Harrison v. Blue Cross Blue Shield CV-99-346-JD 08/17/99

UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF NEW HAMPSHIRE

Paula Harrison

v. Civil No. 99-346-JD

Blue Cross Blue Shield
New Hampshire

O R D E R

Paula Harrison brings an action under the Employee Retirement Income Security Act, 29 U.S.C.A. § 1001, et seq., seeking coverage from Blue Cross Blue Shield New Hampshire ("BCBSNH") for knee surgery to repair damaged cartilage by autologous chondrocyte transplantation (ACT). BCBSNH denied coverage under the experimental procedures endorsement to Harrison's policy. The court considers Harrison's request for a mandatory preliminary injunction to require BCBSNH to cover the ACT procedure for her.

Background

The plaintiff is a thirty-six year old woman with a chronic knee condition due to chondral lesions on the femoral chonryle, causing the bones in her knee to come into direct contact without a cartilage buffer. The bone contact causes substantial pain during any weight-bearing activity. As a result, the plaintiff

had to leave work for several months and has returned on only a part-time basis. She is a single mother of two daughters. She has been diagnosed with depression because of the stress and pain caused by her knee condition.

The plaintiff's treating orthopedic surgeon, Dr. James Karlson, recommends that the plaintiff undergo the ACT procedure. The plaintiff has previously had other procedures that have not had long-lasting results. Dr. Karlson reports that the plaintiff's progress, following surgical reconstruction of her anterior cruciate ligament in September of 1997, has been slowed by her knee pain. During the ACL reconstruction, Dr. Karlson took a biopsy of her healthy cartilage, which has been processed and stored by Genzyme Tissue Repair for an ACT procedure. In Dr. Karlson's opinion, without an ACT procedure the plaintiff will continue to suffer pain while her knee degenerates until such time as a knee replacement procedure will be required. Because knee replacements last only ten to fifteen years, the plaintiff would be expected to need several knee replacements during her lifetime. A second opinion, by Dr. Arnold D. Scheller, confirmed the recommendation of the ACT procedure for the plaintiff.

When the plaintiff agreed to the ACT procedure, Dr. Karlson contacted BCBSNH for precertification of the procedure. His request was denied based on the experimental procedures

endorsement in the plaintiff's BCBSNH policy. The endorsement provides, "BCBSNH will not pay for services or supplies which BCBSNH determines in its sole discretion, are Experimental/Investigational services." Dr. Karlson's appeal was denied on August 20, 1998. The plaintiff, assisted by Genzyme Tissue Repair, then appealed the decision to the Claims Committee.[1] On December 3, 1998, the Claims Committee upheld the decision to deny coverage. In May of 1999, the plaintiff, through counsel, sent additional medical literature to BCBSNH pertaining to the ACT procedure. BCBSNH notified the plaintiff in June that BCBSNH found no reason to change the decision.

The plaintiff filed her complaint on July 30, 1999, seeking coverage of the costs of the ACT procedure, asking that a fine be imposed on BCBSNH for failing to provide requested information, and requesting a preliminary injunction to require BCBSNH to cover the cost of the ACT procedure for her. A hearing was held on August 4, 1999, on the plaintiff's request for a preliminary injunction. BCBSNH subsequently filed a memorandum in opposition to the plaintiff's requested relief.

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[1]Genzyme Tissue Repair is the company that developed and markets an autologous chondrocite product called Carticel, and related supplies, for use in the ACT procedure. Although it is not clear from the record, the court assumes that Genzyme Tissue Repair and the Genzyme company are the same or related entities.

Discussion

To succeed on a motion for a preliminary injunction, the plaintiff must establish that "(1)[she] is substantially likely to succeed on the merits of [her] claim; (2) absent the injunction there is a significant risk of irreparable harm; (3) the balance of hardships weighs in [her] favor; and (4) the injunction will not harm the public interest." I.P. Lund Trading Aps v. Kohler Co., 163 F.3d 27, 33 (1st Cir. 1998) (quotation omitted). In the context of a dispute over medical insurance benefits, "[t]he heart of the matter is whether the harm caused plaintiff without the injunction, in light of the plaintiff's likelihood of eventual success on the merits, outweighs the harm the injunction will cause defendants." United Steelworkers of America v. Textron, Inc., 836 F.2d 6, 7 (1st Cir. 1987) (quotation omitted).

A. Likelihood of Success on the Merits

The applicable BCBSNH policy confers discretionary authority to the BCBSNH medical director to construe the terms of the policy. For that reason, the decision to deny coverage would ordinarily be entitled to discretion and would be reversed only if it were found to be arbitrary or capricious. See Terry v. Bayer Corp., 145 F.3d 28, 37 (1st Cir. 1998). The plaintiff

argues that because BCBSNH both makes coverage decisions and pays for coverage, the decision to deny coverage was decided under a conflict of interest.

The fact that BCBSNH would have to pay benefits out of its own pocket does not establish that the denial was made under a conflict of interest. See Doyle v. Paul Revere Life Ins. Co., 144 F.3d 181, 184 (1st Cir. 1998). A general interest in conserving resources is insufficient to support a finding of conflict of interest. See Doe v. Travelers Ins., 167 F.3d 53, 57 (1st Cir. 1999). Instead, the burden is on the plaintiff to show that the challenged decision was improperly motivated. Doyle, 144 F.3d at 184. Absent proof of improper motivation, the decision is reviewed for reasonableness. Doe, 167 F.3d at 57.

As the plaintiff here makes no showing of an improper motivation, the decision is reviewed under the reasonableness standard. Therefore, BCBSNH's decision will be reviewed in light of the record before the court to determine "whether [BCBSNH] had substantial evidentiary grounds for a reasonable decision in its favor." Doyle, 144 F.3d at 184.

The plaintiff argues that BCBSNH's decision in her case is unreasonable because BCBSNH approved coverage for an ACT procedure for another patient, because the Food and Drug Administration has approved the cartilage product used in the ACT

procedure, because ACT coverage is mandated for federal employees under Blue Cross policies, and because Blue Cross plans in other states cover the ACT procedure. The plaintiff also contends that BCBSNH's decision that the ACT procedure is experimental or investigational is unreasonable because it is not based on substantial evidence and ignores current medical evidence.

1. Approval for another insured.

In her motion for injunctive relief, the plaintiff argued that because BCBSNH had approved an ACT procedure for another insured, its decision to deny her approval was a selective application of its policy and unreasonable. At the hearing on August 4, counsel for BCBSNH explained that an ACT procedure was approved for another BCBSNH insured by mistake but that the procedure was not in fact done. The decision, therefore, was an error and did not show selective application by BCBSNH of its policy against ACT.

The plaintiff also argues that another BCBSNH insured underwent an ACT procedure in 1996. BCBSNH contends that it did not provide coverage. Instead, after it denied coverage for the procedure, the insured's employer paid for the costs of the surgery.

2. FDA approval.

On August 22, 1997, the FDA approved Carticel, an autologous cultured chondrocyte, marketed by Genzyme Tissue Repair, "for the repair of clinically significant, symptomatic, cartilaginous defects of the femoral condyle (medial, lateral or trochlear) caused by acute or repetitive trauma." FDA Summary Basis of Approval at 1. The product was judged under the standards for accelerated approval provided in 21 C.F.R. § 601.41. Id. at 19. Because of the accelerated approval process, post-approval studies are required, and Genzyme Tissue Repair committed to further development and testing, "to confirm the long-term clinical benefit of this product and to assess the contribution of the autologous cells to observed benefit of the procedure." Id. at 20.

The plaintiff argues that BCBSNH's determination that the ACT procedure is experimental contravenes the FDA's approval of Carticel.[2] The plaintiff cites language from the FDA rule defining the scope of the accelerated approval process to show that FDA approval constitutes a finding that the approved product

[2]If the plaintiff also intended to argue that BCBSNH violated federal law by denying coverage, the argument fails since the plaintiff has not cited any federal law that requires BCBSNH to cover all products or procedures that have FDA approval.

is safe, effective, and provides benefits to patients over existing treatments. 21 C.F.R. § 601.40 (1998) ("This subpart applies to certain biological products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefits to patients over existing treatments.") That language, the plaintiff contends, shows that BCBSNH's determination in its denial letter that medical evidence is insufficient to show health improvement in ACT patients contradicts FDA approval.

In response, BCBSNH asserts that the bases for the exclusion of experimental procedures under the policy are different than the FDA's approval requirements. BCBSNH notes that its medical policy on ACT explains that ACT is not covered "because the scientific evidence is insufficient to show improvement in health outcomes for patients." BCBSNH/MTHP Medical Policy effective 11/26/97. BCBSNH argues that because the FDA rule applicable to accelerated approval, 21 C.F.R. § 601.41, applies to treatment for life-threatening conditions, it does not require scientific proof of health outcomes, as BCBSNH's experimental procedures exclusion does. See 21 C.F.R. § 601.41 (providing, in pertinent part, as follows:

> FDA may grant marketing approval for a biological product on the basis of adequate and well-controlled clinical trials establishing that the biological

> product has an effect on a surrogate endpoint that is reasonably likely based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity.)

BCBSNH also argues that transcripts of the FDA advisory committee that reviewed the Carticel application show that the FDA approval process does not require the same degree of scientific research on the effect of a procedure that BCBSNH requires for coverage approval.

While the FDA rules suggest that the product must show a benefit over existing treatment to gain approval, the context of the benefit may be, as BCBSNH suggests, a strong influence that is not relevant to the BCBSNH experimental procedures exclusion. The meaning of the FDA standards for accelerated approval is not sufficiently clear to compare FDA requirements with BCBSNH requirements based on the record presented.

In addition, FDA approval of Carticel, and by implication the ACT procedure, is one of the requirements (Part C of the experimental procedures endorsement) for approval of an otherwise experimental procedure under the BCBSNH policy exclusion. If the BCBSNH experimental procedures endorsement requirements were interpreted to be identical to FDA approval requirements, the four criteria listed in Part B of the exclusion, which is

applicable to the plaintiff's determination, would be mere surplusage. Common principles of contract interpretation counsel against construing a contract in such a way as to render parts meaningless. See Jimenez v. Peninsular & Oriental Steam Navigation Co., 974 F.2d 221, 223 (1st Cir. 1992); see also Rodriguez-Abreu v. Chase Manhattan Bank, N.H., 986 F.2d 580, 585 (1st Cir. 1993) (ERISA federal common law based on state law principles of contract interpretation). Based on the record presented for a preliminary injunction, the plaintiff has not shown that FDA approval of Carticel requires BCBSNH to approve an ACT procedure for her.

3. Coverage of ACT by other plans.

The plaintiff argues that coverage of ACT procedures by other insurers shows that BCBSNH's decision is unreasonable.[3] The plaintiff represents that all health plans participating in the Federal Employee Health Benefit Program, including BCBSNH, are required to provide coverage for ACT procedures for federal

[3]The plaintiff says that coverage has been approved for ACT procedures by Blue Cross Blue Shield of Kansas, Minnesota, California, New York, New Jersey, Maine, and Massachusetts, and by other insurers, Fallon Health Plan, Aetna/USHealthcare, PHCS, Allmerica, and Harvard Pilgrim Health Plan. BCBSNH notes that the BCBS entities in different states are licensed to use the trademarks and names but are otherwise independent and unrelated.

employees. Because particular medical insurance benefits depend on the policy and the level of coverage purchased, the fact that coverage for ACT procedures is offered or mandated in other policies does not obligate BCBSNH to offer the same coverage under the plaintiff's policy. Determinations by other insurers that the ACT procedure is not experimental, however, may be instructive as to the reasonableness of BCBSNH's determination.

In particular, the plaintiff points to approval of ACT procedures by Blue Cross Massachusetts ("BCBSMA") to show that BCBSNH's decision was unreasonable. BCBSMA policies apparently do not have an endorsement excluding experimental procedures, as BCBSNH policies do, but instead BCBSMA uses "Medical Technology Assessment Guidelines" to determine whether to approve particular procedures based on "whether a technology improves health outcomes such as length of life, ability to function or quality of life." BCBSMA Guidelines, 7/96, at 1. The BCBSMA Guidelines and the BCBSNH experimental procedures endorsement require substantially similar evidence and assurance of the safety and efficacy of technology.

BCBSNH issued a policy statement on ACT procedures on November 26, 1997, reviewed on July 7, 1999, based on a review by the Technology Evaluation Center ("TEC"), saying "We do not cover autologous chondrocyte transplantation . . . because the

scientific evidence is insufficient to show improvements in health outcomes for patients." Medical Policy, 11/26/97 at 1. BCBSMA issued a policy statement on ACT procedures in April of 1998 that was reviewed in March of 1999.[4] The BCBSMA policy statement noted that TEC "determined that there is not enough scientific evidence to make conclusions about health outcomes for patients" and that "the long-term effects of cartilage harvesting on knee function and the long-term safety of cartilage implantation are unknown." BCBSMA policy at 1. Nevertheless, BCBSMA decided to cover ACT procedures on a case by case basis for those insureds who are determined to be likely to benefit from the procedure. Id. Although both BCBSMA and BCBSNH found insufficient scientific evidence of the patient health outcomes of ACT procedures, they came to different conclusions about coverage. BCBSMA did not, however, conclude that the ACT procedure was not experimental; instead, it exercised its discretion in favor of approving the procedure in limited circumstances despite the lack of material scientific evidence. It does not follow that the limited approval of the procedure by BCBSMA demonstrates that BCBSNH's decision not to approve ACT

[4]The BCBSMA policy statement refers to the procedure as autologous chondrocyte implantation ("ACI") rather than transplantation ("ACT"). At least in the present record, there appears to be no difference between ACI and ACT.

procedures was unreasonable.

4. Evidence to support BCBSNH's decision.

BCBSNH's experimental procedures endorsement provides certain guidelines for the medical director to follow in determining whether a particular treatment is experimental. If the procedure is approved by the FDA and is not part of a protocol, informed consent, or an ongoing Phase I or II clinical trial, the medical director "may require that demonstrated evidence exists, (as reflected in the published Peer Review Medical Literature)" to satisfy four criteria pertaining to positive health outcomes. The four criteria are: (1) evidence that the procedure "has proved a positive health outcome through well designed investigations that have been reproduced by non-affiliated authoritative sources with measurable results supported by the positive endorsements of national medical bodies or panels regarding scientific efficacy and rationale"; (2) "the beneficial effects [of the procedure] outweigh any harmful net effects"; (3) the procedure "is more effective in improving net health outcomes than established technology"; and (4) "improvement in health outcomes is achievable in standard conditions of medical practice outside clinical investigatory settings."

BCBSNH denied coverage based on its medical policy on ACT that states:

> Currently there are no well-designed published studies comparing this new procedure to other treatments. The FDA has required Genzyme company to do additional human trials to research the role of the Carticel product in the knee repair process, to compare autologous chondrocyte implantation to other knee repair procedures, and to evaluate long-term effects. This trial is expected to be completed after the year 2002. Today, the long-term effect of cartilage harvesting on knee functions and the long-term safety of cartilage implantation are unknown.

BCBSNH Medical Policy, 11/26/97, at 1. BCBSNH's medical policy on ACT is in turn based on an evaluation of medical literature between 1985 and January of 1996 by TEC. Id. at 3. According to the medical policy statement, TEC found "one small Swedish study of 23 patients," the Brittberg study, that showed "good clinical results one year out," but no further follow-up. The policy statement notes "no published study compares ACT to prosthetic knee arthroplasty" and concludes that the Brittberg study, "while encouraging, is insufficient to permit determination about improved health outcome compared to prosthetic knee arthroplasty." Id. at 3.

The plaintiff does not challenge BCBSNH's four criteria pertaining to positive health outcomes in the experimental procedures exclusion. Instead, the plaintiff contends that BCBSNH's decision is unreasonable because it was based on an out-

of-date policy on ACT procedures, failed to consider more recent medical studies and information about ACT, and imposed an unreasonable condition that a study compare prosthetic knee arthroplasty with ACT.

BCBSNH responds that its reliance on TEC assessments for ACT policy is reasonable because, as TEC describes itself in promotional literature, "TEC offers a comprehensive and objective technology assessment program that gives decision makers access to the largest pool of assessment information, knowledge, and experience available today." Decision Makers' Guide to TEC at 1. TEC however is not an independent agency or a public information source. Instead, TEC is affiliated with the national Blue Cross Blue Shield Association and apparently is limited to providing information to BCBS programs: "The Blue Cross Blue Shield Association provides assessments on selected health technologies for use by program subscribers only." Id. TEC also cautions, "TEC Assessments are scientific opinions, provided for informational purposes only." Id.

BCBSNH argues that TEC's assessment is not out of date. TEC issued an assessment of ACT in February of 1998 and reviewed its assessment in December of 1998. In December, TEC's medical advisory board heard from a panel of four orthopedists, two designated by the Genzyme company, maker of Carticel used in ACT

procedures, and two designated by BCBS Association. In the TEC Bulletin of April 16, 1999, volume 16, number 3, TEC said that it was in the process of updating the February 1998 assessment, but reported that "[t]he Medical Advisory Panel has not changed its position that ACT does not meet TEC criteria" because "empirical evidence is necessary to demonstrate the clinical effectiveness of autologous cultured chondrocytes." Bulletin at 2. The plaintiff has not addressed the more recent TEC assessments.

Since the determination of whether a procedure is experimental is defined by the BCBSNH policy, the medical director's discretion does not extend to ignoring the policy criteria in favor of different criteria to deny coverage. See, e.g., Smith v. CHAMPUS, 97 F.3d 950, 962 (7th Cir. 1996). If appropriate evidence about the ACT procedure satisfies the stated policy criteria, the medical director's determination to the contrary would be unreasonable regardless of what other information he may have used in making the determination. See, e.g., Wilson v. CHAMPUS, 65 F.3d 361, 364-66 (4th Cir. 1995). Therefore, if BCBSNH relied on a negative TEC assessment of ACT that is based on different grounds than the experimental procedures endorsement criteria or that is contradicted by other appropriate information, BCBSNH's reliance may not have been reasonable. Cf. Martin v. Blue Cross & Blue Shield of Virginia,

115 F.3d 1201, 1207-08 (4th Cir. 1997) (affirming experimental determination where Blue Cross extensively reviewed applicable medical literature and evidence showed procedure did not meet one of the four experimental criteria).

The plaintiff submitted the following articles and information to BCBSNH in support of her request for approval of ACT: Mats Brittberg, et al., Treatment of Deep Cartilage Defects in the Knee with Autologous Chondrocyte Transplantation, New England Journal of Medicine, (Oct. 6, 1994); Bert R. Mandelbaum, et al., Articular Cartilage Lesions of the Knee, The American Journal of Sports Medicine, Vol. 26, No. 6 (1998); Cartilage Repair Registry, Periodic Report, vol. 5,(Jan. 1999); Scott D. Gillogly, et al., Treatment of Articular Cartilage Defects of the Knee with Autologous Chondrocyte Implantation, Journal of Orthopedic and Sports Physical Therapy, Vol. 28, No. 4, (Oct. 1998); Press Release by Genzyme Tissue Repair (Feb. 3, 1999); Tom Minas and Stefan Nehrer, Current Concepts in the Treatment of Articular Cartilage Defects, Orthopedics, vol. 20, no. 6 (June 1997); Tom Minas, Chrondrocyte Implantation in the Repair of Chondral Lesions of the Knee: Economics and Quality of Life," The American Journal of Orthopedics (Nov. 1998); Cartilage Repair Registry, Summary Report, vol. 5, (Feb. 1999). BCBSNH dismisses the medical articles and registry information provided by the

plaintiff as recent commentaries on old research, the Brittberg clinical study and the Genzyme registry of ACT patients.

a. The Brittberg study and Genzyme registry.

BCBSNH contends that neither the Brittberg study nor the Genzyme registry is sufficient to support a conclusion as to the effect of ACT on patient health outcomes. BCBSNH also criticizes those studies as "single-arm series with incomplete follow-up and reporting and no concurrent control group." BCBSNH Medical Policy, 11/29/97, at 3. The policy statement says that although the Brittberg study was promising, it was insufficient because of its small size, lack of follow-up results after a year, and the lack of a study comparing ACT and prosthetic knee arthroplasty.

The plaintiff argues that it is not reasonable to require comparison between ACT and prosthetic knee arthroplasty (knee replacement) because the procedures are intended for entirely different patients. A prosthetic knee, apparently, is expected to last only ten to fifteen years, and therefore the procedure is more appropriate in older patients and patients with osteoarthritis, a condition that is not treatable with ACT. ACT, apparently, is expected to last longer than a knee prosthesis, and is therefore appropriate for younger patients until a knee replacement is necessary. However, absent qualified medical

opinion on the efficacy of comparing ACT and knee replacement, in the context of showing whether ACT is "more effective in improving net health outcomes than established technology," the reasonableness of BCBSNH's requirement cannot be assessed on the current record.

The plaintiff does not specifically contradict BCBSNH's conclusion that the Brittberg study and the Genzyme registry are insufficient evidence that ACT is not experimental in the context of the experimental procedures endorsement criteria.

B. Additional information.

Even if the Brittberg study and the Genzyme registry information are insufficient, as BCBSNH contends, at least some of the plaintiff's articles seem to include more evidence of ACT health outcomes than BCBSNH has acknowledged. The Mandelbaum article in The American Journal of Sports Medicine discusses previous treatments for cartilage lesions, such as debridement, and explains why those results have not lasted over time, putting the benefits of ACT in context of other established treatments for damaged cartilage. The Mandelbaum article also discusses a reported study by Dr. Lars Peterson with results based on unpublished data of one hundred patients followed from two to nine years that shows good to excellent results in 96% of the

patients with isolated femoral condyle defects (similar to the plaintiff's condition).

Gillogly and his co-authors discuss the deterioration of results in current cartilage treatments. They also discuss Peterson's study with ACT patients. Gillogly reports results of forty-one of his own patients, treated with ACT, noting that twenty-nine of the forty-one patients had undergone a total of fifty previous surgeries that did not alleviate their knee symptoms. He documents improvement in a variety of evaluation fields and characterizes the results as promising.

Minas and Nehrer discuss current treatments and outcomes for cartilage repair and provide more detail about the Peterson study in their article, saying that Peterson reported on ACT knee treatment of 246 patients in Sweden. Minas also reported his experience with fifty patients and that after eighteen months there was "near complete resolution of pre-treatment pain." Minas and Nehrer, Orthopedics, vol. 20, no. 6 at 534. Minas's study of forty-four patients treated with ACT is published in The American Journal of Orthopedics, where Minas reported that after twelve months, 72% of the patients improved, while 14% stayed the same, and 14% had a deterioration in their condition.

BCBSNH ignores updates in the Genzyme registry and the additional studies and information in the medical articles. The

articles and registry information appear to provide some evidence that the benefits of the ACT procedure outweigh the harms, that net improvement exists in outcomes compared to other procedures, and results in medical practice. There appears to be no evidence, however, that the Brittberg study, the Genzyme registry, or the additional studies and information meet the first criteria requirements of "well designed investigations . . . reproduced by non-affiliated authoritative sources with measurable results supported by the positive endorsements of national medical bodies . . . ." Although the articles and information submitted may include sufficient evidence, the plaintiff has failed to carry her burden to show that the ACT procedure meets all four of the criteria listed in the experimental procedures exclusion.[5] Therefore, based on the record presented for preliminary injunctive relief, the plaintiff has not shown that she is likely to succeed in proving that the medical director's decision was unreasonable.

B. The Remaining Requirements for Preliminary Injunctive Relief

Since the plaintiff has not demonstrated that she is likely to succeed on the merits of her claim for coverage against

[5]The experimental procedures exclusion also requires that the evidence exist in peer review medical literature, which is defined in the endorsement.

BCBSNH, the remaining preliminary injunction requirements require little consideration. The plaintiff argues that irreparable harm is presumed in circumstances when insurance coverage for medical care is at issue. The cases the plaintiff cites, involving a loss of coverage for all medical care or coverage for treatment of a life threatening illness, do not presume irreparable harm in all circumstances, but instead find harm in the circumstances presented. See, e.g., Harris v. Blue Cross, 995 F.2d 877 (8th Cir. 1993); United Steelworkers of America v. Textron, Inc., 836 F.2d 6 (1st Cir. 1987). Irreparable harm cannot be presumed in this case.

Plaintiff's counsel argued at the hearing that the plaintiff has a narrow window of opportunity for an ACT procedure before the plaintiff's lesions become too large. Plaintiff's counsel did not explain how much time is left for the plaintiff to undergo a successful ACT procedure. In his affidavit, Dr. Karlson, the plaintiff's treating orthopedic surgeon, did not mention a medical urgency in scheduling the procedure although he discussed the plaintiff's condition and prognosis. As a result, it is not possible to assess the harm further delay in treatment may cause.

With an insufficient showing of the plaintiff's likelihood of success and risk of irreparable harm, it is not necessary to

weigh the relative harm to BCBSNH to pay the substantial cost of the ACT procedure in advance of having the coverage issue determined.

Conclusion

For the foregoing reasons, the plaintiff's motion for a preliminary injunction (document no. 2) is denied. The motion with respect to a permanent injunction is denied, and the issue of permanent relief will be considered at the time the court acts on the merits of the plaintiff's ERISA claims.

SO ORDERED.

Joseph A. DiClerico, Jr.
District Judge

August 17, 1999

cc: Scott F. Johnson, Esq.
Michael A. Pignatelli, Esq.