

United States Court of Appeals,
Second Circuit.

Nickolas ZERVOS, Plaintiff-Appellant-Cross-
Appellee,

v.

VERIZON NEW YORK, INC., f/k/a Verizon
Communications Inc., f/k/a Nynex
Corporation, f/k/a New York Telephone Company,
and Empire Healthchoice, Inc.,
f/k/a Empire Blue Cross Blue Shield, Defendants-
Appellees-Cross-Appellants,
United Healthcare Co., Inc., a/k/a United Healthcare,
Defendant.

Docket Nos. 01-9213(L), 01-9234(XAP).

Argued Oct. 29, 2001.

Decided Jan. 28, 2002.

Steven G. Storch, Storch, Amini & Munves, P.C.,
New York, NY, for Plaintiff-Appellant.

Randy M. Mastro, Gibson, Dunn & Crutcher, LLP,
New York, NY, for Defendants-Appellees-Cross-
Appellants Verizon New York, Inc. and Empire
HealthChoice, Inc.

Before: JACOBS, POOLER and KATZMANN,
Circuit Judges.

Judge JACOBS dissents in a separate opinion.

POOLER, Circuit Judge.

Nickolas Zervos suffers from metastatic breast cancer, an essentially incurable condition that often can be held at bay temporarily either by repeated cycles of conventional chemotherapy or by a single cycle of high dosage chemotherapy followed by an autologous blood stem cell transplant ("HDCT"). On his physician's advice and after being warned that HDCT often involves more--and more severe--side effects than conventional chemotherapy, Zervos elected to use HDCT because he believed it gave him a chance at a longer period of remission. However, Empire HealthChoice, Inc. ("Empire"), the carrier for Zervos' health care coverage from his employer,

Verizon New York, Inc. ("Verizon"), declined to pre-certify Zervos' eligibility for coverage for HDCT, finding that the treatment was investigational and experimental. As part of its internal appellate process, Empire referred Zervos' case to an outside reviewer. Although that reviewer found that HDCT was effective for treatment of Zervos' condition and that the clinical trial in which he would be treated was well-designed, Empire again denied coverage--this time because HDCT had not been proven to be superior to conventional chemotherapy.

Zervos began this litigation in January 2001 and concomitantly requested a preliminary injunction. The district court denied Zervos' request for injunctive relief and we affirmed. *Zervos v. Verizon New York, Inc.*, 252 F.3d 163 (2d Cir.2001) ("*Zervos II*"). In affirming, we noted that Zervos might be able to establish that the administrator applied the health insurance plan's "Experimental/Investigational" exclusion erroneously on appeal by defining it in a manner not supported by the language of the plan. *Id.* at 174. On remand and after a bench trial, the district court found that Empire's appellate process was arbitrary and capricious and remanded to Empire, directing that a different outside consultant review Zervos' eligibility. Because the denial of benefits based on the record at the time of the remand was unreasonable, and the remand did not account for the fact that each day was crucial in this case, we find that the remand was an abuse of discretion and reverse and remand for the entry of an injunction requiring coverage. [FN1]

FN1. We entered an order to that effect on October 30, 2001, with an opinion to follow.

***639 BACKGROUND**

I. Request for Treatment

In February 2000, Zervos discovered a lump in his right breast. A biopsy demonstrated that the lump was malignant, and the subsequent mastectomy at Parkway Hospital indicated that the cancer had spread to twelve out of the twelve lymph nodes examined. After further testing, Zervos learned that the malignancy probably had infiltrated his sternum. [FN2] Based on these findings, Parkway referred Zervos to Columbia Presbyterian Medical Center for more aggressive chemotherapy. On October 13, 2000, Dr. Charles S. Hesdorffer, Zervos' physician at Columbia Presbyterian, requested insurance approval

to proceed with HDCT following a protocol that he attached. Zervos already was receiving standard chemotherapy in the form of Adriamycin and Cytosan, which he "tolerated well." He subsequently responded to this conventional chemotherapy and to a course of radiation, and his cancer went into remission. *Zervos v. Verizon New York, Inc.*, No. 01-CIV-685, 2001 WL 253377, *4 (S.D.N.Y. March 14, 2001) ("*Zervos I*").

FN2. Because Zervos' cancer had spread to the sternum, doctors identified it as Stage IV or metastatic. Stage IV cancer has a less favorable prognosis than other more localized stages.

II. Relevant Policy Provisions

The policy covering Zervos provided coverage for "medically necessary" treatments, defined as treatments that "are required for the necessary treatment of Injury, Illness, or pregnancy, as distinct from those which are unnecessary or Experimental/Investigational." Under the policy, "Experimental/Investigational" means "services or supplies which are not of proven benefit for the diagnosis or treatment of the Covered Person's condition, or are not generally recognized by the medical community as effective or appropriate for that condition, as determined by the Claims Administrator."

Dr. Steven Wolinsky, Empire's medical policy director, testified that he himself decided whether a treatment was experimental or investigational "based on literature, research and evidence," or, at his discretion, he referred the decision to Empire's Technology Assessment Committee ("TAC"). The TAC consists of Empire medical personnel and academic physicians from the New York City or Albany area. In determining whether a procedure is of "proven benefit," within the meaning of the policy, Wolinsky or the TAC considers "the efficacy [of the treatment] balanced by the toxicity and whether that net positive health effect compares favorably with other standard treatments." Toxicity, in Wolinsky's view, includes any side effects of the treatment from the most minor to the most toxic.

The policy also provides for an internal appeal, the resolution of which is committed to the discretion of Empire, as Appeals Administrator. Empire refers

these appeals to an external reviewer, usually the Medical Care Ombudsmen Program ("MCOP"), an organization that was set up about five years ago to handle appeals of coverage decisions. MCOP, which has no ties to Empire other than the payment it receives for handling an appeal, refers each case to a doctor who has expertise concerning the insured's condition. Dr. Wolinsky then poses a series of questions to the external consultant, who answers them based on the patient's records, his or her own expertise, and the medical literature. Dr. Wolinsky first told the district court that Empire "abide[s] by whatever decision the external reviewer makes." *640 However, at trial, he admitted that Empire accepted only the reviewer's determination of what the medical literature showed and her "clinical expertise [on] what's the best treatment for the patient at the given time."

III. The Evolution of Empire's HDCT Policy

For several years in the 1990s and based on the available medical research, Empire covered HDCT for patients who, like Zervos, had metastatic breast cancer and had responded to standard chemotherapy. At that time, several Phase II studies, which are summarized in Edward A. Stadtmauer, M.D., et al., *Conventional-Dose Chemotherapy Compared with High-Dose Chemotherapy Plus Autologous Hematopoietic Stem-Cell Transplantation for Metastatic Breast Cancer*, 342 *New Eng. J. Med.* 1069 (2000), [FN3] and one Phase III randomized study--the "Bezwooda" study--supported the conclusion that HDCT provided an overall survival benefit for patients with metastatic breast cancer. [FN4] However, in May 1999, Dr. Wolinsky became aware of abstracts that had been presented at an American Society of Clinical Oncology ("ASCO") meeting. These abstracts discussed controlled, randomized Phase III studies and in Dr. Wolinsky's view did not show an improvement in result for HDCT. Dr. Wolinsky therefore convened a meeting of the TAC in July 1999. At that meeting, Empire decided to continue coverage based in part on a presentation from Zervos' treating physician, Dr. Hesdorffer.

FN3. The Phase II trials "consistently reported high overall rates of response (combined complete and partial responses), ranging from 73 to 100 percent. Despite a median survival of only 10 to 24 months, 7 to 18 percent of patients in these studies

remained free of progressive disease for up to 5 years after the treatment." *Id.* at 1069.

FN4. Tests evaluating medical treatment are categorized as Phase I, Phase II, or Phase III studies. Phase I studies evaluate the potential toxicity of a recommended treatment. Phase II studies are non-randomized studies that evaluate the proposed treatment against the results historically obtained for proven treatments. Although helpful in establishing the efficacy of a treatment, Phase II trials may be affected by the nature of the patients who participate in them. Randomized Phase III studies present the best evidence of whether a treatment is effective.

Later in 1999 evidence of fraud discredited the Bezwoda study. In addition, the principal study showing "little or no benefit" from HDCT, the Stadtmauer study, had gained greater acceptance in the oncology community. This new information caused Wolinsky to again convene the TAC. At a meeting in March 2000, Dr. Diana Lake of Sloan Kettering Memorial Hospital presented the results of three randomized Phase III studies of the use of HDCT in Stage IV breast cancer patients: the Philadelphia trial involved in the Stadtmauer article, a French trial, and a study at Duke University. The French trial showed a three-year overall survival rate of 59% in the HDCT group versus 28% in the control group. The Duke study, on the other hand, showed a three-year survival rate of 41% in the HDCT patients versus 55% in the control group. The Stadtmauer study, which considered the largest population of patients, showed no significant difference in overall survival and mortality between the control group and the HDCT group. Based on Lake's presentation, the TAC determined to initially deny coverage for HDCT for metastatic breast cancer.

Dr. Wolinsky also testified that at the time of the March 2000 TAC decision, he was aware of ASCO's position that because there was a "lack of persuasive data demonstrating *641 superior effectiveness" of HDCT, that treatment "should only be performed in the context of a high quality clinical trial." He denied that cost played any role in determining whether a treatment was of proven benefit or considered effective or appropriate by the medical community.

Since the March 2000 TAC meeting, Empire has denied three of the four requests it received for coverage of HDCT. It also initially denied coverage to the fourth applicant, a woman whose cancer was not as advanced as Zervos' cancer, but reversed its position after receiving a letter from an outside reviewer stating that HDCT was as effective for this woman's condition as conventional chemotherapy and was the best possible treatment for her because it would be administered in a well designed and randomized clinical trial. The appellate decision to grant coverage was made by Empire's Dr. Downs, not Dr. Wolinsky.

IV. Empire's Action on Zervos' Request

Empire denied Dr. Hesdorffer's request for coverage for Zervos on October 18, 2000, because "*Autologous Peripheral Stem Cell Harvest/Transplant is Experimental and Investigational in Breast Cancer Stage IV.*" Zervos' physician appealed, and Empire sent Zervos' records along with a list of questions to Dr. Thomas R. Spitzer, director of the bone marrow transplant program and deputy chief of the hematology-oncology unit at Massachusetts General Hospital. Dr. Spitzer indicated, based on available data, that HDCT would not improve Zervos' health outcome. [FN5] However, he also said that "[h]igh dose chemotherapy and autologous stem cell transplantation appears to be as effective as prolonged combination chemotherapy for metastatic breast cancer. A possible benefit of high dose chemotherapy is the avoidance of a protracted course of continuous combination chemotherapy." Finally, Dr. Spitzer indicated that Dr. Hesdorffer's study was well designed.

FN5. Dr. Spitzer noted that the Bezwoda study included only a small number of patients and the conventional chemotherapy regimes were not equal, and that Bezwoda had been proven guilty of scientific misconduct. He also stated that the Stadtmauer study had been criticized "for the high number of patients who were lost to follow-up and the 'nonstandard' (extended duration) nature of the chemotherapy control group," but that the oncology community nevertheless had widely accepted the results "and many have advocated abandonment of [HDCT] as 'standard of care' for metastatic breast cancer."

In reviewing Dr. Spitzer's answers, Dr. Wolinsky ignored Dr. Spitzer's assertion that HDCT was as beneficial as any other treatment because, in Dr. Wolinsky's view, Dr. Spitzer's other answers demonstrated that HDCT had not been proven to be beneficial. Dr. Wolinsky assumed that Dr. Spitzer had overlooked the toxicity portion of a proven benefit analysis. On October 24, 2000, Dr. Wolinsky sent Zervos a notice reaffirming the initial denial and stating:

"There are no convincing data to show that high dose chemotherapy and Autologous Peripheral Stem Cell Transplant is superior to conventional chemotherapy alone for males with metastatic breast cancer." The Autologous Peripheral Stem Cell Harvest and Transplant remains denied as experimental and investigational.

After learning of Empire's denial, Zervos received radiation treatments in an effort to stabilize his condition. As a result of those treatments and conventional chemotherapy, Zervos' cancer was in remission as of the end of February 2001, *642 and he was eligible to receive HDCT in Hesdorffer's study.

V. Initial District Court Proceedings

On January 29, 2001, Zervos filed a complaint against Empire and Verizon [FN6] in the United States District Court for the Southern District of New York and moved for a preliminary injunction directing Empire to cover the cost of HDCT. Zervos claimed that Empire discriminated against him based on his disability and gender and that its denial of coverage was arbitrary and capricious and thus violated the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1001, *et seq.* Three days after Zervos began his lawsuit, Empire--at the request of co-defendant Verizon--obtained a second medical opinion from an MCOP outside reviewer, Dr. Raymond B. Weiss. Weiss said that "[t]here is no published evidence that indicates [HDCT] for men with metastatic breast cancer is any more beneficial than any other form of chemotherapy" and that Dr. Hesdorffer's study was not well designed.

FN6. Zervos also sued United Healthcare Co., Inc., but the parties later stipulated to dismiss the complaint against United Healthcare.

The district court denied Zervos' request for a preliminary injunction, finding that his evidence failed to demonstrate irreparable injury because he did not show that HDCT would improve his likelihood of survival and that defendants reasonably concluded HDCT was experimental and investigational. *Zervos I*, 2001 WL 253377, at *8-10.

VI. The First Appeal

We affirmed the district court's order. We agreed that Zervos failed to establish that he had a likelihood of success on any of his claims including the ERISA claim, at least insofar as he premised that claim on the administrative record presented to the district court. *Zervos II*, 252 F.3d at 173. We noted, however, that

Our decision ... does not necessarily mean that Zervos may not be able to develop a successful federal claim.... Zervos may be able to establish that, under the plan, the focus of an "arbitrary and capricious" inquiry should not be on Empire's initial decision to deny coverage for HDCT--that is, the decision that Empire made after the TAC meeting. Rather, Zervos may be able to show (1) that judicial review here should focus on the *final*, definitive decision to deny coverage (which was all but made by an *external* reviewer); (2) that in this case that decision was the one communicated to Zervos by letter dated October 24, 2000; and (3) that *that* decision was "arbitrary and capricious" because it was based on a material misunderstanding of what is meant under the plan by the term "Experimental/Investigational." *Compare The Plan* at 6 (defining "Experimental/Investigational") as "services ... which are not of proven benefit for the ... treatment of the Covered Person's condition, or are not generally recognized by the medical community as effective or appropriate for that condition" *with* Letter from Empire to Zervos (Oct. 24, 2000) ("We are unable to authorize [HDCT] for the following reason: 'There are no convincing data to show that [HDCT] is *superior* to conventional chemotherapy alone for males with metastatic breast cancer.' [HDCT] remains denied as experimental and investigational.").

Id. at 174-75 (footnote omitted). We also cautioned that "[i]n this case--whatever it *643 may ultimately require--justice can tolerate no substantial delays." *Id.* at 174.

During the pendency of the appeal, Zervos

unfortunately suffered a recurrence of his metastatic disease, making him ineligible to receive HDCT. A new three- month course of chemotherapy did not reduce the size of the metastatic lesions, which now were in his lung. However, another experimental course of chemotherapy begun in May 2001 substantially improved Zervos' condition. Zervos had significant complications from this treatment, including damage to the right lung.

VII. Proceedings on Remand

On July 30, 2001, two days after testing that established Zervos' renewed eligibility to participate in the Hesdorffer protocol, Zervos renewed his request for a preliminary injunction and asked to combine that application with a trial on the merits. At a conference on August 13, 2001, the district court denied Zervos' request for an accelerated trial because defendants had made a summary judgment motion. The court heard oral argument on the summary judgment motion on September 6, 2001. On October 1, 2001, the first date of the scheduled trial, Judge Daniels granted Empire's motion for summary judgment dismissing Zervos' ADA claim but refused to dismiss his ERISA claim.

During the five-day trial, the district court heard testimony from the key players in the formation of Empire's policy on HDCT and from the doctors who played a role in reviewing Zervos' initial claim and internal appeal. In addition, Dr. Weiss and several expert witnesses offered their opinions. At the conclusion of the trial, on October 5, 2001, the district court stated that it intended to issue a decision early the following week. However, on October 11, 2001, Judge Daniels' chambers called Zervos' attorney and asked whether Zervos could wait for a decision until the following week. The attorney replied that based on Zervos' physician's advice and the strong likelihood of an appeal to this court by the non-prevailing party, Zervos could not wait for a decision beyond October 16, 2001. On October 16, chambers staff advised Zervos that the court had not yet reached a decision and asked how much longer Zervos would be eligible to receive HDCT. The following day Zervos submitted a declaration from Dr. Hesdorffer who stated that Zervos remained eligible for HDCT but that within the past month his cancer markers had increased slightly, indicating that the disease was about to "bounce back." Dr. Hesdorffer also said:

[U]nless the Treatment is administered to Mr. Zervos by the end of October, there is a grave risk

that his metastatic disease will return, as it did in March of this year, and he will again become ineligible to receive the Treatment. This time, however, because tumor cells develop resistance to chemotherapy with each course of therapy, the chance of finding another chemo- agent that will yield another response sufficient to make him eligible for the Treatment a third time is remote at best.... [W]ithout [HDCT], Mr. Zervos' treatment options going forward are fairly limited, and his long-term prognosis, based just on continuing with his current treatment, would be severely limited because there is a limit to the amount of his current treatment that he can ultimately tolerate.

On October 22, 2001, the district court issued two memorandum opinions and orders: the first gave the court's reasons for dismissing the ADA claim, and the second addressed the ERISA claim without specifically addressing Zervos' renewed request for a preliminary injunction. In his *644 second decision, Judge Daniels found that (1) Empire's decision to stop covering HDCT was not arbitrary and capricious; (2) Empire's initial decision to deny coverage for Zervos' HDCT was not arbitrary and capricious; but (3) Empire's appellate process was conducted in an arbitrary and capricious manner because the questions asked did not directly relate to policy terms and were confusing, Wolinsky weighed the answers to the same question by different reviewers inconsistently, and Empire sometimes, but not always, covered Experimental/Investigational treatment. *Zervos v. Verizon New York, Inc.*, No. 01-CIV-685, 2001 WL 1262941, at *7-15 (S.D.N.Y. Oct.22, 2001) ("*Zervos III*"). The court remanded the case to Empire for "an immediate expedited review within 48 hours of plaintiff's submission of current relevant information." *Id.* at * 15. It directed that Empire ask a new MCOP reviewer to answer questions "that elicit a clear and unequivocal response regarding whether the treatment is of proven benefit or generally recognized by the medical community as effective or appropriate." *Id.* at *15. Judge Daniels further ordered that the new reviewer "be clearly and directly asked whether there is any other medical or clinical reason that the patient should receive the treatment despite its experimental/investigational nature." *Id.* The court neither explicitly retained jurisdiction nor explicitly directed the entry of judgment.

VIII. The Second Appeal

Upon receipt of the district court's opinion and order,

Zervos immediately filed a notice of appeal and a motion requesting that we consider that portion of the appeal that contested the appropriateness of the remand on an expedited basis and issue a decision no later than October 31, 2001. The motion was granted, and Chief Judge Walker referred the appeal to this panel. Empire cross-appealed from the district court order to the extent that it found Empire's appellate process to have been arbitrary and capricious. We heard oral argument on October 29, 2001, after which the panel directed the parties to appear before a CAMP mediator. The settlement discussion failed. On October 30, 2001--with Judge Jacobs dissenting--we issued an order reversing the district court's order and directing the entry of an injunction requiring that Empire cover the cost of HDCT for Zervos. [FN7] Judge Daniels promptly entered an order in compliance with this directive.

FN7. In connection with the appeal, Empire submitted the opinion of a third MCOP doctor, which it obtained after the district court's remand order. This doctor strongly recommended that Zervos not receive HDCT.

On October 31, 2001, Empire moved for a stay and for recall of the mandate, and Zervos informed the court that Empire declined to obey Judge Daniels' order. We unanimously denied Empire's motion.

Zervos asserts that we have jurisdiction of his appeal pursuant to 28 U.S.C. § 1292(a)(1) because the district court, in effect, denied his request for immediate injunctive relief. Empire argues that we lack appellate jurisdiction because the district court did not make a final determination on the request for injunctive relief. On the merits, Zervos argues that the district court abused its discretion in remanding the case to a plan administrator instead of entering an injunction ordering treatment.

DISCUSSION

I. Jurisdiction

[1] Section 1292(a)(1) gives the courts of appeals jurisdiction of appeals from *645 "[i]nterlocutory orders of the district courts ... granting, continuing, modifying, refusing or dissolving injunctions, or refusing to dissolve or modify injunctions." 28 U.S.C. § 1292(a)(1). A party may appeal from an order that does not explicitly deny an injunction if (1)

it has the practical effect of denying injunctive relief and (2) it has a "serious, perhaps irreparable, consequence." *Carson v. Am. Brands, Inc.*, 450 U.S. 79, 83-84, 101 S.Ct. 993, 67 L.Ed.2d 59 (1981) (internal quotation marks omitted). In *Carson*, the Supreme Court held that the court of appeals had jurisdiction over an appeal from a district court order declining to approve a settlement agreement because the order to proceed to trial deprived the plaintiffs of the advantages the settlement agreement conferred, which included immediate injunctive relief. *Id.* at 87-89, 101 S.Ct. 993. The Court found that these combined circumstances "constitute[d] serious, perhaps irreparable consequences that petitioners can effectually challenge only by an immediate appeal." *Id.* at 90, 101 S.Ct. 993 (internal quotation marks omitted). We also have found that we had jurisdiction over an appeal from an interlocutory order that dismissed without leave to amend particular counts on which the plaintiff sought injunctive relief because the denial of injunctive relief pending appeal from a final judgment was "likely to have a serious and irreparable impact upon [the plaintiffs'] ability to compete." *Volvo N. Am. Corp. v. Men's Int'l Profl Tennis Council*, 839 F.2d 69, 76 (2d Cir.1988).

[2] In this case, we find that the practical effect of the district court's refusal to order immediate injunctive relief, despite (1) an established violation of ERISA; (2) the fact that the district court issued its order at a time when the plaintiff's cancer could recur at any day; and (3) our earlier recognition that time was of the essence, was an effective denial of the plaintiff's request for injunctive relief. Time has always been a critical factor in this case. As early as June of last year when the plaintiff had not established his ERISA claim, we instructed that justice would not tolerate any further "substantial delays." Then in October 2001, Dr. Hesdorffer generally predicted that the plaintiff might become ineligible for HDCT treatment if it was not administered approximately by the end of October. Thus, the record shows that when the district court entered its order towards the end of October, any further delays would increase the risk that the plaintiff would become ineligible for the relief sought.

Of course the presence of time pressure alone is insufficient to establish that the district court's remand was an effective denial of the plaintiff's request for relief. For example, even in cases where time is of the essence, a remand is probably not a

final determination when the district court is unable to determine whether there has been a violation of ERISA because of an incomplete record. But in this case, the record was sufficiently complete for the district court to find that the appeals process was arbitrary and capricious. As we discuss below at III, the record also supported coverage for Zervos. Thus, the main purpose the remand served was to give the defendants an opportunity to remedy their defective appeals process. Even assuming that the defendants ordinarily should be allowed this opportunity, here the remand essentially decided that the plaintiff, who had established the predicate condition for relief, and whose cancer could recur at any time, would not receive the treatment for another week or two. We hold that because Zervos established that (1) the appeals process was arbitrary and capricious both procedurally and, as we discuss below, substantively, and (2) his request for relief could be rendered moot *646 before he received relief, the delay triggered by the remand effectively denied injunctive relief.

Moreover, plaintiff established that this effective denial had a "serious, perhaps irreparable, consequence." The denial is serious because each delay meant that there was a risk that Zervos would become ineligible for HDCT. And it is "perhaps irreparable" because the Hesdorffer declaration established that Zervos probably has run out of conventional treatment options based on the increase in his cancer markers, the toxicity of his current treatment, and the increasing resistance of his cancer to conventional treatments. At this juncture, HDCT may well be the only effective or appropriate treatment available to Zervos.

Consequently, we find that we have jurisdiction over this appeal. We stress, however, that this holding is limited to the exigent and unique circumstances of this case. We do not reach the issue of whether a remand to a plan administrator is a final judgment within the meaning of 28 U.S.C. § 1291, [FN8] and we do not suggest that a district court order granting a remand rather than the preliminary injunctive relief that a party requested ordinarily would be appealable immediately pursuant to Section 1292(a).

FN8. This issue is unresolved in this circuit. *Crocco v. Xerox Corp.*, 137 F.3d 105, 108 (2d Cir.1998).

II. Standard of Review and Definition of the

Record

[3][4][5][6] The parties agree that Empire had discretion to interpret the provisions of the plan it administered. Therefore, reviewing courts can disturb Empire's interpretations and actions only if they are arbitrary and capricious. *Miller v. United Welfare Fund*, 72 F.3d 1066, 1070 (2d Cir.1995). A decision is "arbitrary and capricious [if it] is without reason, unsupported by substantial evidence or erroneous as a matter of law." *Id.* (internal quotation marks omitted). Because this standard is highly deferential, we have said that "the trial court should not conduct a *de novo* hearing on a rejected applicant's eligibility for benefits." *Miles v. New York State Teamsters Conference Pension and Retirement Fund Employee Pension Benefit Plan*, 698 F.2d 593, 599 (2d Cir.1983). We also have implied that the district court should not accept information from the insurer that was not part of the original record unless the insured is instrumental in causing the information to be added to the record. *See Zuckerbrod v. Phoenix Mut. Life Ins. Co.*, 78 F.3d 46, 50 n. 2 (2d Cir.1996). Even where the district court exercises *de novo* review of the plan administrator's determination, the district court "ought not" to accept additional evidence absent "good cause." *DeFelice v. American Int'l Life Assurance Co. of NY*, 112 F.3d 61, 66 (2d Cir.1997).

[7] We review *de novo* the district court's assessment of the plan administrator's decision. *Miller*, 72 F.3d at 1070.

[8] Zervos argues that the district court should have conducted, and we must conduct, a review limited to the administrative record and thus not consider the testimony of Empire's experts and of Dr. Weiss. In light of *Miles*, *Zuckerbrod*, and *DeFelice*, we agree that our review must be limited to evidence that was before Empire when it (1) determined in March 2000 that it would deny coverage for HDCT, (2) denied Zervos coverage on October 18, 2000, or (3) rejected Zervos' appeal on October 24, 2000. Although the incompleteness of an administrative record *647 might--under certain circumstances--constitute good cause for hearing additional evidence, the record before Empire at the time it made the October 24, 2000, decision was not incomplete. Rather, Empire followed the steps in handling Zervos' application and appeal that it followed for any other insured up to and including its solicitation of Dr. Spitzer's opinion. The additional information that Empire obtained after Zervos filed this lawsuit appears to be aimed at

bolstering its legal position and not at providing fuller review of Zervos' claim. Therefore, we limit our review of Empire's decision to the administrative record as it is described by the testimony of Dr. Wolinsky and by the minutes of the TAC meeting. This record includes the written submissions of Drs. Spitzer and Hesdorffer made prior to October 24, 2000.

III. The Merits

[9] For purposes of this appeal, neither party questions either the TAC's initial decision to deny coverage for HDCT to insureds with metastatic breast cancer or Wolinsky's October 18, 2000, initial denial of coverage to Zervos. Therefore, we have no cause to review these determinations, and, in any case, little basis to question them. The studies before the TAC reasonably could be read to establish that HDCT did not provide a survival benefit over long term conventional chemotherapy for patients with metastatic breast cancer. These studies also demonstrated that although HDCT conveyed approximately the same survival benefit as very long term conventional chemotherapy, it had more side effects and more serious side effects. The evidence that the TAC considered, and particularly ASCO's view that HDCT is appropriate in the context of a well designed clinical trial, also supports Zervos' contention that HDCT can be appropriate for individual patients in the context of a well designed clinical trial. The TAC took all of this evidence into account by determining to initially deny coverage but to allow coverage if an external reviewer found HDCT was appropriate for an individual patient.

Thus, we focus our review on (1) the correctness of the district court's conclusion that Empire's appellate process functioned in an arbitrary and capricious manner and (2) the appropriateness of remand rather than injunctive relief as a remedy.

[10] We agree that Empire's appellate process was arbitrary and capricious, primarily because Dr. Wolinsky required that a treatment be superior to another existing treatment in order to avoid exclusion under the policy's experimental/investigational language while the language itself requires only that the treatment be effective--not more effective than alternatives--and considered to be appropriate by the relevant medical community. Thus, contrary to basic ERISA principles, Dr. Wolinsky in effect added additional language to the policy. *See, e.g., Gallo v. Madera*, 136 F.3d 326, 330 (2d Cir.1998) ("Even

when trustees of a pension plan are entitled to deference in interpreting the terms of the plan, deference cannot be so broad as to permit them to graft additional requirements onto unambiguous plan definitions."). Dr. Wolinsky also acted in an arbitrary and capricious manner by refusing to consider Dr. Spitzer's opinion that HDCT would benefit Zervos as much as long-term conventional chemotherapy. Dr. Wolinsky testified that the question which produced Dr. Spitzer's favorable response was one of the three which ordinarily "carr[ied] the most weight." Because Dr. Wolinsky's basis for rejecting Dr. Spitzer's answer was his unfounded assumption that Dr. Spitzer had not considered side effects, it was completely lacking in reason.

*648 [11] Having adopted the district court's view that Empire's internal appellate process was arbitrary and capricious at least as applied to Zervos, we review the district court's choice to remand rather than grant injunctive relief for abuse of discretion. *See Kinek v. Paramount Comm., Inc.*, 22 F.3d 503, 508 (2d Cir.1994); *see also Halpin v. W.W. Grainger, Inc.*, 962 F.2d 685, 697 (7th Cir.1992) (reviewing district court's choice of remedy for an ERISA violation for abuse of discretion). We find that remand in this case was an abuse of discretion.

[12] First, a remand of an ERISA action seeking benefits is inappropriate "where the difficulty is not that the administrative record was incomplete but that a denial of benefits based on the record was unreasonable." *Zuckerbrod*, 78 F.3d at 51 n. 4. On October 24, 2000, when Dr. Wolinsky denied Zervos' appeal, the evidence in the record did not support a denial. The materials that the TAC considered established that (1) HDCT and conventional chemotherapy produced essentially the same survival benefit; (2) HDCT had greater but shorter side effects than repeated cycles of conventional chemotherapy; and (3) HDCT can be an appropriate therapy only if it is administered in a high-quality clinical trial. Although Zervos did not establish that the trial in which he would participate was of high quality when he made his initial application, the Spitzer letter unequivocally stated that the trial was of high quality and that the treatment would be effective and appropriate for Zervos. Moreover, Dr. Wolinsky's assumption that Dr. Spitzer failed to consider side effects when he said HDCT was as effective as conventional chemotherapy was completely lacking in reason because Dr. Spitzer specifically referred to the lesser duration of side effects with HDCT. Because the record was complete

and it supported coverage for Zervos' treatment, we find that the substance of the plan administrator's appellate decision also was arbitrary and capricious.

In addition, the remand order was arbitrary and capricious because it did not adequately address the time constraints Zervos faced. Any delay necessitated by a remand could effectively deny justice in this case, as we observed over half a year earlier even before the plaintiff had established a violation of ERISA. Because there was sufficient evidence to conclude that the denial of benefits was unreasonable and the record establishes that each day mattered, the district court's remand, which served primarily to give the defendants an opportunity to retool a defective system, was an abuse of discretion. Here the administrative record did not contain substantial evidence supporting a denial of benefits and in fact could only be read to support granting coverage. Therefore, remand was an inappropriate remedy, and the district court should have reversed the determination to deny benefits and directed Empire to provide the requested coverage.

CONCLUSION

Because (1) Empire's argument that the district court's conclusion that its appellate process was arbitrary and capricious lacks merit; (2) Empire's decision to deny benefits was also substantively erroneous; and (3) seen in the light of the exigency of Zervos' situation, the flaws in the appellate process, and the lack of support in the record for Empire's decision, the remand order was an abuse of discretion, the order of the district court is reversed. By our order of October 30, 2001, we have directed the district court to order Empire to provide the requested coverage.

***649** JACOBS, Circuit Judge, dissenting:

I respectfully dissent. In my view, the district court recognized and applied the settled principles that govern this controversy, and was proceeding with admirable dispatch and thoroughness to decide the case. The majority has preempted the district court's exercise of discretion, impeached without record support the good faith of the plan administrator, excluded from consideration virtually all the record facts that bear upon the question of medical coverage, and decided the case in a way that illustrates why judicial deference is properly owed to doctors and

plan administrators in matters of medical insurance.

I write at some length in order to demonstrate that although the result in this case is wrong, the governing principles are left intact. Indeed, this case shows what happens when the patterns of deference mandated by precedent are suspended, even for supposedly unique facts and circumstances, and medical decisions are made by judges who (I say with respect) have no more medical expertise than I do. The result is that the majority deems arbitrary and capricious a refusal to pay for a treatment the supposed efficacy of which rests on a study acknowledged to be a scientific fraud.

A

Nickolas Zervos, who suffers from metastatic (Stage IV) breast cancer, seeks coverage for a medical treatment that involves a single cycle of high-dose chemotherapy followed by an autologous blood stem cell transplant ("HDCT"). The largest and most well-respected Phase III [FN1] randomized clinical study comparing HDCT with conventional-dose chemotherapy for the treatment of metastatic (Stage IV) breast cancer determined that (1) HDCT provides no survival benefit over conventional chemotherapy, (2) HDCT actually produces a survival disadvantage for patients (such as Mr. Zervos) who are over age 42, and (3) HDCT is significantly more toxic than conventional chemotherapy. See Edward A. Stadtmauer et al., *Conventional-Dose Chemotherapy Compared with High-Dose Chemotherapy Plus Autologous Hematopoietic Stem-Cell Transplantation for Metastatic Breast Cancer*, 342 *New Eng. J. Med.* 1069 (2000) (reporting the results of the National Cancer Institute-sponsored study) (the "Stadtmauer study"). Multiple other Phase III (i.e., randomized) studies have confirmed these findings.

FN1. For an explanation of the categorization of clinical studies, see *majority op.*, at 640 n. 4.

As the majority opinion concedes (*majority op.* at 640, 641, n. 5), the only Phase III study to find a survival benefit for HDCT--the "Bezwoda" study--has been exposed as a fraud.

In March 2000 the American Society of Clinical Oncology warned: "Given the lack of persuasive data demonstrating superior effectiveness of this *very*

toxic therapy, ... [HDCT] for breast cancer should only be performed in the context of a high quality clinical trial." See *High-Dose Chemotherapy with Bone Marrow Transplant for Breast Cancer Patients*, at <http://www.asco.org/people/nr/html/genpr/m-0300bmtposition.htm> (March 2000) (emphasis added). ECRI, a non-profit health services research institution that studies healthcare technology and healthcare risk, has similarly cautioned that use of HDCT should be confined to National Cancer Institute-sponsored randomized (Phase III) controlled clinical trials. Medicare no longer provides coverage of *650 HDCT for the treatment of breast cancer. According to testimony at trial, the treatment is no longer offered at Memorial Sloan Kettering Hospital and Mount Sinai Medical Center in New York and the Dana-Farber Cancer Institute and Brigham & Women's Hospital in Boston--four of the world's most prestigious cancer institutes.

The Columbia Journalism Review recently cited favorable news coverage about HDCT as a horrible example of how lazy reporters can be gulled by pseudo-science and quackery:

Throughout the 1990s, some 30,000 women underwent [HDCT].... There was no proof that the \$50,000-to-\$100,000 procedure arrested the disease. In fact, two years ago, results from four clinical trials gave the definitive answer: it did not work.

Trudy Lieberman, *Covering Medical Technology*, Columbia Journalism Review (September/October 2001), at <http://www.cjr.org/year/01/5/lieberman.asp>.

B

The legal principles governing this case are settled and can be stated briefly.

Where, as here, an insurance plan gives its administrator broad discretion to construe the terms of the plan and to determine whether a claimant is entitled to payment of benefits, a court may reverse the administrator's decision only if it is arbitrary and capricious. See *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 115, 109 S.Ct. 948, 103 L.Ed.2d 80 (1989); *Zuckerbrod v. Phoenix Mut. Life Ins. Co.*, 78 F.3d 46, 49 (1996). A decision is arbitrary and capricious if it is "without reason, unsupported by substantial evidence or erroneous as a matter of law." *Pagan v. NYNEX Pension Plan*, 52 F.3d 438, 442 (2d Cir.1995) (internal quotations marks omitted). Substantial evidence is defined as "such evidence that a reasonable mind might accept

as adequate to support the conclusion reached by the [administrator and] ... requires more than a scintilla but less than a preponderance." *Miller v. United Welfare Fund*, 72 F.3d 1066, 1072 (2d Cir.1995) (internal quotations marks omitted). A court is not "not free to substitute [its] own judgment for that of the [plan administrator] as if [it] were considering the issue of eligibility anew." *Pagan*, 52 F.3d at 442. While we review *de novo* the district court's assessment of the plan administrator's decision, in so doing we must review the administrator's decision itself under the arbitrary and capricious standard. See *Miller*, 72 F.3d at 1070-71. And if the defect is insufficiency, the appropriate remedy is a remand:

[I]f upon review a district court concludes that the [administrator's] decision was arbitrary and capricious, it must remand to the [administrator] with instructions to consider additional evidence unless no new evidence could produce a reasonable conclusion permitting denial of the claim....

Id. at 1071.

The district court's findings of fact may not be set aside unless they are clearly erroneous. See *Zuckerbrod*, 78 F.3d at 49. We review a district court's fashioning of relief--including the decision to remand--under an abuse of discretion standard. See *Kinek v. Paramount Communications, Inc.*, 22 F.3d 503, 508 (2d Cir.1994). "A district court 'abuses' or 'exceeds' the discretion accorded to it when (1) its decision rests on an error of law (such as application of the wrong legal principle) or a clearly erroneous factual finding, or (2) its decision--though not necessarily the product of a legal error or a clearly erroneous factual finding--cannot be located within the range of permissible decisions." *Zervos v. Verizon New York, Inc.*, 252 F.3d 163, 169 (2d Cir.2001) ("Zervos II").

*651 C

Under the terms of the plan covering Zervos, Empire excludes coverage of procedures that are "Experimental/Investigational," which is defined as "services or supplies which are not of proven benefit for the diagnosis or treatment of the Covered Person's condition, or are not generally recognized by the medical community as effective or appropriate for that condition, as determined by the Claims Administrator." In this case, Empire considers the relevant medical community to be "the general community of academiconcologists." The term "proven benefit," which is not further defined in the policy, is construed by Empire to mean that what

must be proven is a positive net health effect--i.e., "the efficacy [of the treatment] balanced by the toxicity and whether that net positive health effect compares favorably with other standard treatments."

For much of the 1990s, Empire provided coverage for HDCT as a treatment for breast cancer. At a meeting of Empire's Technology Assessment Committee ("TAC") in March 2000, however, Empire determined that HDCT as a treatment for breast cancer should be re-categorized as Experimental/Investigational under the terms of the policy. Empire principally based this decision on the various studies (listed above) that found [i] no survival benefit for HDCT over conventional chemotherapy and [ii] significantly greater toxicity.

Empire's decision to reclassify HDCT as Experimental/Investigational for the treatment of breast cancer is unchallenged in this case: the majority concedes that "[t]he studies before the TAC reasonably could be read to establish that HDCT did not provide a survival benefit over long term conventional chemotherapy for patients with metastatic breast cancer ... [and] also demonstrated that ... it had more side effects and more serious side effects." *Majority Op.* at 18-19.

Six months after this change in policy, Zervos applied for coverage of HDCT for the treatment of his metastatic breast cancer. Consistent with the policy it had adopted, Empire's responded to Zervos by denying coverage: "Autologous Peripheral Stem Cell Harvest/Transplant is Experimental and Investigational in Breast Cancer Stage IV."

At the request of Zervos's treating physician, Empire submitted its decision to an external review. Empire refers external reviews to an unaffiliated organization, the Medical Care Ombudsmen Program ("MCOP"), which selects reviewers on a rotating basis according to the reviewer's specialty, clinical experience, and availability. Empire plays no role in selecting the reviewer.

Empire submits to MCOP a series of questions the purpose of which is to elicit the reviewer's expert opinion about the current state of the medical literature and about whether the treatment is generally recognized as effective or appropriate for a given patient. The reviewer is not expected to be an expert on the contract or on how the language of the contract applies. Empire then examines the answers provided by the reviewer within the context of the

policy language and makes a coverage decision. Before the review process begins, the treating physician is asked to submit any literature or information he or she would like considered on the appeal.

MCOP assigned Zervos's case to Dr. Thomas R. Spitzer, director of the bone marrow transplant program at Massachusetts General Hospital and deputy chief of its hematology-oncology unit. Asked, "Does the scientific evidence support a result of improvement in health outcome?" Dr. Spitzer answered, "No"; and after outlining *652 the various studies mentioned above, he explained: "[T]he conclusions of [the Stadtmauer study] have been widely accepted by the Oncology community, and many have advocated abandonment of this therapy as 'standard of care' for metastatic breast cancer." Asked, "Is this a well designed study for which the patient is a good candidate?" Dr. Spitzer answered, "Unable to respond"; and then added that, while the "proposed research protocol is a well designed phase II study evaluating [HDCT] for ... metastatic breast cancer[,] [t]he protocol title refers to [HDCT] support in *women*. ... Thus, it is not clear whether Mr. Zervos is eligible for the study that was enclosed for my review." (emphasis in original) Asked, "Is the recommended treatment plan the best treatment plan available for this patient at this time?" Dr. Spitzer answered, "No"; he then explained: "there are no convincing data to show that [HDCT] is a superior approach to conventional chemotherapy alone for male patients with metastatic breast cancer."

The only answer given by Dr. Spitzer that is arguably supportive of HDCT is in response to the question "Is the technology as beneficial as any of the established alternatives?" Dr. Spitzer explained that "[HDCT] appears to be as effective as prolonged combination chemotherapy for metastatic breast cancer. A possible benefit of [HDCT] is the avoidance of a protracted course of continuous combination chemotherapy." (The majority wholly relies on this one question and answer, ignoring all of Dr. Spitzer's other responses.)

Empire considered Dr. Spitzer's answers in light of its view that a "proven benefit" is a "positive net health effect" and that the relevant medical community for this case is "the general community of academic oncologists." Empire again determined that Zervos's claim should be denied as Experimental/Investigational, and so advised Zervos by letter dated October 24, 2000, which quoted Dr.

Spitzer's finding that "[t]here are no convincing data to show that [HDCT] is superior to conventional chemotherapy alone for males with metastatic breast cancer."

Zervos commenced this litigation on January 29, 2001, seeking a preliminary injunction ordering Empire to cover the cost of HDCT. After the suit was filed, Verizon (Zervos's employer and the payor on the policy) asked Empire to submit Zervos' case for a second review. Where (as here) ERISA applies, Empire always complies when an employer makes such a request.

This time, MCOP designated Dr. Raymond Weiss, a clinical professor of medicine and breast cancer specialist at the Lombardi Cancer Center of Georgetown University. After outlining the various studies alluded to above, Dr. Weiss stated that "[m]ost oncologist are of the opinion at this time that transplant therapy ... is of unproven efficacy" and that those who remain convinced of its efficacy are "in a distinct minority among oncologists." Moreover, Dr. Weiss observed, the clinical study in which Zervos wishes to participate is identified "as a study for *women*, not men. (emphasis in original) Entering a single male who is ineligible for such a study would be considered inappropriate science by most research-oriented clinicians." Dr. Weiss's conclusion was categorical:

There is absolutely no justification for treating such a patient under this protocol as part of a scientific study, and even more so, there is no scientific justification for treating him with such therapy at all, within or outside any clinical trial. I could perhaps be convinced of the scientific validity of such treatment if he were to be entered on a trial for which *653 he is eligible, one using an innovative therapy, and one focused on stage IV disease. However, this is not the case on all three points.

Finally, asked whether the clinical study is "a well designed study for which this patient is a good candidate," Dr. Weiss answered, "No," and added:

[Zervos] is not eligible for a study in which women are to be treated in the manner proposed, and there is no evidence that [HDCT] provides a net benefit for women with metastatic breast cancer either. The protocol provided with the records of this patient is a phase II "catch-all" protocol ... for women with any stage of breast cancer.... There is nothing innovative about this protocol, and I do not consider it a "well designed study."

Once again, Empire sent notice to Zervos informing him that his claim was denied, quoting many passages from Dr. Weiss's report.

On October 22, 2001, the district court found that "Empire's decision to deny coverage for HDCT for breast cancer was based on substantial evidence and is not arbitrary and capricious." *Zervos v. Verizon New York, Inc.*, No. 01- CIV-685, 2001 WL 1262941, at *11 (S.D.N.Y. Oct.22, 2001) ("Zervos III"). But the court concluded that Empire's appeals process was arbitrary and capricious, principally because "none of the questions posed to the reviewers are direct questions that elicit a clear and unequivocal response regarding whether the treatment is of proven benefit or generally recognized by the medical community as effective or appropriate for the condition." *Id.* at *13. Nevertheless, the district court held that,

based on the administrative record, this Court cannot find that the treatment is not experimental/investigational as defined in the contract or that there is some other medical or clinical reason that the patient should receive this treatment. This is still a medical determination to be made by a full and fair review by medical experts based on the current state of the medical literature and plaintiff's current medical condition and suitability for the proposed treatment.

Id. at *15.

The district court therefore remanded for the supplementation of the record that it deemed crucial. Such a remand is the proper step to take under the principles enunciated by this Court in *Miller*: "[I]f upon review a district court concludes that the [administrator's] decision was arbitrary and capricious, it must remand to the [administrator] with instructions to consider additional evidence unless no new evidence could produce a reasonable conclusion permitting denial of the claim..." 72 F.3d at 1071. The remand order directed Empire to conduct an immediate and accelerated MCOP review within 48 hours of Zervos's submission of current relevant information, the review to include "direct questions that elicit a clear and unequivocal response regarding whether the treatment is of proven benefit or generally recognized by the medical community as effective or appropriate ... [as well as] whether there is any other medical or clinical reason that the patient should receive the treatment despite its experimental/investigational nature." *Zervos III*, at *15. The district court signaled that "[t]he totality of the evidence presented does not convince this Court

that a different determination is necessarily likely or appropriate. However, plaintiff is entitled to a full and fair review." *Id.*

The third MCOP review (as ordered by the district court) was completed on October 25, 2001--three days after the district court issued its order and four days before *654 this Court heard oral argument on this expedited appeal. This time, MCOP designated Dr. Joyce O'Shaughnessy, a board certified medical oncologist whose primary areas of expertise include high dose chemotherapy for breast and ovarian cancer. Asked, "Is the proposed treatment of 'proven benefit' for the treatment of the patient's condition?" Dr. O'Shaughnessy answered, "No," adding:

I believe that the available data permit us to conclude that there [is] no proven clinical benefit associated with [HDCT] compared with standard therapy for patients with metastatic breast cancer. The morbidity and mortality of [HDCT] are greater than that associated with standard therapy. [HDCT] does not represent accepted standard care for patients with metastatic breast cancer and is not medically necessary.

Asked whether "the proposed treatment [is] 'generally recognized by the medical community as effective or appropriate' for the patient's condition," Dr. O'Shaughnessy answered, "No," adding: "most medical oncologists feel that [HDCT] is ineffective therapy for patients with metastatic breast cancer in general, and for patients like Mr. Zervos, in particular, who have largely chemotherapy-resistant and heavily-pretreated metastatic breast cancer." She warned: "I believe that [HDCT] could even be harmful for Mr. Zervos because he is unlikely to benefit, i.e., to achieve a durable remission of his disease, and [HDCT] is substantially more toxic than treatment with conventional chemotherapy agents for metastatic breast cancer." Finally, in response to the question "If your answer to either of the first two questions is 'no', is there any other medical or clinical reason that the patient should receive the treatment, despite its 'experimental/investigational' nature?" Dr. O'Shaughnessy answered: "I believe Mr. Zervos should not receive the proposed [HDCT] because it is highly unlikely to benefit him, and, due to its associated toxicity, may even be harmful.... I do not think there is a medical or clinical reason for him to receive this therapy."

D

The district court therefore did what we have mandated: "[I]f upon review a district court

concludes that the [administrator's] decision was arbitrary and capricious, it must remand to the [administrator] with instructions to consider additional evidence unless no new evidence could produce a reasonable conclusion permitting denial of the claim...." *Miller*, 72 F.3d at 1071. It is certainly hard going for the majority to decide in this case that "no new evidence could produce a reasonable conclusion permitting denial of the claim": as it happens, the third review, ordered by the district court and rendered before this Court's hearing of this appeal, *was* new evidence (albeit confirmatory of the earlier medical evidence) and did support "a reasonable conclusion permitting denial of the claim."

The majority opinion deals with this embarrassment by ruling that the only relevant coverage issue was settled by a single answer given by Dr. Spitzer to a single question, and that therefore the record--thus complete--required no supplementation. *Majority Op.*, at 648 (citing *Zuckerbrod v. Phoenix Mut. Life Ins. Co.*, 78 F.3d 46, 51 n. 4 (2d Cir.1996) (finding a remand to the administrator inappropriate "where the difficulty is not that the administrative record was incomplete but that a denial of benefits based on the record was unreasonable"))).

After thus shrinking the administrative record in this case to a few lines, the majority declares that it can "only be read *655 to support granting coverage." *Majority Op.* at 648.

This ruling is premised on several errors. First, the majority reads the policy to furnish any medical procedure that is "effective" regardless of the toxicity of the treatment. Second, the majority truncates the record to omit everything other than Dr. Spitzer's single isolated response. Third, the majority rules that the remand order was an abuse of discretion because the district court failed to act with the dispatch required by the medical exigency. *Id.*

1. *The Policy Wording*

To repeat, the district court ruled that Empire's appellate process was arbitrary and capricious principally because the questions posed to the reviewers did not track the wording of the Experimental/Investigational exclusion, and therefore (according to the district court) the answers elicited by these questions did not settle the issue of whether HDCT fell under the terms of the exclusion. Accordingly, the district court concluded that the

record was incomplete and remanded for its completion.

The majority opinion agrees that the appeals process was arbitrary and capricious (a point I do not consider), but for a different reason. If the majority *agreed* that the record was incomplete, the majority would be hard pressed to ignore Dr. O'Shaughnessy's categorical opinion rendered on remand. Instead, the majority finds that the record was in fact complete because the only record evidence that matters is Dr. Spitzer's answer to a single question: "[HDCT] appears to be as effective as prolonged combination chemotherapy for metastatic breast cancer." The majority holds that Empire's appellate process was arbitrary and capricious because it denied coverage notwithstanding that response:

[Empire] required that a treatment be superior to another existing treatment in order to avoid exclusion under the policy's experimental/investigational language while the language itself requires only that the treatment be effective--not more effective than alternatives--and considered to be appropriate by the relevant medical community. Thus, contrary to basic ERISA principles, [Empire] in effect added additional language to the policy.

Majority Op. at 647 (citing *Gallo v. Madera*, 136 F.3d 326, 330 (2d Cir.1998) ("Even when trustees of a pension plan are entitled to deference in interpreting the terms of the plan, deference cannot be so broad as to permit them to graft additional requirements onto unambiguous plan definitions.")).

The majority misreads the policy language and fails to give deference to Empire's reasonable interpretation of it. The actual wording of the policy requires a treatment to be of "proven benefit" for the claimant's condition and to be "generally recognized by the medical community as effective or appropriate" for that condition. The term "proven benefit" is not self-reading, and lends itself to interpretation. And Empire as the plan administrator is entitled to deference in interpreting the terms of the plan. *See Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 115, 109 S.Ct. 948, 103 L.Ed.2d 80 (1989); *Miller*, 72 F.3d at 1070.

Empire interprets "proven benefit" as a (proven) positive *net* health effect-- i.e., "the efficacy [of the treatment] balanced by the toxicity and whether that net positive health effect *compares favorably* with other standard treatments." (emphasis added) The district court concluded that this is a natural reading

of the term:

*656 Medically, a treatment cannot be said to be of proven benefit where its toxicity or side effects outweigh the benefits gained from the treatment. Moreover, a treatment cannot be said to be of proven benefit where it merely matches the benefits gained from other treatments, but exposes patients to greater harm and potential death.

Zervos III, 2001 WL 1262941, at *8. Dr. Weiss concurred at his deposition: "if the outcome, the overall survival is the same, yet the treatment is more toxic, you don't want to use the more toxic therapy because there is no gain for the cost." Zervos's own expert witness also agrees: "if the costs in terms of higher morbidity and mortality rates are much greater, but the benefits are only shown to be slightly greater ..., then it's totally appropriate not to give that treatment over standard therapy." [**Zervos Ex. F at 417-18**]

HDCT is a treatment so invasive and verges so closely on killing the patient that the netting out of risks is no minor miscalculation. [FN2] In medicine, as in virtually everything else, a calculation of benefit entails the netting out of the pluses and minuses. Otherwise, the concept of benefit becomes absurd: if medical benefit were a matter of pure efficacy, regardless of detriment, amputation would be deemed a beneficial therapy for athlete's foot.

FN2. We have previously described HDCT as follows:

The treatment is a procedure by which stem cells are harvested from the bone marrow of the patient's body and purified of cancer cells. The patient is placed under general anesthesia while the bone marrow is extracted by needle. The bone marrow is then frozen and stored while the patient receives high, and potentially toxic, doses of chemotherapy. In some cases, the chemotherapy is administered in doses which exceed one thousand times the standard dosage for conventional chemotherapy treatment. This high dose chemotherapy kills not only the cancer, but also the patient's remaining bone marrow which produces white blood cells to protect the body from infection. The bone marrow, which is the most sensitive of all the body tissue, is also the most damaged by chemotherapy. After the chemotherapy is completed, the patient's stored bone marrow

is reinfused intravenously so that it may re-engage. The bone marrow then multiplies rapidly to replace the marrow destroyed during the high-dose chemotherapy. Given that the bone marrow is the patient's own tissue, there is little danger of rejection. There are, however, significant dangers associated with administering high-dose chemotherapy without some additional treatment to regenerate the bone marrow. Because the toll on a patient's white blood cells is significant, the secondary treatment is essential to the patient's chances for survival. Thus, the bone marrow must be quickly reintroduced after high-dose chemotherapy treatment to "rescue" the patient from otherwise almost certain death. *Zervos v. Verizon New York, Inc.*, 252 F.3d 163, 166 n. 1 (2d Cir.2001) (quoting Sharona Hoffman, *A Proposal for Federal Legislation to Address Health Insurance Coverage for Experimental and Investigational Treatments*, 78 Or. L.Rev. 203, 211-12 (1999)).

Empire therefore is not "graft[ing] additional requirements onto unambiguous plan definitions." *Gallo*, 136 F.3d at 330. This case is distinguishable from *Gallo*, on which the majority relies. In *Gallo*, the insurance company attempted to add a "break-in-service" clause to the eligibility section of a pension plan; the insurance company did not claim to be interpreting a provision of that section, but instead wanted to "import" the clause from another unrelated section. *Gallo*, 136 F.3d at 328.

2. Truncation of the Record

The majority's key ruling is that the administrative record in this case can "only be read to support granting coverage." *Majority Op.* at 648. In defense of this ruling, the majority has excluded from "the record" all of what Dr. Weiss and Dr. O'Shaughnessy had to say, has ignored (or *657 misinterpreted) most of what Dr. Spitzer had to say, and has seemingly forgotten that Empire's decision to end funding for HDCT was supported by extensive medical learning and is unchallenged.

The majority excludes the second and third MCOP reviews from the administrative record on the ground that Empire procured these additional reviews to "bolster" its legal position rather than to provide a

fuller review of Zervos's claim. *Majority Op.* at 647. There simply is no factual support for the idea that, if either review had recommended HDCT for Zervos's condition, Empire would have disregarded this recommendation and denied the claim. It is undisputed that the second MCOP review (by Dr. Weiss) was conducted because Verizon asked for it, and Empire testified that it always complies with such requests from the claimant's employer; and the third MCOP review (by Dr. O'Shaughnessy) was conducted pursuant to the order of the district court. These second opinions were thus conducted at the behest of the employer (who would pay the bill) and the district court (which could order the bill paid).

These reviews were therefore part of an ongoing review of Zervos's claim that would ultimately determine whether or not his claim would be paid. *See Zuckerbrod*, 78 F.3d at 50 n. 2 (upholding a district court's inclusion in the administrative record of a doctor's review received after the insurance company denied the claim, because "it was ... not clear error for the district court to treat the insurer's ultimate decision as having been rendered after [the doctor's] review"). In any event, I do not see how Empire can be taxed with improperly bolstering its case with additional opinions by eminent, neutral doctors selected by an unaffiliated intermediary.

Finally, the majority's key finding (that the record only supports coverage) ignores the body of evidence accumulated when Empire changed its policy in March 2000 and decided as a matter of policy to deny coverage of HDCT--a decision that the majority concedes was perfectly reasonable. *Majority Op.* at 647-48. And it ignores as well the opinion of all the medical experts in this case--including Zervos's own physician as well as his expert witness--that HDCT is significantly more toxic than conventional chemotherapy, i.e., that it has significantly higher morbidity and mortality rates. Given this uncontested view, it is not enough for HDCT to be *as* effective as conventional chemotherapy for the treatment of metastatic breast cancer; in order to compete ("compare favorably") with conventional chemotherapy in terms of benefit, HDCT must be *more* effective. This is why Dr. Spitzer was able to say, without self-contradiction, [i] that HDCT is as effective as conventional chemotherapy for the treatment of metastatic breast cancer and [ii] that HDCT is not the best treatment available to Zervos. And that is how Dr. Spitzer characterized his views in the deposition he gave in this case: "the reason that the treatment is not well adopted by the oncology

community anymore is that there isn't an advantage, and given potential disadvantage of the treatment in terms of morbidity, ... it probably does not have a substantial place in the treatment of [metastatic breast cancer]." [Empire Ex. M at 20-21]

This case is a far cry from *Zuckerbrod*, upon which the majority relies. 78 F.3d at 51 n. 4 (finding a remand to the administrator inappropriate "where the difficulty is not that the administrative record was incomplete, but that a denial of benefits based on the record was unreasonable"). In *Zuckerbrod*, we granted an injunction mandating coverage when two reports *658 upon which the insurance company claimed to rely stated that it was absolutely essential that claimant receive the full-time private duty nursing care that the insurer refused to fund. *Zuckerbrod*, 78 F.3d at 49-50. No one, including Dr. Spitzer, has suggested here that it is absolutely essential that Zervos receive HDCT.

The majority also attempts to reinforce its conclusion by citing Dr. Spitzer's characterization of the proposed research protocol involved in this case as a "well designed Phase II study" and by alluding to a prior case in which Empire provided coverage for HDCT after the MCOP reviewer characterized the proposed research protocol involved in that case as a "well-designed randomized phase III trial." However, Dr. Spitzer indicated that the proposed protocol involved in this case is for women, not men; and Dr. Weiss explained why that matters. It is therefore not clear that Zervos is even eligible to participate in the proposed protocol at issue here. As to the prior claim, there are material differences between Zervos's case and that case. In the prior case, the patient had Stage II breast cancer and was seeking participation in a randomized Phase III clinical trial; here Zervos has a more severe form of breast cancer (Stage IV) and is seeking participation in a lower quality clinical trial (Phase II). As the district court found:

[The] evidence indicates that coverage for the treatment was provided for the female patient and denied for Mr. Zervos because of the quality of the clinical study. This Court cannot conclude that Empire acted arbitrarily and capriciously in providing coverage for one patient and denying coverage for another where there are seminal differences in the state of the patients' disease and the quality of the studies for which they sought coverage.

Zervos III, 2001 WL 1262941, at 12.

3. Time Constraints

The majority opinion finds an abuse of discretion on the ground that the district court ordered a remand in disregard of the exigency presented by Zervos's condition and the risk that his condition might change in a way that would render him ineligible for HDCT. I think that the district court acted with energy and speed, ordering an immediate expedited review within 48 hours of Zervos's submission of current relevant information. That expedited review was completed four days before we heard oral argument on this appeal. There is every reason to think that the district court would have ruled on this third review as rapidly as we ruled on this appeal.

* * *

Fortunately, the majority opinion expressly casts its ruling in terms of the "exigent and unique circumstances of this case," *majority op.* at 646, a limitation that invites fact-based distinctions in any subsequent case, however similar. In short, the majority opinion has not altered the law of this Circuit in any fashion.