO ORDERED.

United States District Judge

Norfolk, Virginia

September , 1994

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