IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CARLENA FRECCIA, in her capacity as Executrix of the Estate of JENNIFER L. ERCOLE,	)	
Plaintiff,	)	
v.	)	Civil Action No. 03-186 GMS
CONECTIV and COVENTRY HEALTH CARE OF DELAWARE, INC.,	)	
Defendants.	)	

Ben T. Castle, Esquire of YOUNG CONAWAY STARGATT & TAYLOR, LLP, Wilmington, Delaware. Attorney for Plaintiff.

Joseph A. Naylor, Esquire of PEPPER HAMILTON, LLP, Wilmington, Delaware, and William Kelleher, Esquire of BALLARD SPAHR ANDREWS & INGERSOLL, LLP, Wilmington, Delaware. Attorneys for Defendants.

OPINION

November 29, 2004.
Wilmington, Delaware

SLEET, District Judge

I. INTRODUCTION

On February 10, 2003, the above-captioned action was filed, alleging violations of the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1001 *et seq*.[1] In this action, Freccia seeks to recover the cost of a bone marrow transplant ("BMT"), which she claims is due under the Coventry Health Care of Delaware, Inc. ("Coventry") Point of Service Plan (the "Plan"), a medical benefits plan sponsored by Conectiv ("Conectiv").[2]

Presently before the court is Conectiv's motion for summary judgment. For the following reasons, the court will grant the motion.

II. BACKGROUND

Ms. Ercole, as the spouse of a Conectiv employee, was receiving medical benefits under the Plan. The Plan is "self-funded" by Conectiv – that is, Conectiv pays for covered benefits and manages the financial risks. Coventry, as the third-party administrator, reviews requests for advance approval of procedures. Conectiv, however, makes the final decision as to whether it will grant or deny pre-approval. The Plan provides coverage for authorized medical services but excludes, among other things, "experimental procedures or treatments."

In 2002, Ms. Ercole's treating oncologist, Dr. S. Eric Martin ("Dr. Martin") diagnosed her with Chronic Lymphocytic Leukemia ("CLL"). He then sought authorization from Coventry for a pre-transplant evaluation to determine whether a BMT would be appropriate. On December 4, 2002, Coventry authorized "evaluation services for an allogeneic bone marrow transplant."

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[1] Jennifer L. Ercole ("Ms. Ercole"), now deceased, was originally the named plaintiff. Carlena Freccia ("Freccia"), executrix of Ms. Ercole's estate, has been substituted as the plaintiff in this action.

[2] Coventry was dismissed from this action, with prejudice, on April 26, 2004.

Following the pre-transplant evaluation, Dr. Martin recommended that Ms. Ercole undergo a non-myeloablative allogeneic BMT.[3] Before she could do so, however, the Plan required her to seek pre-authorization from Coventry. As noted previously, the Plan excludes treatments that are "experimental."[4] Coventry defines "experimental," in relevant part, as follows:

> - Any health product or service that is subject to Investigational Review Board (IRB) review or approval;
>
> - Any health product or service that is the subject of a clinical trial that meets criteria for Phase I, II, or III as set forth by FDA regulations;
>
> - Any health product or service that is not considered standard treatment by the medical community, based on clinical evidence reported by peer-review medical literature and by generally recognized academic experts.

D.I. 62 Exh. 5. On January 14, 2003, Coventry denied pre-authorization for the requested transplant because it determined that the procedure was "experimental" and, therefore, not a covered benefit under the Plan.

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[3] A BMT involves removing a piece of the patient's bone marrow ("marrow"). Once the marrow is removed, a large dose of chemotherapy is given, which destroys both the cancer and the marrow remaining in the body. The removed marrow is then re-infused to reconstitute the marrow already in the body – that is, the marrow destroyed by the chemotherapy is replaced. When the marrow is taken from the cancer patient it is called an autologous transplant. When the marrow is donated from a volunteer, it is called a allogeneic transplant. Ms. Ercole received an allogeneic transplant because CLL is a cancer of the marrow. Thus, if Ms. Ercole was re-infused with her own marrow, Dr. Martin would have re-infused cancer cells.

There are two types of volunteer donors, or human leukocyte antigen ("HLA") donors, sibling donors and unrelated donors. If the donor is a sibling donor, he or she can either be an identical sibling donor, with identical HLA typing, or a related sibling donor, with close HLA typing. However, if the patient's sibling is not closely related or the patient has no sibling, then the patient uses a registry to try to find an unrelated donor. An unrelated donor is one who is not a sibling, but whose marrow is a close match. In the present case, Ms. Ercole received an HLA-matched unrelated donor allogeneic BMT. *See* D.I. 15.

[4] According to Coventry's definition, "experimental" is synonymous with "investigational." (D.I. 62 Exh. 5). The court will use the term experimental because that is the term used in the Plan.

Ms. Ercole sought an expedited appeal of the initial denial. On January 16, 2003, Coventry upheld its denial. Ms. Ercole again appealed, utilizing the internal appeals procedure provided for in the Plan. Once again, her request for authorization was denied on the basis that the procedure was experimental. Lastly, Ms. Ercole appealed to the ERISA Claims Sub-Committee of the Conectiv Benefits Committee ("the Committee") on January 27, 2003.

The Committee treated the claim as "urgent" and met to discuss it on January, 30, 2003. According to Conectiv, the Committee reviewed the Coventry definition of experimental; Coventry's January 16, 2003 and January 30, 2003 letters to Ms. Ercole; Ms. Ercole's letter to the Committee, dated January 27, 2003; Dr. Martin's letter and opinion, dated January 20, 2003; and the opinions of three independent oncologists ("independent examiners") regarding the issue of whether the proposed transplant was experimental. In addition, the Committee contacted providers of other health care alternatives offered to Conectiv employees, to determine if there were other views as to whether the procedure was experimental. On January 31, 2003, the Committee upheld Coventry's determination that the procedure was experimental and thus excluded under the terms of the Plan.

Having exhausted her rights of appeal under the Plan, Ms. Ercole filed the above-captioned action and a motion for a Temporary Restraining Order ("TRO") seeking advance approval for the BMT procedure. The court held a hearing on the motion for the TRO on February 12, 2003. On February 13, 2003, the court denied the motion for the TRO without prejudice.[5] In denying the motion, the court found that Ms. Ercole had not presented enough evidence to show that the procedure was the standard of care (*i.e.* non-experimental), or that the Committee's decision was tainted.

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[5] Ms. Ercole subsequently received the BMT.

III. STANDARD OF REVIEW

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c); *see also Boyle v. County of Allegheny Pa.*, 139 F.3d 386, 392 (3d Cir. 1998). Thus, summary judgment is appropriate only if the moving party shows there are no genuine issues of material fact that would permit a reasonable jury to find for the non-moving party. *Boyle*, 139 F.3d at 392. A fact is material if it might affect the outcome of the suit. *Id*. (citing *Anderson v. Liberty Lobby*, *Inc*., 477 U.S. 242, 247-248 (1986)). An issue is genuine if a reasonable jury could possibly find in favor of the non-moving party with regard to that issue. *Id*. In deciding the motion, the court must construe all facts and inferences in the light most favorable to the non-moving party. *Id*.; *see also Assaf v. Fields*, 178 F.3d 170, 173-74 (3d Cir. 1999).

IV. DISCUSSION

A. Whether the Court Should Employ a Heightened Arbitrary and Capricious Standard

When considering a plan administrator or fiduciary's denial of benefits under ERISA, district courts are generally instructed to employ *de novo* review. *See Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 115 (1989). However, where plan terms grant discretion to the plan administrator or fiduciary to determine a claimant's eligibility for benefits, the decision is subject to review under an "arbitrary and capricious" standard (*i.e.* a determination of whether the plan administrator abused its discretion in reaching its decision). *See Mitchell v. Eastman Kodak Co.*, 113 F.3d 433, 437 (3d Cir. 1997). Where discretion is reserved, the court may overturn the decision only if it is "'without reason, unsupported by substantial evidence or erroneous as a matter of law.'" *Abnathya v. Hoffman-LaRoche, Inc.*, 2 F.3d 40, 45 (3d Cir. 1993) (citations omitted). However,

where the administrator's decision is potentially clouded by a conflict of interest, such as where a plan administrator also funds the plan it administers, the conflict must be considered in assessing the amount of deference to be given to the administrator's decision. *See Pinto v. Reliance Standard Life Ins. Co.,* 214 F.3d 377, 387 (3d Cir. 2000). Thus, in those circumstances, a modified or "heightened" arbitrary and capricious standard of review is appropriate. *See id.* at 390-92.

In the present case, the Plan at issue contains explicit language granting Conectiv discretion to determine eligibility for benefits. In particular, the Master Welfare Benefit Plan provides that:

> The Sponsor or the Administrator [*i.e.* Committee] shall have the power to interpret and construe the provisions of the Plan, to determine eligibility to participate in the Plan, to make and enforce such rules and regulations as the Administrator shall deem necessary and proper for the efficient administration of the Plan, including interpretation of ambiguous plan provisions, determination of disputed facts, or application of plan provisions to unanticipated circumstances.

Master Welfare Benefit Plan § 8.04 (D.I. 62 Exh. 3).[6] The parties agree that, given this explicit vesting of discretion to determine eligibility for benefits, this case does not fall under the line of authority establishing the *de novo* standard of review. Furthermore, it is undisputed that Conectiv funds the plan which it administers, also removing this case from *de novo* review. However, the parties disagree as to whether the court should apply a standard or heightened arbitrary and capricious review. Conectiv maintains that the court should apply a standard arbitrary and capricious review in this case because the risk of a conflict of interest is decreased where the administrator and funder of the plan is an employer. *Smathers v. Multi-Tool, Inc.*, 298 F.3d 191, 200 (3d Cir. 2002). Conectiv asserts that it has the same incentive as other stable employers to maintain employee morale by administering its benefit plans fairly.

While Conectiv is correct that the risk of a conflict of interest may be decreased where the

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[6] The Plan is a component of the Conectiv Master Welfare Benefit Plan.

administrator and funder of the Plan is an employer, it is clear to the court that any savings in employee benefits will revert to Conectiv because it is directly funding the Plan and is benefitted by denying the claims.[7] Thus, the court will review the Committee's denial under a heightened arbitrary and capricious standard. *See Smathers*, 298 F.3d at199 (employing a heightened arbitrary and capricious review). However, because the conflict is not that extraordinary, the review will be only somewhat heightened. *See id.*

B. Application of the Heightened Arbitrary and Capricious Review to the Facts

Under a standard arbitrary and capricious review, the court is limited to determining whether the fiduciary's decision was without reason, unsupported by evidence, or erroneous as a matter of law. *See Pinto*, 214 F.3d at 390-92. Under the heightened arbitrary and capricious standard, however, the court need not give complete deference to the administrator's decision to deny benefits. *See id*. The court, therefore, must "look not only at the result - whether it is supported by reasons - but at the process by which the result was achieved." *Id*. The court may consider all evidence available to Conectiv during the entire appeals process. *See Mitchell v. Eastman Kodak Co*., 113 F.3d 433, 440 (3d Cir. 1997).

Applying a heightened arbitrary and capricious standard, the Third Circuit has suggested the presence of certain factors may indicate that less deference to the administrator's decision is warranted. *See Pinto*, 214 F.3d at 393 (discussing the "sliding scale"). Specifically, the administrator's decision-making process may not be entitled to deference if it reverses an earlier decision without receiving any additional medical information. *See id*. Additionally, the court need not accept the decision if the administrator uses a self-serving approach to the evidence that

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[7] Indeed, Conectiv states in its Memorandum of Law in Support of Its Motion for Summary Judgment that it "pays for covered benefits and manages financial risks" under the Plan. (D.I. 62, at 2).

selectively relies upon the evidence that supports a denial of benefits, but rejects the evidence that supports the granting of benefits. *See id*. Finally, if the administrator appears unwilling to listen to advice from its staff that recommends continuation of benefits, the decision may be questioned. *See id*. at 394. Ultimately, however, the inquiry is fact specific and must be considered under the totality of the circumstances. *Id.* at 392.

In the present case, the first and third factors are not at issue. Conectiv has never reversed its position regarding pre-authorization of Ms. Ercole's transplant procedure. There is also no evidence in the record before the court that any of its staff opined that the transplant procedure was not experimental and, therefore, covered under the Plan. Freccia suggests, however, that the second factor, which instructs the court to consider whether the administrator was self-serving in its consideration of the evidence, is more problematic. According to her, this is so because the Committee's use of Coventry's definition of "experimental," a definition that was neither referenced in the Plan nor provided to her or Conectiv prior to her appeal of Coventry's initial denial, was unreasonable. For the following reasons, the court disagrees.

1. Whether the Court Should Allow the Parties to Supplement the Record

As a preliminary matter, the court must determine whether the parties should be allowed to supplement the record with data generated after Conectiv's last decision to deny Ms. Ercole's appeal. In her opposition brief to Conectiv's motion for summary judgment, Freccia has submitted an affidavit from Dr. Martin as evidence that the procedures he performed on her were not experimental. In the report attached to his affidavit, Dr. Martin opines that the procedures are not experimental because: (1) other insurers, including Aetna and Medicare, authorize and cover the procedures he performed; (2) his sub-specialty of medicine recognizes that the procedures are

reliable and time-tested; and (3) the procedures he performed were effective on Ms. Ercole and offered her the best probability of survival. (D.I. 68 Exh. 8). Dr. Martin's affidavit is dated February 4, 2004, more than one year after the Committee's decision to deny pre-authorization.

Under both a standard and heightened arbitrary and capricious review, "the [c]ourt is limited to the evidence that was before the administrator when [it] made the decision being reviewed." *O'Sullivan v. Metropolitan Life Ins. Co.*, 114 F. Supp. 2d 303, 309 (D.N.J. 2000) (quoting *Mitchell v. Eastman Kodak Co.*, 113 F.3d 433, 440 (3d Cir. 1997)); *see Russell v. Paul Revere Life Ins. Co.*, 148 F. Supp. 2d 392, 405 (D. Del. 2001) ("Because the court is applying the arbitrary and capricious standard of review, it again notes that its review is limited to the record that was before the administrator."). If a term is vague, however, the court may look to evidence that was not before the administrator for assistance in interpreting the plan or explaining the medical terms and procedures. *See O'Sullivan*, 114 F. Supp. 2d at 310. A court should not receive new "evidence to resolve disputed material facts, for instance 'a fact that the administrator relied on to resolve the merits of the claim itself.'" *Id.* The court finds that Dr. Martin's affidavit presents the type of evidence that *O'Sullivan* precludes, *i.e.* evidence that goes to the merits of the claim.

Furthermore, Dr. Martin's affidavit is supported by materials created months after the Committee decided Ms. Ercole's appeal. The Third Circuit has addressed whether a party could support his or her claim by submitting evidence that was created after the final benefit determination. In *Abnathya v. Hoffmann-La Roche, Inc.*, 2 F.3d 40 (3d Cir. 1993), the court determined that:

> [N]one of these evaluations were submitted until months after the Committee's final decision to affirm the discontinuation of . . . benefits. Thus, these evaluations cannot be considered by the court in deciding whether the discontinuation of . . . benefits was arbitrary and capricious.

Id. at 48, n.8. The Aetna policy cited by Dr. Martin is dated August 8, 2003, and the Medicare

policy was implemented on May 9, 2003, months after the Committee decided Ms. Ercole's appeal. Moreover, Dr. Martin's affidavit was created more than one year after the Committee's decision. As such, these materials did not form part of the record considered by the Committee, and must be excluded from this review. The court, therefore, will not allow Freccia to supplement the record with Dr. Martin's affidavit.

2. Whether the Committee's decision to Deny Pre-Authorization Was Arbitrary and Capricious

Freccia asserts that the court should deny Conectiv's summary judgment motion because Coventry's definition of "experimental" is not entitled to deference and the Committee's decision was, therefore, arbitrary and capricious. As previously discussed, Ms. Ercole was given a Plan Summary listing: (1) Inpatient Hospital care; (2) Outpatient Chemotherapy; and (3) Human Organ Transplant as covered "100%, [n]o copay," and excluding "[e]xperimental procedures or treatments." (D.I. 68 Exhs. 1, 2). It is undisputed that the Plan and the Plan Summary given to Ms. Ercole neither define experimental nor enumerate experimental procedures. In addition, Steven M. Baccino ("Baccino"), Conectiv's Benefits Department Manager, testified at deposition that an employee would not receive a copy of Coventry's definition of experimental until "[she] initially submit[ted] claims for procedures that may potentially be considered experimental." (*Id.* Exh. 6). Freccia contends that the definition is not entitled to deference because it was not referenced or defined in the Plan, citing *Heasly v. Belden & Blake Corp.*, 2 F.3d 1249 (3d Cir. 1993). Freccia further contends that the court should not give deference to Coventry's definition because the Plan gives the Committee the right to interpret ambiguous plan provisions, creating an opportunity for self-serving benefit denials. *Id.*

The Third Circuit, in *Heasly*, rejected the defendant's definition of experimental because it was not referred to or defined in its plan. The court then reviewed the expert testimony provided

and established a non-inclusive list of factors that district courts should consider when reviewing a plan's determination as to whether a procedure is experimental including: (1) the judgment of other insurers and medical bodies; (2) the amount of experience with the procedure; and (3) the determined effectiveness of the procedure. *Id.* at 1263. The Third Circuit realized, however, that "any determination of whether a particular procedure is experimental will necessarily turn on the facts of the particular case." *Id.* at 1265.

Conectiv contends that *Heasly* is distinguishable because the Third Circuit engaged in a *de novo* review. Conectiv further contends that the court should give deference to Coventry's definition because, although it was not included in the Plan, the Committee properly considered the definition pursuant to its discretion to interpret the Plan.

The court agrees that *Heasly* is distinguishable. In *Heasly*, the Third Circuit employed a *de novo* standard of review to the plan administrator's decision, including its definition of "experimental," because the plan at issue did not contain a clear grant of discretionary authority. As discussed previously, because the Committee was given discretionary authority in the present case, the court is applying a heightened arbitrary and capricious review, not a *de novo* review. However, the court need not decide whether Coventry's definition is entitled to deference because, when the *Heasly* factors are applied here, it is clear that Conectiv must prevail.[8]

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[8] The court would like to express its concern with the issue raised by Freccia regarding self-serving benefit denials. As previously discussed, the Plan does not contain a definition of "experimental," a term that is ambiguous and "resistant to [a] precise definition." *Heasly*, 2 F.3d at 1260. According to the Plan, the Committee has the power to interpret and construe ambiguous terms, including the term "experimental." However, the Plan does not provide any standards to which the Committee must adhere when interpreting ambiguous terms. This troubles the court, especially in light of the fact that the Plan does not include a definition of the term experimental that sets forth the criteria that the Committee should consider when making its determinations. The type of discretion given to Conectiv's Committee, under its self-funded plan, creates an inherent risk of abuse and enables it to immunize itself from liability. *Id.* A more prudent approach might be to include in the Plan a definition of experimental, or a non-

The first *Heasly* factor is whether other insurers and medical bodies cover the procedure. The Committee contacted Independence Blue Cross ("IBC") and Aetna, two commercial insurers, to determine if there were other views as to whether the transplant procedure was experimental. According to Conectiv, the committee received a report that IBC considered the procedure experimental and, therefore, not covered under its plan. (D.I. 62 Exh. 10, 16). Aetna failed to respond to Conectiv's request. In addition, at the hearing for the TRO, Dr. Bernard J. Mansheim ("Dr. Mansheim"), Senior Vice President and Chief Medical Officer at Coventry, testified that he consulted the National Cancer Institute ("N.C.I.") guidelines for cancer treatment, in the Physicians Data Query ("P.D.Q."), when he reviewed Ms. Ercole's pre-authorization request. Dr. Manshiem testified that the P.D.Q. contained a comment that BMT for CLL is under clinical evaluation, *i.e.* experimental, whether it is full allogeneic or non-myeloablative. (D.I. 15, at 48:12-49:5, 84:18-21). The evidence that Freccia offers in support of her position was developed after the Committee's decision to deny Ms. Ercole's appeal. It is therefore not relevant to this discussion. *See* Section IV.B.1. *supra*. Thus, the court finds that this factor weighs in favor of Conectiv.

The second *Heasly* factor requires the court to consider the amount of experience with the procedure. While the number of transplants performed may not always indicate a procedure is experimental, it is a factor to consider. *Heasly*, 2 F.3d at 1263. At the TRO hearing, Dr. Mansheim testified that the procedure would not be performed on that many people because it is highly toxic and needs to undergo clinical studies. In addition, one of the independent examiners noted in his review that "[y]oung patients (less than 60 years of age) with CLL are not common, therefore, large

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exclusive list of objective criteria that a procedure must meet to be deemed non-experimental. This approach would help make certain that employees are informed of the criteria that the Committee will consider when making its decision to approve or deny pre-approval and coverage for a procedure.

trials with large case loads will never be possible." (D.I. 62 Exh. 8, at 8). Thus, the court recognizes that, in this case, it must consider more than the number of transplants.

In reviewing Dr. Martin's January 20, 2003 letter, the court does not find evidence that would indicate much experience with the procedure. Dr. Martin discusses two clinical studies, performed on only limited numbers of patients. One of the studies, a Phase I toxicity study, contained seventeen patients with CLL. Each of the patients in the study received non-myeloablative allogeneic stem cell transplant from an HLA-identical sibling donor. In contrast, Ms. Ercole received her transplant from an HLA-matched unrelated donor. Thus, this study would seem to have little bearing on the amount of experience that oncologists have with Ms. Ercole's procedure. Nevertheless, the author of the study noted that "nonmyeloablative allogeneic stem cell transplant *may* become an effective alternative therapy for CLL." (D.I. 62 Exh. 14, at 5) (emphasis added). This language suggests to the court that practitioners in this sub-specialty of oncology do not have much experience with the procedure outside of limited clinical studies.

In the other study discussed in Dr. Martin's letter, 192 patients were treated with HLA-matched sibling donor grafts, and 63 patients received HLA-antigen matched unrelated donor transplantation. Of the 255 patients treated, 24 had been diagnosed with CLL. The author of the study noted that both related and unrelated non-myeloablative hematopoietic stem cell transplantation "is feasible and potentially curative in patients with advanced hematological malignancies who have no other treatment options." (*Id.* at 4). Again, this language suggests a lack of experience with the procedure in patients with CLL. Upon considering the facts of the case and the evidence in the record that bear on the amount of experience with the procedure, the court finds that this *Heasly* factor weighs in favor of Conectiv.

The last *Heasly* factor requires the court to consider the demonstrated effectiveness of the

procedure, including the long-term survival rate associated with the procedure, the likelihood of reocurrence of the cancer, and the post-operative mortality rate. Data on these rates must be compared to data associated with no treatment or with alternative treatments. *Heasly*, 2 F.3d at 1264. Turning to the evidence of effectiveness, Ms. Ercole testified at the TRO hearing that Dr. Martin estimated an 80 to 100% success rate over five years. (D.I. 15, at 14:23-15:2).[9] Conversely, Dr. Manshiem testified that he was aware of "no evidence in the medical literature . . . that says that non-myeloablative bone marrow transplant with patients with chronic lymphocytic leukemia has an eighty percent chance of survival over five years." (*Id.* at 61:21-25). He also testified that when he reviewed the medical literature in order to determine whether the procedure was investigational, he read a review addressing BMTs in patients with CLL, published by Johns Hopkins University. The review's conclusion stated that "long-term disease free and overall survival will need to be shown before bone marrow transplants . . . will gain widespread acceptance." (*Id.* at 54:5-7). He then testified that there has been virtually no controlled trial of bone marrow transplants in patients with CLL, and that the procedure contains many complications that could cause patient illness or death, including graft versus host disease ("GVHD") and susceptibility to infection. (*Id.* at 62).

One of the independent examiners noted in his review that "there is currently no substantial proof that allogeneic bone marrow transplantation offers . . . [the patient] any survival advantage over traditional therapy." (D.I. 62 Exh. 8, at 6). Another stated that "[r]ecent reports from major centers . . . indicate that allogeneic transplant yields about a 26% chance of cure in patients with CLL." (*Id.* at 8-9). The third independent examiner noted that the "consensus opinion of medical experts in this field is that further clinical studies are needed to better define the safety and efficacy of nonmyeloablative allogeneic transplants in the treatment of CLL." (*Id.* at 3). This examiner

[9] Dr. Martin did not testify at the TRO hearing.

commented on studies that have been undertaken to determine the safety and efficacy of the procedure. The examiner noted that although studies have demonstrated the feasibility of the procedure, most have not addressed the efficacy. In addition, the examiner pointed out that "[a] limiting factor in the use of allogeneic transplant with a myeloablative conditioning regimen is transplant related mortality - the transplants are less well tolerated with increasing age and with increasing numbers of prior therapies." (*Id.* at 4).

The studies cited by Dr. Martin provided some results. However, none of the studies compared allogeneic HLA-matched unrelated donor BMTs to traditional therapy, suggesting to the court that these studies have not yet been performed. In the study containing 255 patients, including 63 who received unrelated donor transplantations, 54% were living and 14% had disease progression or relapse after 190 days. Graft rejection occurred in 27% of patients, including nine out of fifteen patients receiving marrow grafts and acute GVHD occurred in 63% of 46 engrafted patients. Lastly, chronic GVHD, requiring therapy, occurred in 50% of patents. (D.I. 62 Exh. 14, at 5).[10] In the study performed by Dr. Issa Khouri ("Dr. Khouri"), in which 17 patients with CLL received non-myeloablative allogeneic stem cell transplants from HLA-identical sibling donors following non-myeloablative immunosuppressive preparative chemotherapy, the two year survival rate was 78%. This was comparable to a historical control group of younger patients who received high-dose chemotherapy and allogeneic transplantation. (*Id.* at 3-4). This study did not address stem cell transplants from HLA-matched unrelated donors. Therefore, the court cannot determine whether these results would be obtained in patients undergoing Ms. Ercole's transplant procedure.

The dearth of comparative data regarding the long-term survival rate associated with non-

[10] Not all of the 63 patients in this study had CLL. Thus, patients with other diagnoses are included in the reported results.

myeloablative allogeneic transplant, the likelihood of reoccurrence of CLL in patients, and/or the post-operative mortality rate, suggests to the court that the procedure has not been demonstrated to be effective in patients with CLL. At most, the data suggest that the efficacy of the procedure is still under investigation. The court, therefore, finds that this factor weighs in favor of Conectiv.

Considering the objective factors addressed above, the court finds there is insufficient evidence upon which to reach the conclusion that the transplant procedure was not experimental. As of January 31, 2003, the date of the Committee's final decision to deny pre-authorization, other insurers and medical bodies treated the procedure as experimental and excluded it from coverage. In addition, the medical literature suggested that there was a lack of experience with the procedure in patients with CLL and that the effectiveness of the procedure was still being determined by clinical studies. Thus, the Committee's decision was not arbitrary and capricious, and Conectiv is entitled to summary judgment.

V. CONCLUSION

For the aforementioned reasons, Conectiv's motion for summary judgment is granted.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CARLENA FRECCIA, in her capacity as Executrix of the Estate of JENNIFER L. ERCOLE,	)	
Plaintiff,	)	
v.	)	Civil Action No. 03-186 GMS
CONECTIV and COVENTRY HEALTH CARE OF DELAWARE, INC.,	)	
Defendants.	)	

O R D E R

IT IS HEREBY ORDERED that:

1. The defendant's Motion for Summary Judgment (D.I. 61) is GRANTED;

2. Judgment be and is hereby entered in favor of the defendant;

3. The Clerk of the Court is directed to close this case.

Dated: November 29, 2004

Gregory M. Sleet
UNITED STATES DISTRICT JUDGE