Gripkey v. Mail Handlers Benefit Plan

United States District Court for the District of South Carolina, Columbia Division

February 14, 1994, Decided ; February 14, 1994, FILED; February 15, 1994, Entered

CIVIL ACTION NO. 3:94-378-0

Reporter
1994 U.S. Dist. LEXIS 20619 *

LUANNE GRIPKEY, Plaintiff, -vs- MAIL HANDLERS BENEFIT PLAN and CIVILIAN HEALTH AND MEDICAL PROGRAMS OF THE UNIFORMED SERVICES (CHAMPUS), Defendants.

Core Terms

experimental, investigational, cell, coverage, peripheral, rescue, stem, transplantation, regulations, chemotherapy, marrow, merits

Case Summary

Procedural Posture
Plaintiff patient sought a preliminary injunction to bar defendant insurer from denying coverage for a course of high dose chemotherapy coupled with peripheral stem cell rescue (HDC/PSCR). The insurer denied coverage of the treatment claiming it was experimental and investigational and was precluded from coverage.

Overview
The patient was diagnosed with breast cancer and it was recommended she undergo HDC/PSCR. The insurer denied coverage under its experimental/investigational exclusion. The court granted the motion for preliminary injunction. The court found that there was a significant likelihood that the patient could show that the treatment she sought was generally accepted in the medical community, and that she was entitled to appropriate reimbursements. The insurer based its decision to deny coverage on factors that were not authorized by statute or regulation and acted in an arbitrary and capricious manner. A per se application of rules that were no where set forth in the insurer's official rule making to all decisions whether or not a procedure was experimental was clearly arbitrary and capricious. The patient had a reasonable, if not substantial, likelihood of success on the merits, therefore, the injunction was granted. The insurer was enjoined from denying coverage for the treatment until the matter was tried on the merits.

Outcome
The patient's motion for a preliminary injunction to bar the insurer from denying coverage for a course of HDC/PCSR was granted.

LexisNexis® Headnotes

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

Military & Veterans Law > Servicemembers > Enlisted Personnel

Pensions & Benefits Law > Equal Protection > Veteran Discrimination

HN1[] The exclusion for experimental or investigational procedures in the insurer's program 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.

Counsel: **[*1]** For Luanne Gripkey, Plaintiff: Victoria L. Eslinger, Reginald I. Lloyd, NEXSEN PRUET JACOBS & POLLARD, Columbia, South Carolina.

For Defendants: Brad W. Spencer, Esquire, Gordon & Barnett, Washington, D.C. R. Emery Clark, Esquire, U.S. Department of Justice, Columbia, SC.

Judges: MATTHEW J. PERRY, UNITED STATES DISTRICT JUDGE

Opinion by: MATTHEW J. PERRY

Opinion

ORDER

This matter has come before the Court on a motion for a preliminary injunction seeking to bar the Defendants from denying coverage for a course of high dose chemotherapy coupled with peripheral stem rescue. Plaintiff has facilitated the Court's expedited review of the motion by stipulating that she was not presently seeking a preliminary injunction against Mail Handlers Benefit Plan. Accordingly, Civilian Health and Medical Programs of the Uniformed Services ("CHAMPUS"), a government program within the Department of Defense organized pursuant to *10 U.S.C. § 1071 et seq.*, is for the present purposes the only Defendant before the Court. [1]

[*2] The Court has considered the affidavit evidence and live testimony (by Dr. David Bogner, medical director of Defendant CHAMPUS), the memoranda presented by the parties, and the extensive argument presented at a hearing on February 11, 1994. In view of this information, the Court concludes that CHAMPUS, by basing its decision to deny coverage exclusively on factors that are not authorized by statute or regulation, has acted in an arbitrary and capricious manner. Further, the Court finds that there is a significant likelihood that the Plaintiff can show that the treatment she seeks is generally accepted in the medical community, and, in accordance with the standard set forth in the regulations, she is entitled to appropriate reimbursements under the CHAMPUS program. The government has founded its argument against the issuance of a preliminary injunction solely on its assertion that the Plaintiff cannot succeed on the merits. Thus, the government has conceded that other factors to be considered in issuing a preliminary injunction (see *Blackwelder Furniture Co. v. Seilig Mfg. Co., Inc., 550 F.2d 189, 195 (4th Cir. 1977)* are sufficiently satisfied. Accordingly, the Court finds that, **[*3]** upon Plaintiff's giving sufficient security as defined below, CHAMPUS is enjoined from denying coverage for Plaintiff's treatment until this matter is tried on the merits and judgment on the merits has been entered.

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[1] Without concluding that the wrong party has been named, the Court notes that the government has not defended on the grounds that the proper party has not been named in this action.

Plaintiff, Luanne Gripkey, is a 53 year old, married woman residing in Columbia, South Carolina. In November, 1993, the Plaintiff was diagnosed as having Stage III breast cancer and underwent a mastectomy. See, Affidavit of Luanne Gripkey. Mrs. Gripkey has been advised by Dr. Robert Smith that her cancer has spread to ten lymph nodes and that high dose chemotherapy with peripheral stem cell rescue ("HDC/PSCR") is her best chance for survival. *Id.; Affidavit of* Robert Smith. According to Dr. Smith, Plaintiff's condition is likely to deteriorate to the point where it will be impossible to administer the treatment after February 15, 1994. *See, Affidavit of* Robert Smith. Assurance that Plaintiff has the means to pay for the treatment is required before the treatment will be provided. Affidavit of Luanne Gripkey.

The Plaintiff has primary health care benefits with Mail Handlers Benefit Plan and secondary coverage with CHAMPUS. Plaintiff filed a claim for pre-certification **[*4]** of coverage with Mail Handlers and has received an oral denial based on the Plan's written provisions. Affidavit of Luanne Gripkey. Plaintiff also filed a claim for pre-certification of coverage with CHAMPUS. By letter dated December 15, 1993 to the provider of HDC/PSCR treatment, Response Technologies, CHAMPUS denied Plaintiff's claim on the grounds that high dose chemotherapy with peripheral stem cell rescue is considered investigational/experimental for the treatment of breast cancer. See, Letter of December 15, 1993 from CHAMPUS Medical Director.

CHAMPUS's 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. For the Court to determine whether HDC/PSCR qualifies as an experimental or investigational procedure under the CHAMPUS policy, the Court must look to the specific language of the regulations. ***HN1***[↑] The exclusion for experimental or investigational procedures in the CHAMPUS program is set forth in *32 C.F.R. § 199.4(g)(15)*:

> *Not in accordance with accepted standards, experimental or investigational.* Services **[*5]** 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 that do not qualify for benefits

under the program. 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.* * * * Any medical services or supplies provided under a scientific research grant . . . 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 . . . is considered experimental.

See, Exhibit B to Affidavit of Martha M. Maxey (emphasis added).

The CHAMPUS Policy Manual elsewhere (at Chapter **[*6]** 3, Section 6.38245.1, Page 38245.1) enumerates those conditions for which bone marrow transplantation is an authorized. There is some dispute about whether this section is applicable to peripheral stem cell rescue. Defendant argues that bone marrow transplantation and peripheral stem cell rescue accomplish the same thing, namely to provide the patient (after her chemotherapy treatment that is toxic to blood cells) 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 stern cell rescue. For the purposes of resolving this motion, the Court assumes this section applies to peripheral stern cell rescue. Nonetheless, the Court still needs to resolve whether this policy, even though committed to writing, has any rational relationship to the standard for denying experimental treatments set forth in the regulations. Additionally, the government has conceded that CHAMPUS reviews all assertions that a given marrow transplantation procedure is no longer experimental on a case by case basis. Accordingly, the issue again comes down to whether a given procedure is **[*7]** experimental as defined by the regulations.

In support of its denial of benefits, CHAMPUS submits to the Court a 1988 study conducted by the Office of Technology Assessment, the affidavit of the head of that Office asserting that he still stands by that study, a January, 1990 evaluation prepared by the American Medical Association, and a report by certain participants in an international conference, all of which documents characterize HDC/PSCR as an experimental or investigational treatment. In addition, CHAMPUS cites ongoing clinical trials and its continuous review of the medical literature. *See,* Affidavit of David F. Bogner.

Much of the evidence submitted by Defendant CHAMPUS on this issue is based on information that is no more recent than November 1989. 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). Furthermore, Plaintiff **[*8]** has submitted recent affidavits from five practicing oncologists, whom the Court finds to be fairly representative of the "general medical community," who maintain that HDC/PSCR is generally accepted in the medical community and is not experimental or investigational. *See, Affidavits of* Robert Smith, L.J. McElveen, William Babcock, William H. West and Lee Schwartzberg.

CHAMPUS asserts that this Court cannot merely find that Plaintiff has a likelihood of success in showing that the HDC/PSCR is not experimental or investigational. It asserts that since the determination to the contrary was made by a specialized agency pursuant to the task delegated to it by Congress, its decision is due substantial deference. Accordingly, that decision would have to have been arbitrary, capricious or unreasonable for this Court to overturn it. Assuming this to be so, the Court notes that the government's testimony stated that its decision not to confer benefits was based first on the following criteria:

1. that the procedure is safe;
2. that the procedure is proven effective; and
3. that the procedure is superior to or auxiliary to current therapies.

Second, CHAMPUS requires that these **[*9]** criteria generally be proved by Phase III testing. Yet, 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. Furthermore, the government's testimony emphasized that cost effectiveness was not a part of their Congressional mandate - yet the requirement that

generally a procedure must be superior to a current therapy is clearly a measure of cost-effectiveness, and the application of this rule arguably is unreasonable on this basis.

The report from the international conference submitted by the government concludes that "there is currently insufficient evidence to justify the use of HDC plus [stem cell] transplantation outside the setting of a clinical trial." However, the Court notes that the writers of the report relied on many of the criteria that were outlined by the government's testimony but which find no basis in statute or the formal regulations of CHAMPUS.

In assessing the Plaintiff's case therefore, the Court is mindful of the Seventh Circuit's recent observation that "there is a growing and confusing body **[*10]** of case law that addresses whether HDC-ABMT [autologous bone marrow transplantation] is an experimental procedure for the purposes of insurance coverage. The courts 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, [2] the Court finds that Plaintiff has a reasonable, if not substantial, likelihood of success on the merits. Accordingly, the Court finds that the Plaintiff's motion should be granted.

[*11] CHAMPUS is to be restrained from denying health coverage for high dose chemotherapy with peripheral stem cell rescue and is to pay such costs for that treatment as would be its usual practice for an approved medical procedure during the period prior to judgment on the merits. Plaintiff is to give security in the amount of $ 5,000, which amount the Court finds to be the value of her ownership interest in the equity in her house.

IT IS SO ORDERED

MATTHEW J. PERRY

UNITED STATES DISTRICT JUDGE

Columbia, South Carolina,

Date February 14, 1994

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[2] See, e.g., Helman v. *Plumbers & Steamfitters Local 166 Health a Welfare Trust, 803 F. Supp. 1407, 1413 (N.D. Ind. 1992)* ("recent cases have determined that a finding that ABMT 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)*.