



Mashburn v. Mail Handlers Benefit Plan

United States District Court for the Middle District of Tennessee, Nashville Division

August 4, 1994, Decided ; August 4, 1994, Entered

No. 3:94-0549

Reporter

1994 U.S. Dist. LEXIS 19779 *; 18 Employee Benefits Cas. (BNA) 2668

PEGGY JO MASHBURN v. MAIL HANDLERS BENEFIT PLAN, the OFFICE OF CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES (CHAMPUS), a subdivision of the United States of America, and WILLIAM PERRY, in his official capacity as Secretary of Defense for the United States of America

denial of coverage by CHAMPUS was arbitrary and capricious, that it was not supported by substantial evidence, that the treatment was not experimental and was supported by the medical community, that equitable relief through a permanent injunction was the appropriate form of relief, and that there was no adequate legal relief available to the patient.

Core Terms

experimental, coverage, permanent injunction, breast cancer, arbitrary and capricious, substantial evidence, bone marrow, injunction, transplant, parties, medical community, oncologists, Services, patient

Outcome

The court granted the permanent injunction and enjoined CHAMPUS from denying coverage for the patient's breast cancer treatment.

Case Summary

Procedural Posture

Plaintiff patient filed an action against defendants, employee benefit plan and the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), that sought an order permanently enjoining defendants from denying coverage for the patient's breast cancer treatment. CHAMPUS filed an opposition to the patient's action.

Civil Procedure > Preliminary Considerations > Equity > General Overview

[HN1](#) Preliminary Considerations, Equity

A district court is vested with broad discretionary power in shaping equity decrees. Equitable remedies are a special blend of what is necessary, what is fair, and what is workable.

Overview

The patient had health insurance coverage through her husband's employment and his status as a former member of the military. The patient was diagnosed with an advanced stage of breast cancer and made claims for pre-treatment coverage from the employee benefit plan and CHAMPUS. Both plans denied the patient's claim and argued that the treatment was experimental and investigational and was therefore not covered. The patient filed an action for a permanent injunction against the employee benefit plan and CHAMPUS and CHAMPUS opposed the action. The matter was expedited because of the patient's failing health and the court granted the injunction. The court found that the

Civil Procedure > Remedies > Injunctions > Permanent Injunctions

[HN2](#) Injunctions, Permanent Injunctions

An injunction involves a balancing of the interests of the parties who might be affected by the court's decision. The main requirement for obtaining injunctive relief is a finding by the court that a plaintiff is being threatened by some injury for which she has no adequate legal

remedy. The legal remedy is inadequate if any one of a number of factors is present. Such factors include monetary award would be speculative, legal relief requires multiple actions, a continuing injury or damages would not adequately compensate the plaintiff.

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

[HN3](#) **Injunctions, Grounds for Injunctions**

The most common method of demonstrating that a legal remedy is inadequate is by showing that the plaintiff will suffer irreparable harm if the court does not intervene. **The plaintiff must demonstrate that the irreparable injury contemplated is real and actual, not prospective.**

Administrative Law > Judicial Review > Standards of Review > Abuse of Discretion

Environmental Law > Administrative Proceedings & Litigation > Judicial Review

Administrative Law > Agency Rulemaking > Formal Rulemaking

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

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

[HN4](#) **Standards of Review, Abuse of Discretion**

Where an agency action is involved in a controversy, the standard of review is governed by the Administrative Procedure Act, 5 U.S.C.S. § 706, which states that the reviewing court shall hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

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

Environmental Law > Administrative Proceedings & Litigation > Judicial Review

Administrative Law > Judicial Review > Standards of Review > Substantial Evidence

[HN5](#) **Standards of Review, Arbitrary & Capricious Standard of Review**

When reviewing an agency action, a court must affirm unless the action is arbitrary or capricious or unsupported by substantial evidence. Substantial evidence is relevant evidence as a reasonable mind might accept as adequate to support a conclusion. An agency's action is due deference and a reviewing court may not reverse the action merely because it would have interpreted the regulation in a different manner.

Healthcare Law > ... > Insurance Coverage > Health Insurance > Experimental Treatment

Military & Veterans Law > Veterans > General Benefits > Hospitals, Medical Care & Nursing Homes

Military & Veterans Law > Servicemembers > Enlisted Personnel

[HN6](#) **Health Insurance, Experimental Treatment**

[32 C.F.R. § 199.4\(g\)\(15\)](#) excludes from coverage medical treatment which is not in accordance with accepted standards, experimental or investigational.

Military & Veterans Law > Veterans > General Benefits > Hospitals, Medical Care & Nursing Homes

Pensions & Benefits Law > Equal Protection > Veteran Discrimination

Military & Veterans Law > Servicemembers > Enlisted Personnel

[HN7](#) **General Benefits, Hospitals, Medical Care & Nursing Homes**

Experimental is defined under [32 C.F.R. § 199.2](#) 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. For the purposes of the Civilian Health and Medical Programs of the Uniformed Services, any medical services or supplies provided under a scientific research grant, either public or private are classified as experimental. Use of drugs and medicines and devices not approved by the U.S. Food and Drug Administration for commercial marketing, that is for general use by humans also is considered experimental.

Counsel: [*1] For PEGGY JO MASHBURN, plaintiff: Michael Alan Meyer, Sidwell & Barrett, Franklin, TN. Robert E. Hoskins, Foster & Foster, Greenville, SC.

For CIVILIAN HEALTH AND MEDICAL PROGRAMS OF THE UNIFORMED SERVICES (CHAMPUS), WILLIAM PERRY, defendant: Robert C. Watson, Michael L. Roden, Office of the United States Attorney, Nashville, TN.

Judges: JOHN T. NIXON, CHIEF JUDGE, UNITED STATES DISTRICT COURT

Opinion by: JOHN T. NIXON

Opinion

MEMORANDUM

Pending before the Court is Plaintiff's Motion for Permanent Injunction (Doc. No. 11), filed on July 21, 1994, to which Defendant CHAMPUS filed an Opposition (Doc. No. 14) on July 22, 1994. Pursuant to a telephone conference with the Court on July 15, 1994, the parties agreed to a decision by the Court based on the briefs and administrative record filed with the Court. For the reasons stated below, the Court grants Plaintiff's Motion for Permanent Injunction.

I. BACKGROUND

The Plaintiff, Peggy Jo Mashburn, is a fifty-nine year-old married female. Her husband Bobby Mashburn is employed with the United States Government, and through his employment he maintains health insurance coverage for them through the Mail Handlers Benefit Plan ("Mail Handlers"). Also, as a retired Marine, Plaintiff's husband maintains health insurance coverage with CHAMPUS, which is a subdivision of the United States Government. Both Mail Handlers and CHAMPUS

were initially named as Defendants in this action.¹

[*2] In April of 1993, Plaintiff was diagnosed with Stage IV breast cancer which is advanced breast cancer. The Plaintiff's physician, Dr. Greco, recommends Plaintiff undergo high-dose chemotherapy ("HDC") with peripheral stem cell rescue ("PSCR").² [*3] Dr. Greco asserts that this treatment represents Plaintiff's best opportunity for sustained health and life. Moreover, he states that if Plaintiff does not receive the treatment in a timely fashion, Plaintiff's condition will likely deteriorate to the point where she may not be physically able to withstand this particular type of treatment. Plaintiff states that she does not have the money to pay for the subject treatment and without a guaranty of payment, the provider of the treatment will be unable to provide the treatment to the Plaintiff.³

Plaintiff made a claim for a pre-treatment coverage commitment from both Defendants and both denied Plaintiff's claim. Defendant Mail Handlers claims to have a specific exclusion for the subject treatment, while Defendant CHAMPUS claims the subject treatment is "experimental" and "investigational" under the terms of its plan and is therefore excluded. Thereafter, Plaintiff filed a Motion for Expedited Trial on July 7, 1994, seeking a declaration of coverage by one or both of the Defendants.

After a telephone conference with the Court on July 15, 1994, the parties agreed to submit the administrative record and any filings the parties wanted the Court to consider in making its decision. Pursuant to this agreement, Plaintiff filed a Motion for Permanent Injunction to which Defendant filed an Opposition.

II. STANDARD OF REVIEW

¹After Plaintiff filed her complaint, all parties agreed and stipulated that Mail Handlers could be dismissed because it likely has no coverage. Thus, the Court's decision on Plaintiff's Motion for Permanent Injunction only affects Defendant CHAMPUS.

²The HDC/PSCR treatment is administered in several stages and the Plaintiff has already undergone the first stage which entails low doses of chemotherapeutic agents. The next stage involves moderate doses of chemotherapeutic agents followed by removal of blood components known as stem cells. In the final stage the Plaintiff will receive high doses of chemotherapeutic agents followed by being reinfused with the previously collected stem cells.

³The subject treatment is estimated to cost between \$ 80,000 and \$ 150,000.

Initially, the Court notes that [HN1](#) a district court is vested with broad discretionary power in shaping equity decrees. [Lemon v. Kurtzman, 93 S. Ct. 1463, 1469-70, 411 U.S. 192, 201, 36 L. Ed. 2d 151 \(1973\) \[*4\]](#) (per Burger, C.J.). "Equitable remedies are a special blend of what is necessary, what is fair, and what is workable." *Id.* [HN2](#) An injunction involves a balancing of the interests of the parties who might be affected by the court's decision. See C. Wright & A. Miller, 11 *Federal Practice and Procedure*, § 2942 at 367-68 (1973). The main requirement for obtaining injunctive relief is a finding by the court that plaintiff is being threatened by some injury for which she has no adequate legal remedy. [Detroit Newspaper Publishers Ass'n v. Detroit Typographical Union No. 18, 471 F.2d 872, 875-77 \(6th Cir. 1972\)](#), certiorari denied 93 S. Ct. 2149, 411 U.S. 967, 36 L. Ed. 2d 687. The legal remedy is inadequate if any one of a number of factors is present. Such factors include monetary award would be speculative, legal relief requires multiple actions, a continuing injury or damages would not adequately compensate plaintiff. See generally C. Wright & A. Miller, 11 *Federal Practice and Procedure* § 2944 at 397-99 (1973). [HN3](#) The most common method of demonstrating that a legal remedy is inadequate, [*5] however, is by showing that plaintiff will suffer irreparable harm if the court does not intervene. *Id.* Plaintiff must demonstrate that the irreparable injury contemplated is real and actual, not prospective. [Detroit Newspaper, 471 F.2d at 877.](#)

The Court also recognizes that [HN4](#) because an agency action is involved in this controversy, the standard of review is governed by the Administrative Procedure Act ("APA"), 5 U.S.C. § 706.

The reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be...arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

5 U.S.C. § 706(2)(A). The Sixth Circuit has held that [HN5](#) when reviewing an agency action, a court must affirm unless the action is arbitrary or capricious or unsupported by substantial evidence. [Medical Rehabilitation Services, P.C. v. Shalala, 17 F.3d 828, 831 \(6th Cir. 1994\)](#). Substantial evidence is relevant evidence as a reasonable mind might accept as adequate to support a conclusion. *Id.* (citations omitted). An agency's [*6] action is due deference and a reviewing court may not reverse the action merely because it would have interpreted the regulation in a different manner. *Id.*

III. DISCUSSION

Plaintiff contends she is entitled to coverage from CHAMPUS in that she has complied with all of the terms and conditions of the health plan and because the plan provides for coverage of such treatment. Defendant CHAMPUS, however, contends that its insurance coverage is a statutory entitlement program and the agency's interpretation of the governing regulation was not arbitrary or capricious, but rather was an administrative decision supported by substantial evidence.

CHAMPUS's denial of Plaintiff's request for pre-treatment coverage was based on the general exclusion for experimental or investigational procedures in the CHAMPUS policy as set forth in [32 C.F.R. § 199.4\(g\)\(15\)](#). [HN6](#) [Section 199.4\(g\)\(15\)](#) excludes from coverage medical treatment which is "not in accordance with accepted standards, experimental or investigational." [HN7](#) The CHAMPUS policy defines "experimental" as:

medical care that essentially is investigatory or an unproven procedure or treatment regimen (usually performed under controlled medicolegal [*7] conditions) that does not meet the generally accepted standards of usual professional medical practice in the general medical community. . . .For the purposes of CHAMPUS, any medical services or supplies provided under a scientific research grant, either public or private are classified as 'experimental.' Use of drugs and medicines and devices not approved by the U.S. Food and Drug Administration (FDA) for commercial marketing, that is for general use by humans also is considered experimental.

[32 C.F.R. § 199.2.](#)

The CHAMPUS position regarding the experimental nature of HDC/PSCR is based upon a 1988 study conducted by the Office of Health Technology Assessment ("OHTA"), ⁴ [*8] a January, 1990 evaluation prepared by the American Medical Association Diagnostic and Therapeutic Technology Assessment ("AMA DATTA"), ⁵ and a June 1993 study

⁴The study is entitled "Public Health Service Reassessment: Autologous Bone Marrow Transplantation" and was prepared by the OHTA and authored by Harry Handelsman.

⁵The evaluation is entitled "Autologous Bone Marrow Transplantation Reassessment" and was authored by Dr. Elizabeth Brown.

published by ECRI.⁶ All of these studies essentially characterize HDC/PSCR as experimental treatment. In addition, CHAMPUS noted there had been no new evidence which would warrant a departure from the original coverage determination.

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.

First, the Court notes that the HDC/PSCR treatment does not fall under any of the CHAMPUS definitions of "experimental" as provided in the CHAMPUS regulations. See 32 C.F.R. § 199.2. For example, the drugs/medicines used for the treatment are approved by the FDA. The medical services to be provided in this case would not be provided under a scientific research grant. The medical treatment is not an unproven procedure which does not meet the generally accepted standards of usual professional medical practice in the general medical community. From the evidence presented to Defendant by Plaintiff, it seems clear that the medical community now supports [*9] this treatment. In fact, Plaintiff submitted to Defendant for consideration the affidavits of four local oncologists who stated that the procedure was not experimental and that they have used the procedure on other breast cancer patients. Moreover, the Plaintiff submitted to the Defendant a letter from leading American oncologists and bone marrow transplant specialists stating that the treatment was not considered experimental in the medical community.

Second, the Court especially finds the Defendant's denial was arbitrary and capricious in that it either failed to consider or obviously gave little weight to the most relevant aspect of all--the opinion of the medical oncological community. In Defendant's June 27, 1994, letter informing Plaintiff of its decision not to cover the subject treatment, Defendant invited Plaintiff to submit pertinent documentation to support the position that HDC/PSCR does "meet the generally accepted standards of usual professional medical practice in the general medical community" if Plaintiff disagreed with its determination. Plaintiff submitted an overwhelming amount of evidence to that effect. As stated earlier, Plaintiff submitted to Defendant for [*10] consideration the opinions of four local oncologists, including Dr. Ray

⁶The study is entitled "Autologous Bone Marrow Transplant and Peripheral Blood Stem Cell Rescue for the Treatment of Breast Cancer."

Lamb, Dr. Tony Greco, Dr. Lee Schwartzberg, and Dr. William H. West. All four of these local oncologists testified that they considered the HDC/PSCR treatment to be established and not experimental.

Moreover, Plaintiff submitted to Defendant a letter from the Directors/Physicians of top oncological centers across the country. In that letter the Directors strongly supported paying for bone marrow transplant procedures for breast cancer. Also, Plaintiff submitted to Defendant evidence that the American Society of Clinical Oncology ("ASCO") recently issued a position paper outlining under what circumstances a third party payor should provide coverage for a specific treatment. Based on those circumstances, the HDC/PSCR at issue meets every term established by the ASCO for reimbursement.

While the Court realizes Defendant has a hierarchy of assessment sources used to evaluate emerging medical technologies,⁷ the Court points out that Defendant's own hierarchy has national professional medical associations (i.e. ASCO) before national expert opinion organizations (i.e. DATTA). Therefore, by the Defendant's own hierarchy [*11] of sources, it should have given greater weight to the ASCO opinion that HDC/PSCR is not experimental and should be covered than the DATTA opinion that the treatment is still experimental. Moreover, the DATTA opinion is over four years old while the ASCO position is very recent.

The Court finds it was unreasonable for the Defendant to rely on outside scientific opinion to such an extent that it selectively ignored the professional opinions of both national and local oncologists, as well as Plaintiff's treating physicians. In light of all this evidence presented to Defendant, it seems clear there is evidence which would warrant Defendant changing its original coverage determination despite the Defendant's argument to the contrary. Furthermore, the Defendant's administrative decision is not supported by substantial evidence. In fact, the great weight of the evidence appears to be in favor of determining that the subject treatment is not experimental.

Third, the Court finds [*12] it noteworthy that many other federal courts have determined that findings which hold that the HDC/PSCR and/or a similar procedure known as autologous bone marrow transplant ("ABMT") is "experimental" cannot be sustained even under the most deferential standard of review. See *Helga A.*

⁷ See *Bogner Aff.* P 11. (Doc. No. 14.)

Hawkins v. Mail Handlers Benefit Plan and Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), CV No. 1:94 CV6, 1994 WL 214262 (W.D. N.C. Jan. 28, 1994) (granting preliminary injunction to breast cancer patient and requiring CHAMPUS to pay for HDC/PSCR; recognizing the results would be identical under either standards for preliminary injunction or standards for administrative review); *Kekis v. Blue Cross/Blue Shield of Utica Watertown, Inc.*, 815 F. Supp. 571 (N.D.N.Y. 1993); *Helman v. Plumbers & Steamfitters Local 166*, 803 F. Supp. 1407, 1413 (N.D.Ind. 1992) (holding incorrect a determination to deny benefits on grounds that medical treatment known as ABMT was "experimental"); *Wilson v. Group Hospitalization and Medical Services, Inc.*, 791 F. Supp. 309, 313 (D.D.C. 1992) (holding that plans [*13] can no longer exclude ABMT as "experimental"); *Bucci v. Blue Cross Blue Shield of Connecticut, Inc.*, 764 F. Supp. 728, 732-33 (D. Conn. 1991) (holding denial of coverage for HDC/ABMT for breast cancer patient was arbitrary and capricious); *Kulakowski v. Rochester Hospital Service, Corp.*, 779 F. Supp. 710 (W.D. N.Y. 1991) (granting preliminary injunction in favor of breast cancer patient because decision that ABMT is "experimental" arbitrary and capricious); *White v. Caterpillar, Inc.*, 765 F. Supp. 1418, 1421-23 (W.D. Mo. 1991) (granting temporary injunction in favor of breast cancer patient because determination that ABMT is "investigational" treatment arbitrary and capricious); *Adams v. Blue Cross/Blue Shield of Maryland*, 757 F. Supp. 661, 669-76 (D. Md. 1991) (holding ABMT not "experimental" and determination as such arbitrary and capricious).⁸

[*14] After determining the Defendant's denial of coverage to Plaintiff was arbitrary and capricious and not based on substantial evidence, the Court next finds that equitable relief such as a permanent injunction is the appropriate form of relief for Plaintiff in that she will suffer an irreparable harm if the Court does not intervene. Also, there is no adequate legal relief available to Plaintiff. Plaintiff needs the specific medical

⁸ The Court realizes that there have been a few federal courts which have upheld insurance companies' determinations that the HDC/ABMT procedure is "experimental," however, it does not find the determinations of those few cases to be as compelling as the ones in the cases cited above. See *Green Hospital v. United States 23 Cl. Ct. 393* (1991); *Holder v. Prudential*, 951 F.2d 89 (5th Cir. 1992); *Harris v. Blue Cross and Blue Shield of Texas, Inc.* 729 F. Supp. 49 (N.D. Tex. 1990); *Sweeney v. Gerber Products Co. Medical Benefits Plan*, 728 F. Supp. 594 (D. Neb. 1989).

treatment and damages would not compensate Plaintiff. According to Plaintiff's physicians, the timing of the treatment is essential and Plaintiff must have the treatment soon or it may be of no value to her. Also, Plaintiff states that she does not have the money to pay for the subject treatment and without a guaranty of payment, the provider of the treatment will be unable to provide the treatment to the Plaintiff. Therefore, upon balancing the interests of the parties, the Court finds that harm to Defendant in granting a permanent injunction, if any, is substantially outweighed by the harm to Plaintiff if a permanent injunction is not granted.

IV. CONCLUSION

For the reasons stated above, the Court hereby grants Plaintiff's motion for permanent injunction [*15] against Defendant CHAMPUS. Accordingly, the Court enjoins Defendants CHAMPUS and William Perry from denying coverage to Plaintiff for the HDC/PSCR procedure.

An Order consistent with the findings herein is filed contemporaneously.

Entered this the 4th day of August, 1994.

JOHN T. NIXON, CHIEF JUDGE

UNITED STATES DISTRICT COURT

ORDER

Pending before the Court is Plaintiff's Motion for Permanent Injunction (Doc. No. 11), filed on July 21, 1994, to which Defendant CHAMPUS filed an Opposition (Doc. No. 14) on July 22, 1994.

Consistent with the contemporaneously-filed Memorandum, the Court hereby GRANTS Plaintiff's Motion for Permanent Injunction against Defendants CHAMPUS and William Perry. Accordingly, the Court ENJOINS Defendants CHAMPUS and William Perry from denying health care coverage and benefits to the Plaintiff for the treatment of her advanced breast cancer by the procedure known as HDC/PSCR. Also, the Court directs Plaintiff to submit her claims for attorneys' fees and costs to the Court.

Entered this the 4th day of August, 1994.

JOHN T. NIXON, CHIEF JUDGE

UNITED STATES DISTRICT COURT

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