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

United States Court of Appeals for the Fourth Circuit

July 12, 1995, Argued ; September 15, 1995, Decided

No. 95-1016

Reporter
65 F.3d 361 *; 1995 U.S. App. LEXIS 26105 **; 19 Employee Benefits Cas. (BNA) 2009

GAIL ANN WILSON, Plaintiff-Appellee, v. 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, SECRETARY OF DEFENSE, in his official capacity, Defendants-Appellants.

Prior History: [**1] Appeal from the United States District Court for the Eastern District of Virginia, at Newport News. J. Calvitt Clarke, Jr., Senior District Judge. (CA-94-130).

Disposition: AFFIRMED

Core Terms

Phase, coverage, clinical trial, therapy, cells, breast cancer, investigational, chemotherapy, experimental, arbitrary and capricious, bone marrow, conditions, Services, medical community, policy manual, peripheral, patient's, benefits, permanent injunction, federal regulation, accepted standard, effective, agency's, provides, stem

Case Summary

Procedural Posture
Plaintiff beneficiary brought an action against defendant insurer in which she sought payment for high-dose chemotherapy to treat her cancer. The United States District Court for the Eastern District of Virginia, at Newport News, granted a permanent injunction that prohibited the insurer from denying payment for the treatment. The insurer appealed.

Overview
The beneficiary brought an action against the insurer in which she sought payment for high-dose chemotherapy to treat her cancer. The district court granted a permanent injunction that prohibited the insurer from denying payment for the treatment. The court affirmed the judgment of the district court. The court held that the insurer's denial of benefits was arbitrary and capricious. The court rejected the insurer's contention that there was a lack of certain clinical testing to prove the effectiveness of the treatment. The court stated that there was nothing in the code of federal regulations or in the insurer's policy manual that indicated that the clinical test results were required before a benefit could be provided. The court found that the insurer relied on an unwritten policy that mandated the testing whereas the federal regulations required only that a therapy be generally accepted.

Outcome
The court affirmed the judgment of the district court. The court held that the insurer's denial of payment for the beneficiary's cancer treatment was arbitrary and capricious.

LexisNexis® Headnotes

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

HN1[] See *32 C.F.R. § 199.1(d)*.

Civil Procedure > Remedies > Injunctions > Permanent Injunctions

Civil Procedure > Appeals > Standards of Review > Abuse of Discretion

Civil Procedure > Appeals > Standards of Review > Clearly

summary, extremely high doses of chemotherapy are considered more effective in killing cancer cells, and thus can be used to treat breast cancer. Unfortunately, in addition to killing malignant cells, the treatment also kills healthy white blood cells in the patient's blood stream and bone marrow, leaving her susceptible to deadly infections. To combat this problem, doctors **[**3]** have developed a procedure in which a patient's "peripheral stem cells" are harvested from her blood prior to the administration of high-dose chemotherapy or radiation. This treatment is called peripheral stem cell rescue ("PSCR"). A similar, alternative procedure known as an autologous bone marrow transplant ("ABMT") retrieves such cells from the patient's bone marrow. After the patient's body is flooded with cancer-killing agents, the healthy cells are reinfused, hopefully sufficient to protect her against disease.

Gail Wilson is the wife of a retired member of the United States Navy. As such, she is a beneficiary of CHAMPUS, a health benefits program that provides medical benefits for dependents of active-duty and retired members of the United States military. *See* 10 **[*363]** U.S.C. §§ 1076-79. Established by Congress and **[**4]** administered by the Secretary of Defense, see 10 U.S.C. §§ 1071, 1072(4), 1073, the program supplements the military's system of direct care for members of the armed services. Although it resembles insurance, CHAMPUS "is not an insurance program in that it does not involve a contract guaranteeing the indemnification of an insured party against a specified loss in return for a premium paid." 32 C.F.R. § 199.1(d) (1994).

Pursuant to federal regulations promulgated by the Secretary of Defense, CHAMPUS provides eligible beneficiaries "medically necessary services and supplies required in the diagnosis and treatment of illness and injury." *Id.* § 199.4(a)(1). The regulations specify certain "conditions, limitations [and] exclusions," one of which is the following:

> **HN1**[↑] 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.

Id. § 199.4(g)(15). "Experimental" is defined as:

> Medical care that essentially is investigatory or an unproven procedure or treatment **[**5]** 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.

Id. § 199.2(b). CHAMPUS's policy manual, promulgated to provide guidance in the implementation of the program, labels some sixty-six specific conditions "experimental or investigational." Although the list is "for example purposes only and is not to be construed as being all-inclusive," it does not include HDC, ABMT, or PSCR. *Joint Appendix* at 424-28.

CHAMPUS specifically provides coverage for chemotherapeutic agents and their administration. The CHAMPUS policy manual states, however, that ABMTs are covered only for certain diseases under specific circumstances, and the list of covered conditions does not include breast cancer. *Joint Appendix* at 431-32. In addition, the manual indicates that "harvesting of the required stem-cells by apheresis from peripheral blood rather than bone marrow, can be allowed for those beneficiaries for whom it has been established that bone marrow harvesting can not be accomplished due to documented bone marrow involvement" with **[**6]** cancer. *Id.* at 432.

Dr. David Bogner, CHAMPUS's Medical Director, received Wilson's request for coverage of her treatment with HDC/PSCR on July 15, 1994, and denied her request that very day. According to Bogner's letter of denial, "in the absence of published randomized, prospective trials, CHAMPUS must continue to consider this therapy as investigational for the treatment of breast carcinoma." *Id.* at 442. Neither Wilson's physician nor the treatment's provider would begin HDC/PSCR without an advance commitment from CHAMPUS to cover its cost.

On September 6, 1994, Wilson filed a complaint in the United States District Court for the Eastern District of Virginia. She sought an injunction requiring CHAMPUS and the Secretary of Defense to pay for HDC/PSCR, along with declaratory relief, costs, and attorneys fees. On October 24, 1994, following expedited proceedings, the district court entered a final judgment permanently enjoining the defendants from denying Wilson coverage for the desired treatment. *Id.* at 891-905. Reviewing CHAMPUS's decision under the standard set forth in the Administrative Procedures Act ("APA"), 5 U.S.C. § 706(2)(A), the court found that CHAMPUS and **[**7]** the Secretary had "acted in an arbitrary and capricious

manner in denying Plaintiff coverage." *Joint Appendix* at 895. The defendants filed timely notice of appeal to this court.

II.

HN2[] We review the district court's grant or denial of a permanent injunction for an abuse of discretion. *Lone Star Steakhouse & Saloon, Inc. v. Alpha of Virginia, Inc. 43 F.3d 922, 939 (4th Cir. 1994)*. With respect to injunctive relief, "'what we mean when we say that a court abused its discretion, is **[*364]** merely that we think that [it] made a mistake.'" *Direx Israel, Ltd. v. Breakthrough Medical Corp., 952 F.2d 802, 814 (4th Cir. 1991)*. In making that assessment, we review the district court's factual findings for clear error and its legal conclusions *de novo*. *Lone Star Steakhouse & Saloon, 43 F.3d at 939*; *North Carolina v. Virginia Beach, 951 F.2d 596, 601 (4th Cir. 1991)*.

HN3[] To obtain a permanent injunction, Wilson must have demonstrated that her claim to benefits from CHAMPUS has merit. [2] **[**9]** *Amoco Production Co. v. Village of Gambell, 480 U.S. 531, 546 n.12, 94 L. Ed. 2d 542, 107 S. Ct. 1396*. (1987). To make that showing, she must have established that CHAMPUS's decision to deny coverage is invalid under the APA. **[**8]** *Green Hosp. v. United States, 23 Cl. Ct. 393, 399-400, 403 (1991)*. Under that statute, HN4[] we review an agency's action outside the circumstances of formal proceedings to determine if it was "arbitrary, capricious, and abuse of discretion, or otherwise not in accordance with law." *5 U.S.C. § 706(2)(A)*. [3] Under this narrow standard, we are "'not empowered to substitute [our] judgment for that of the agency.'" *Maryland Dep't of Human Resources v. United States Dep't of Agric., 976 F.2d 1462, 1475 (4th Cir. 1992)* (quoting *Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 416, 28 L. Ed. 2d 136, 91 S. Ct. 814 (1971)*). Rather, "we perform 'only the limited, albeit important, task of reviewing agency action to determine whether the agency conformed with controlling statutes,' and whether the agency has committed 'a clear error of judgment.'" *Id.* (quoting *Baltimore Gas & Elec. Co. v. Natural Resources Defense Council, Inc., 462 U.S. 87, 97, 76 L. Ed. 2d 437, 103 S. Ct. 2246 (1983)*, and *Citizens to Preserve Overton Park, 401 U.S. at 416*) (citations omitted)).

As a benchmark for determining whether CHAMPUS's refusal to pay was arbitrary and capricious, we interpret the federal regulations excluding coverage for treatments that are "not in accordance **[**10]** with accepted standards, experimental or investigational," *32 C.F.R. § 199.4(g)(15)*. We note again that "experimental" is defined as medical care that "does not meet the generally accepted standards of usual professional medical practice in the general medical community." *Id.* § 199.2(b).

CHAMPUS argues on appeal that Dr. Bogner based his decision to deny coverage on several factors. He allegedly relied upon "his continuous review of refereed medical literature on this issue, on discussions with the Office of Technology Assessment at the U.S. Public Health Service concerning this treatment, on the CHAMPUS Policy Manual provision governing high-dose chemotherapy treatments and on various medical and medical technology articles and reports." *Brief for the Federal Appellants* at 16. [4] **[**12]** After **[*365]**

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[2] The other conditions for an injunction, which include irreparable injury and no adequate remedy at law, see *Direx Israel, Ltd., 952 F.2d at 812*, are not disputed.

[3] The parties differ regarding whether the agency's decision is subject to "substantial evidence" review under ***5 U.S.C. § 706(2)(E)***. That standard applies after an agency has conducted formal agency proceedings pursuant to §§ 556 and 557. In this case, there were no such proceedings because of Wilson's failure to pursue a post facto hearing through CHAMPUS's standard process for appealing denied claims. Given the agency's standard policy of denying coverage for HDC/PSCR to treat breast cancer, Wilson's course of action is understandable. We, therefore, decline to invoke "substantial evidence" review. In any event, the applicability of that standard matters little, as we have recognized "it is widely held that there is now little difference in the application of the [substantial evidence and the arbitrary and capricious] standards." *James City County v. EPA, 12 F.3d 1330, 1338 n.4 (4th Cir. 1993)*.

[4] As noted above, the term in CHAMPUS's policy manual entitled "Bone Marrow Transplants" provides that, with the exception of certain specified conditions that do not include breast cancer, ABMTs are not covered. Relying on the provision permitting peripheral stem cell rescue *in those instances*, CHAMPUS argues that an exclusion for HDC/PSCR can be inferred. First, the exclusion of ABMT for breast cancer is quite limited, with no mention of high dose chemotherapy. *Cf.* *Doe v. Group Hospitalization & Medical Services, 3 F.3d 80, 89 (4th Cir. 1993)* (holding that high dose chemotherapy is not a "service[] or supply for or related to" an ABMT). Second, PSCR is a procedure distinct from ABMT that some studies have shown to be more effective. *See Joint Appendix* at 674, 714. At the very least, then, these

closely examining the record in this case, and particularly Dr. Bogner's letter rejecting coverage, we view CHAMPUS's denial of Wilson's request differently. Throughout, there is a disproportionate emphasis on the lack of Phase III clinical trials proving the effectiveness of HDC/PSCR, [5] meaning that the efficacy of the treatment had not been measured against conventional therapy given to **[**11]** a control group in a prospective, randomized experiment. In fact, Bogner's denial letter makes the agency's decision seem relatively straightforward: "In the absence of published randomized, prospective trials, CHAMPUS must continue to consider this therapy as investigational for the treatment of breast carcinoma." *Joint Appendix* at 442. While the letter mentions consultations with "technology assessment panels" and "oncology consultants," it intimates that such endeavors were undertaken for the sole purpose of gathering results of Phase III clinical trials, to which CHAMPUS avowedly gave the "greatest weight." *Id. at 443*; *see also Affidavit of Dr. David F. Bogner*, *id.* at 434-35 ("I determined that the proposed therapies were not CHAMPUS benefits because no Phase III trials have proven HDC/PSCR to be safe, effective and superior to conventional therapies for breast carcinoma . . . .").

Certainly, such tests are important in determining the validity of medical treatments. Moreover, they may be an important factor in determining whether a particular therapy meets the "generally accepted standards of usual professional medical practice in the general medical community." *Id.* § 199.2(b). However, nothing in the Code of Federal Regulations or the CHAMPUS policy manual indicates that published, Phase III clinical trial results are required before a benefit can be provided. Without doubt, a therapy could become standard practice in the medical community before it had been proven more effective than traditional treatments. *Cf. Pirozzi v. Blue Cross-Blue Shield, 741 F. Supp. 586, 593 (E.D. Va. 1990)* ("Many treatments become accepted without phase **[**13]** III studies . . . ."). Such would be the case, for instance, where a highly promising treatment for a terminal illness is known to be harmless, but has yet to be proven efficacious in prospective, randomized testing.

In the record before us, there is considerable evidence that Phase III clinical trials are not the critical aspect in determining whether a therapy has become "generally accepted" within the medical community. CHAMPUS's expert witness, Dr. Bruce Cheson, who is the Medical Director of the Clinical Trial Division of the National Cancer Institute, acknowledged that the American Society of Clinical Oncology recently published a paper "taking the position that third-party payers should be paying for certain treatments administered during the course of a clinical trial." *Joint Appendix* at 332. Dr. Cheson also indicated that a patient "has a very high certainty of getting the best available care if one participates in a clinical trial." *Id.* Moreover, he agreed with Wilson's counsel that, assuming HDC/PSCR was limited to the context of a peer-reviewed clinical trial with which Cheson was familiar, HDC/PSCR "is accepted treatment and it should be mentioned by oncologists **[**14]** as an alternative to their patients." *Id. at 337*. Furthermore, at his deposition, even Dr. Bogner recognized the existence of what is commonly known as "home run treatments"--those "that prove themselves so significantly that phase III trials are not necessary." *Id. at 404.* **[*366]** In addition to overemphasizing the necessity of Phase III clinical trials, CHAMPUS ignored abundant evidence that HDC/PSCR is gaining widespread acceptance within the medical community. For example, a letter from some of the country's premier oncologists [6] noted that "the evidence to support the efficacy of these procedures is far in excess of many commonly used and reimbursed medical treatments." *Id. at 266*. These physicians also cited the "explosive growth of the use of this procedure in the United States"

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procedures are not interchangeable, as CHAMPUS claims. Most importantly, even if the entire HDC/PSCR procedure were found to be excluded inferentially, Dr. Bogner did not rely on that provision at the time he denied Wilson's request. *See infra*; *cf. AT & T Information-Systems, Inc. v. General Services Admin., 258 U.S. App. D.C. 254, 810 F.2d 1233, 1236 (D.C. Cir. 1987)* (noting that the record to be reviewed "consists of the administrative record compiled by the agency in advance of litigation, not any record thereafter constructed in the reviewing court"). Although Bogner enclosed a copy of that part of the policy manual, the text of his two-page denial letter does not mention the provision, suggesting that it played little or no role in the agency's decision.

[5] Phase III is the final stage of medical clinical trials. In Phase I, a new therapy is given to human beings for the first time, in order to make sure that it is not harmful. In Phase II, the treatment is given to a larger group to determine whether the procedure is effective in treating a disease. *Joint Appendix* at 438-40.

[6] Dr. Roy B. Jones, University of Colorado; Dr. William P. Peters, Duke University Medical Center; Dr. Stephanie F. Williams, University of Chicago; Dr. Gary Spitzer, St. Louis University Medical Center; Dr. Richard Champlin, M.D. Anderson Cancer Center in Houston, Texas; and Dr. Nancy Davidson, Johns Hopkins Oncology Center.

as "suggesting that a broad consensus of physicians recognize this efficacy." *Id.* Even CHAMPUS has conceded that "there is ample scientific background for vigorous clinical investigation in the area of high-dose chemotherapy treatment for breast cancer." *Brief for the Federal Appellants* at 16 (citing 12 J. CLINICAL ONCOLOGY 226, 229 (Jan. 1994), *included in Joint Appendix* at 614, 618). **[**15]** Moreover, while the omission is not dispositive, the agency failed to list HDC/PSCR as "experimental or investigational procedure" in its own policy manual. *Joint Appendix* at 424-48.

Despite this evidence, CHAMPUS relied on an unwritten agency policy mandating Phase III trials before a treatment is provided. In contrast, federal regulations require only that a therapy be generally accepted, see *id.* § 199.2(b), not that it prospectively be proven to have a statistically significant effect in curing a disease. While the two categories certainly overlap to a substantial degree, they are not co-extensive, and CHAMPUS wrongly ignored the distinctions between them. Effectively, CHAMPUS **[**16]** imposed a requirement beyond those in the applicable regulations by creating an informal, but nonetheless binding, prerequisite that a treatment pass Phase III trials. The agency did so despite regulations mandating that CHAMPUS pay benefits "subject to all applicable definitions, conditions, limitations or exclusions specified." *32 C.F.R. § 199.4(c)(1)*. We therefore conclude that CHAMPUS acted arbitrarily and capriciously in denying coverage to Wilson. [7] *See Bedford County Memo rial Hosp. v. Health & Human Services, 769 F.2d 1017, 1022* (4th

[17]** Cir. 1985) (noting that "agency action is arbitrary and capricious if the agency relies on factors that Congress did not intend for it to consider").

III.

For the reasons discussed above, we conclude that CHAMPUS's refusal to pay for Wilson's HDC/PSCR was arbitrary and capricious and not in accordance with law. Accordingly, we affirm the district court's judgment granting Wilson a permanent injunction that prohibits CHAMPUS from denying coverage for that treatment.

AFFIRMED

End of Document

[7] We have found no authority on this issue from other federal appellate courts. The decision above, however, is consistent with that in at least four district court cases (in addition to the one before us) holding that CHAMPUS's decision to deny coverage of HDC/PSCR was arbitrary and capricious. *See Hawkins v. Mail Handlers Benefit Plan & CHAMPUS*, No. 1:94 CV6, 1994 WL 214262 (W.D.N.C. Jan. 28, 1994); *Gripkey v. Mail Handlers Benefit Plan & CHAMPUS*, No. 3:94-378-0, 1994 WL 276265 (D.S.C. Feb. 14, 1994); *Wheeler v. Dynamic Eng'g & CHAMPUS, 850 F. Supp. 459 (E.D. Va. 1994)*, *aff'd on other grounds*, ___ F.3d at ___; *Mashburn v. Mail Handlers Benefit Plan & CHAMPUS*, No. 3:94-0549, *1994 U.S. Dist. LEXIS 19779, 1994 WL 715962* (M.D. Tenn. Aug. 4, 1994).