

United States District Court
District of Massachusetts

| | | |
|------------------------------|---|------------------|
| LOUIS F. KRODEL, |) | |
| |) | |
| Plaintiff, |) | |
| |) | |
| v. |) | Civil Action No. |
| |) | 03-11109-NMG |
| |) | |
| BAYER CORPORATION and BAYER |) | |
| CORPORATION WELFARE BENEFITS |) | |
| PLAN, |) | |
| |) | |
| Defendants. |) | |

MEMORANDUM & ORDER

GORTON, J.

Plaintiff, Dr. Louis F. Krodel ("Dr. Krodel"), alleges that Defendant, Bayer Corporation ("Bayer"), provider of the Bayer Corporation Welfare Benefits Plan ("The Plan"), wrongfully denied him certain health benefits to which he is entitled. On November 19, 2004, in response to cross-motions for summary judgment, this Court entered a Memorandum and Order finding procedural deficiencies in Bayer's review process and remanding Dr. Krodel's claim to Bayer for reconsideration. That process has been completed and the parties have filed renewed cross-motions for summary judgment.

I. Background

A. The Plan

The Plan provides an array of benefits to employees of Bayer and delegates responsibility for claim administration to the Connecticut General Life Insurance Company ("CIGNA"). CIGNA receives claims and makes the initial determination as to eligibility for coverage. According to the Summary Plan Description ("the SPD"), an expense is covered if it is a "medical necessity", which is defined as follows:

[a] treatment, service, or supply is usually a "medical necessity" if it is

- Consistent with and appropriate for the condition
- Of proven value and not redundant with other procedures
- Not educational, experimental or investigational and
- Approved by the U.S. Government, if required.

The SPD expressly incorporates by reference CIGNA's more detailed Standard Operating Procedures ("the SOPs") which consist of administrative rules used to administer ERISA plans. The SOPs exclude from coverage any medical supply that is a "biomechanical device", defined as "any external prosthesis operated through or in conjunction with nerve conduction or other electrical impulses".

B. The Dispute

Dr. Krodel participates in the Plan because he is the spouse of a Bayer employee. In 1979, he was struck by a car requiring amputation of his left leg above the knee. In 1999, Dr. Krodel

received a prosthesis manufactured by Next Step Orthotics & Prosthetics, Inc. ("Next Step") which was covered under the Plan. In November, 2001, Dr. Krodel returned to Next Step for a consultation because he had lost 30 pounds which caused the shape of his residual limb to change such that his prosthesis no longer fit properly. He also complained that the knee sometimes "buckled" causing him to lose his balance and fall.

In April, 2002, Dr. Krodel's physician, Dr. Segre, wrote him a prescription for a new, microprocessor-controlled prosthesis called the "C-Leg" that costs \$41,500. In a letter dated May 29, 2002, Next Step sought coverage pre-approval from Bayer. The letter enclosed a prescription for the device and a memorandum from Dr. Segre detailing his opinion of its medical necessity. On August 20, 2002, CIGNA denied coverage the grounds that biomechanical devices are excluded.

Dr. Krodel appealed the denial to Bayer's ERISA Review Committee. By letter dated October 8, 2002, Bayer denied the appeal on the grounds that the C-Leg is a biomechanical device and that "a prosthesis of this type is not considered to be medically necessary because the existing prosthesis addresses [Dr. Krodel's] medical condition".

On November 19, 2002, Dr. Krodel contacted Bayer to request copies of the documents governing the Plan and Bayer responded by providing a copy of the SPD. On March 18, 2003, Dr. Krodel

requested copies of all documents "relevant to the claim" and was provided with 13 pages of documents. Dr. Krodel, however, suspected that he had not received all relevant documents because neither he nor his counsel could determine, based upon the documentation in hand, the source of certain language that was quoted by Bayer in its letter denying coverage. It later became evident that Bayer had relied, in part, upon the SOPs which are not routinely provided to claimants because they are allegedly proprietary to CIGNA.

In April, 2003, for an unknown reason, CIGNA initiated an independent review of Dr. Krodel's claim. The inquiry resulted in an opinion from Dr. Arthur Brown ("Dr. Brown") which stated:

Approve. The information provided does justify the medical necessity of a replacement above knee prosthesis to assure a stable knee joint but does not justify a new prosthesis that will do more than provide a stable knee joint for usual activities.

The parties did not become aware of CIGNA's review until sometime during discovery.

On June 6, 2003, Dr. Krodel filed the instant action. On January 23, 2004, Bayer produced documents, including the SOPs, to Dr. Krodel. Both parties moved for summary judgment and, on November 19, 2004, this Court entered a Memorandum and Order holding that Dr. Krodel had not been provided with a "full and fair" review process, as required under ERISA. Dr. Krodel's claim was remanded to the Bayer ERISA Review Committee ("the Committee") for reconsideration. The Committee was instructed to

consider and provide to Dr. Krodel all information relevant to the claim, including that arising out of CIGNA's April, 2003 inquiry. Dr. Krodel was also to be afforded an opportunity to designate information for consideration.

C. Bayer's Review on Remand

Dr. Krodel designated a number of documents for consideration. He submitted a report from Dr. Nimet Oruc ("Dr. Oruc"), a physician who had been treating him since 2001. Dr. Oruc explained that, due to cardiovascular problems, Dr. Krodel was required to engage in aerobic exercise for at least 30 minutes per day. He opined that:

[t]he C-Leg is the most appropriate prosthesis for Dr. Krodel because it will help him become a more active, functional and safer ambulator. It provides knee stability and, for Dr. Krodel's needs, is superior to any other prosthetic knees.

Robert Emerson, a prosthetist employed by Next Step, concurred via affidavit.

The Committee initiated its own medical review of Dr. Krodel's claim by sending his file to Dr. James Cosgrove ("Dr. Cosgrove"). In his report, Dr. Cosgrove expressed the opinion that "the prescription for the above knee prosthesis, including the [C-Leg], is reasonable and appropriate for Mr. Krodel". He explained his conclusion as follows:

Mr. Krodel does meet the criteria for the use of the [C-Leg] and it will likely provide a qualitative difference in his ambulatory abilities as well as a measure of safety that he does not currently enjoy. While this is certainly an

expensive apparatus and is, indeed, the "Cadillac" of above-knee prostheses, it does represent an appropriate medical expense.

The Committee responded to Dr. Cosgrove and requested a "clarification" of that assessment. After explaining that Dr. Krodel's previous prosthesis had worked "relatively well" prior to his weight loss, the following questions were posed:

[c]onsidering this history, our question is whether a replacement with another "high activity knee with hydraulic swing phase control and a Flex Foot" type device would achieve a reasonable level of support and permit resumption of the "community ambulatory" activity level which the patient enjoyed prior to the weight loss? If not, can you explain the changes in the patient's condition which would make a microprocessor controlled device medically necessary under the definition set forth above?

Dr. Cosgrove responded with a two-page "Addendum" to his report. He answered the first question (whether a hydraulic prosthesis would be reasonable) as follows:

[i]t is my opinion that the prescription of the [C-Leg] is consistent and appropriate for the condition of the above-knee amputation in a vigorous, active, and independent individual. Concerning the phrase "redundant with other procedures", there are certainly other alternative devices that will achieve a similar, but not comparable, therapeutic benefit. By not comparable, I mean that there is a measure of safety and gait pattern that the C-Leg (as well as other micro-processor type devices) offers that the typical pneumatic/mechanical knee joints do not afford.... In the absence of purchasing a C-Leg, refabricating a socket with a knee joint that has stance control would be reasonable.

In response to the Committee's second question, i.e., how Dr. Krodel's condition has changed, after noting that Dr. Krodel had lost weight and experienced periodic falls, Dr. Cosgrove stated:

[c]ertainly, as individuals get older, protective reflexes become somewhat slower increasing the likelihood of falls.

Furthermore, as one gets older, the likelihood of falls causing significant injury increases. As I indicated in my initial letter, the C-Leg does afford a measure of safety that other mechanical devices do not.

If I may offer the following analogy: When driving, wearing a seat belt dramatically decreases your likelihood of significant injury during a [motor vehicle accident]. Think of a standard stance phase control "safety" knee as being a seat belt/shoulder harness mechanism. An inflatable air bag is an additional device which is more expensive than the seat belt and certainly far more sophisticated but, in certain conditions, provides a measure of safety not afforded by the seat belt mechanism alone. Think of the C-Leg as an air bag. Is it "reasonable" to drive a car that does not possess an air bag? Some individuals might say "yes" while others may say "no". Our government does not allow cars to be manufactured without air bags.

On the subject of whether the C-Leg is a biomechanical device, Dr. Krodel provided the Committee with an affidavit from Peter Couture, a letter from Thomas D. Willis, Chief Scientific Officer of ParAllele BioScience, Inc., and a letter from Professor Neville Hogan, of the Massachusetts Institute of Technology. All three confirmed that the C-Leg is not operated through nerve conduction. As Bayer points out, however, none addressed whether it is operated through "electrical impulses". Finally, the Committee considered opinions of Robert Ferguson, Dr. Oruc and Dr. Cosgrove that the C-Leg is not an experimental device.

D. Bayer's Decision

On March 8, 2005, the Committee announced its decision to approve coverage of a replacement prosthesis similar to Dr. Krodel's old one but not the C-Leg. The 13-page decision

recounted the history of this case and the evidence considered on remand. The Committee then considered three issues in reaching its decision.

First, the Committee addressed whether the C-Leg is a biomechanical device. The Committee acknowledged that none of the experts answered affirmatively but discounted those opinions because they did not explicitly address the fact that the definition of biomechanical device includes devices operated through "electrical impulses". Thus, the Committee concluded that:

the position of the claims administrator that a microprocessor-controlled prosthesis is an excluded biomechanical device, as the term is defined in the SOPs, would appear to be supportable and provide a basis to deny pre-authorization of the C-Leg.

The Committee did not, however, base its decision on a biomechanical device exclusion.

Second, the Committee addressed whether the C-Leg is an excluded "experimental supply". It acknowledged the expert opinions submitted by Dr. Krodel that the C-Leg is not experimental but noted that the submissions do not provide citations to authorities which would "demonstrate general acceptance in the medical community". The Committee then referred to the opinions of two other insurance companies that microprocessor-controlled devices are experimental. Ultimately, the Committee concluded that whether the C-Leg is an experimental supply is a "close question" that need not be decided.

The final issue, upon which the Committee did base its decision, was whether the C-Leg is a "medical necessity" because it is "of proven value and not redundant with other procedures". The Committee began its analysis by stating:

[w]e do not have a definition in the SPD or Plan for this phrase, but we interpret it to mean that there are no other reasonable alternatives which would achieve a comparable therapeutic benefit for the patient, in terms of enabling the patient to perform activities of daily living. This definition entails something of a cost/benefit analysis, bearing in mind that we must balance good stewardship with the needs of the beneficiaries.

The Committee conceded that the C-Leg would provide "some benefit" to Dr. Krodel but concluded that the submitting doctors had provided "no statement which opines that Dr. Krodel will be able to achieve a higher level of activity with [the C-Leg] than with the standard prosthesis provided by the Bayer Plan in 1999". The Committee argued that, until Dr. Krodel experienced weight loss in 2001, his prosthesis had worked "relatively well". It thus concluded that the problem with Dr. Krodel's prosthesis is one of fit which could be corrected by a replacement prosthesis of the kind provided in 1999. Coverage of the C-Leg was denied.

On April 14, 2005, Dr. Krodel filed a motion for summary judgment arguing that Bayer's decision on remand was both procedurally and substantively improper. Dr. Krodel also presses his claim for statutory penalties based upon alleged delays in the provision of documents relating to his claim. On May 2, 2005, Bayer filed a cross-motion for summary judgment arguing

that its decision must be affirmed because it was not arbitrary and capricious.

II. Legal Analysis

A. Standard of Review

1. Judicial Review of Action by an ERISA Board

A district court reviews ERISA claims arising under 29 U.S.C. § 1132 de novo unless the benefits plan in question confers discretionary authority upon the administrator to "determine eligibility for benefits or to construe the terms of the plan". Bekiroglu v. Paul Revere Life Ins. Co., 223 F. Supp. 2d 361, 366 (D. Mass. 2002), aff'd 2003 WL 22213863 (1st Cir. 2003). If the plan clearly gives such authority to an administrator (as this one does), then the administrator's decisions are subject to deference and will only be reversed if they were "arbitrary, capricious or an abuse of discretion". Diaz v. Seafarers Int'l Union, 13 F.3d 454, 456 (1st Cir. 1994). Under that standard, a "decision will be upheld if it was within [the administrator's] authority, reasoned, and supported by substantial evidence in the record." Doyle v. Paul Revere Life Ins. Co., 144 F.3d 181, 184 (1st Cir. 1998) (internal citations omitted).

2. Summary Judgment Standard

The role of summary judgment is "to pierce the pleadings and

to assess the proof in order to see whether there is a genuine need for trial." Mesnick v. General Elec. Co., 950 F.2d 816, 822 (1st Cir. 1991) (quoting Garside v. Osco Drug, Inc., 895 F.2d 46, 50 (1st Cir. 1990)). The burden is upon the moving party to show, based upon the pleadings, discovery and affidavits, "that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c).

A fact is material if it "might affect the outcome of the suit under the governing law." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "Factual disputes that are irrelevant or unnecessary will not be counted." Id. A genuine issue of material fact exists where the evidence with respect to the material fact in dispute "is such that a reasonable jury could return a verdict for the nonmoving party." Id.

Once the moving party has satisfied its burden, the burden shifts to the non-moving party to set forth specific facts showing that there is a genuine, triable issue. Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986). The Court must view the entire record in the light most hospitable to the non-moving party and indulge all reasonable inferences in that party's favor. O'Connor v. Steeves, 994 F.2d 905, 907 (1st Cir. 1993). If, after viewing the record in the non-moving party's favor, the Court determines that no genuine issue of material fact exists

and the moving party is entitled to judgment as a matter of law, summary judgment is appropriate.

B. Bayer's Decision on Remand

Dr. Krodel argues that Bayer's decision on remand was both procedurally and substantively erroneous. Substantively, he argues that Bayer's decision was arbitrary and capricious because it: 1) relied upon language from the SOPs which was not contained in the SPD, 2) made the "mistaken assumption" that Dr. Krodel's problems all stemmed from his 2001 weight loss and 3) ignored uncontroverted medical evidence that the C-Leg was a medical necessity.

Bayer responds that there was substantial evidence to support a finding that: 1) prior to 2001, Dr. Krodel had been able to lead an active life with a standard, non-computerized prosthesis, and 2) while the C-Leg may have been "best", a replacement for the 1999 prosthesis was adequate. As a result, it contends, the Committee was within its discretion to employ a cost/benefit analysis to choose the less costly alternative.

Bayer concludes with a plea that:

[a] court should not force upon medical benefit plans, which are coping with monumental and increasing health care costs in any case, a rule that required a Cadillac, when a Ford will get the job done and is consistent with the terms of the Plan and the evidence in the record.

The Committee denied Dr. Krodel's claim on the ground that the C-Leg was not a "medical necessity" for him under the SPD.

In evaluating the Committee's interpretation, the Court is mindful that an important purpose of an SPD is to inform beneficiaries of the "circumstances which may result in ... denial or loss of benefits". 29 U.S.C. § 1022(b). Such information must be presented in a manner that is "calculated to be understood by the average plan participant". § 1022(a). Accordingly, the language of an SPD must be interpreted according to its plain meaning. See Alves v. Harvard Pilgrim Health Care Inc., 204 F. Supp. 2d 198, 207-08 (D. Mass. 2002) ("we may not supplant the natural meaning of ERISA plan terms with rigid definitions or contrary interpretations offered by the parties").

The Plan provides coverage for medical necessities. Under the SPD, a medical supply is a medical necessity if it is "[o]f proven value and not redundant with other procedures". The Committee found that phrase to be in need of elaboration and interpreted it to mean:

there are no other reasonable alternatives which would achieve a comparable therapeutic benefit for the patient, in terms of enabling the patient to perform activities of daily living.

That formulation is suspect because it suggests a more stringent standard for benefit determinations than the SPD would most naturally permit. A device can be valuable to a patient and non-redundant without being the only reasonable alternative available. Plan participants were promised that their claims would be judged by the former standard.