**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF LOUISIANA**

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| **JAMES F. WELCH** | **CIVIL ACTION** |
| **VERSUS** | **NO: 08-4576** |
| **HMO LOUISIANA/BLUE CROSS** | **SECTION: "S" (1)** |

**ORDER AND REASONS**

**IT IS HEREBY ORDERED** that James F. Welch's motion for summary judgment is **GRANTED**. (Document #11.)

**IT IS FURTHER ORDERED** that HMO Louisiana/Blue Cross's motion for summary judgment is **DENIED**. (Document #15.)

## I. BACKGROUND

On December 11, 2007, James F. Welch underwent surgery for a total right knee replacement at Touro Hospital in New Orleans, Louisiana. In performing the surgery, Dr. Richard L. Meyer used a computer-assisted musculoskeletal surgical navigational orthopedic procedure.[1]

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[1] "The term computer-assisted musculoskeletal surgical navigation procedure describes navigation systems that provide additional information during a procedure that attempts to further integrate preoperative planning with intraoperative execution." Blue Cross Blue Shield of

As a full-time employee of Southeast Louisiana Legal Services, Welch was a participant in the Employee Health Benefit Plan, issued through HMO Louisiana, Inc. On July 12, 2007, the insurer denied the portion of Welch's claim for coverage which was attributable to the use of a computer-assisted musculoskeletal surgical navigation procedure because the insurer considered it to be investigational. The insurer paid benefits for arthroplasty, but not for a computer-assisted musculoskeletal surgical navigation procedure.

Welch filed a claim[2] in the Small Claims Division of First City Court, State of Louisiana, New Orleans, Louisiana. HMO Louisiana, Inc. and Louisiana Health Service & Indemnity Company d/b/a Blue Cross and Blue Shield of Louisiana (HMOLA) removed the case to federal court on grounds of Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. § 1001 *et seq.*, preemption. Welch and HMOLA filed cross motions for summary judgment.

## II. DISCUSSION

### A. Legal standard

Summary judgment is proper when, viewing the evidence in the light most favorable to the non-movant, "there is no genuine issue as to any material fact and . . . the moving party is entitled to judgment as a matter of law." Amburgey v. Corhart Refractories Corp., 936 F.2d 805, 809 (5th Cir. 1991); Fed. R. Civ. P. 56(c). If the moving party meets the initial burden of establishing that there is no genuine issue, the burden shifts to the non-moving party to produce

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Louisiana Medical Policy #00179. The most commonly performed orthopedic computer-assisted surgeries include use as an adjunct to hip and knee anthroplasty procedures. Id.

[2] Welch is an attorney proceeding *pro se*.

evidence of the existence of a genuine issue for trial. Celotex Corp. v. Catrett, 106 S.Ct. 2548, 2552 (1986). The nonmovant cannot satisfy the summary judgment burden with conclusory allegations, unsubstantiated assertions, or only a scintilla of evidence. Little v. Liquid Air Corp., 37 F.3d 1069, 1075 (5th Cir. 1994) (en banc).

**B. ERISA**

Welch contends that HMOLA abused its discretion in denying payment for the computer-assisted musculoskeletal surgical navigation procedure. He argues that a higher standard of review should be applied when the insurer is operating under a conflict of interest, *i.e.* it makes the determination of benefits and is the payor.

"The Employee Retirement Income Security Act of 1974 (ERISA) permits a person denied benefits under an employee benefit plan to challenge that denial in federal court." Metropolitan Life Ins. Co. v. Glenn, 128 S.Ct. 2343, 2346 (2008); 29 U.S.C. § 1101 *et seq.*; § 1132(a)(1)(B). "Often the entity that administers the plan, such as an employer or an insurance company, both determines whether an employee is eligible for benefits and pays benefits out of its own pocket." Id. In Firestone Tire & Rubber Co. v. Bruch, 109 S.Ct. 948 (1989), the United States Supreme Court addressed the standard of judicial review of benefit determinations by plan administrators under § 1132(a)(1)(B), setting forth four principles of review. First, a court should be guided by principles of trust law and should analogize a plan administrator to the trustee of a common-law trust performing a fiduciary act. Id. at 954. Second, the court reviews the denial of plan benefits under a *de novo* standard of review, unless the plan provides to the contrary. Id. at 955. Third, if the plan grants the administrator or fiduciary discretionary

authority to determine eligibility, a deferential standard is appropriate. Id. at 954. Fourth, if a benefit plan grants discretion to an administrator who is operating under a conflict of interest, the conflict must be weighed as a factor in determining whether there is an abuse of discretion. Id. at 957.

In this case, there is no dispute that the benefit plan gives the administrator the discretion to interpret the plan provisions. Further, HMOLA both evaluates claims for benefits and pays benefits claims; therefore, "for ERISA purposes, a conflict exists." Metropolitan Life Ins. Co. v. Glenn, 128 S.Ct. at 2349. ERISA imposes a higher standard on insurers and "sets forth a special standard of care upon a plan administrator, namely, that the administrator discharge its duties in respect to discretionary claims processing solely in the interest of the participants and beneficiaries of the plan." Id. at 2350 (quotations omitted); § 1104(a)(1). The statement in Firestone that a conflict should be weighed as a factor in determining an abuse of discretion, however, does not imply a change in the standard of review from deferential to *de novo*. Id. "[C]onflicts are but one factor among many that a reviewing judge must take into account." Id. at 2351.

The court applies a two-step analysis when reviewing under an abuse of discretion standard: whether the determination was legally correct; and if the interpretation was legally incorrect, whether the decision was an abuse of discretion. Stone v. UNOCAL Termination Allowance Plan, 570 F.3d 252, 257 (5th Cir. 2009). Three factors are considered when deciding if an interpretation is legally correct: "(1) whether the administrator has given the plan a uniform construction, (2) whether the interpretation is consistent with a fair reading of the plan, and (3)

any unanticipated costs resulting from different interpretations of the plan." Id. at 258. "The most important factor in this three-part analysis is whether the administrator's interpretation was consistent with a fair reading of the plan." Id.

The plan limits and excludes surgery which is "investigational in nature" as determined by the policies and procedures for such determinations. Article XVIII(B)(A)(4)(f). On April 3, 2008, HMOLA affirmed the initial denial of the procedure services, based on Blue Cross Blue Shield of Louisiana Medical Policy #00179: Computer-Assisted Muscoloskeletal Surgical Navigational Orthopedic Procedure. See HMOLA-172. Under the Medical Policy, the computer-assisted musculoskeletal surgical navigation procedure was deemed to be "investigational" because there is insufficient scientific data to permit accurate conclusions regarding the technology. The plan administrator relied on the Medical Policy generally and did not point to any specific portion of the Medical Policy, other than quoting the definition of "investigational."

In determining whether the denial of the procedure services was legally correct in this case, the relevant factor is "whether the interpretation is consistent with a fair reading of the plan."

The Medical Policy defines "investigational" as follows:

> Investigational–A medical treatment, procedure, drug, device, or biological product is investigational if the effectiveness has not be clearly tested and it has not been incorporated into standard medical practice. Any determination We make that a medical treatment procedure, drug, device, or biological product is investigational will be based on a consideration of the following:
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> A. whether the medical treatment, procedure, drug, device, or biological product

can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other non-affiliated technology evaluation center(s);

2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or

3. reference to federal regulations.

Blue Cross Medical Policy #00179 (2007).

Paragraph A of the criteria for deeming a procedure "investigational" is not applicable. The Medical Policy informs that "the FDA does not require data documenting the intermediate or final health outcomes associated with computer-assisted surgery." Although surgical navigational systems require FDA clearance, they are subject only to 510(k) clearance "since computer-assisted surgery is considered analogous to a surgical information system in which the surgeon is only acting on the information that is provided by the navigation system." A variety of surgical navigation procedures have received FDA clearance through the 510(k) and in general the labeled indications are very broad.

Paragraph B of the criteria for defining "investigational" asks whether the procedure requires further studies or clinical trials to determine its effectiveness or effectiveness as

compared with the standard means of diagnosis.

The "Background/Overview" section of the Medical Policy describes the navigation system as providing "additional information during a procedure that attempts to further integrate preoperative planning with intraoperative execution." The policy explains that navigation involves three steps: data acquisition, registration, and tracking.[3] The stated focus of the use of the procedure is the effectiveness before and during the surgery, rather than the postoperative

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[3] Medical Policy #00179 provides the following definitions:

Data Acquisition

As described by the three new 2004 CPT category III codes, . . . data can be acquired in three different ways, *i.e.* fluoroscopic, guided by computed tomography (CT) or magnetic resonance imaging (MRI), or imageless systems. These data are then used for registration and tracking Image-guided systems are somewhat self-explanatory. The imageless systems rely on other information such as centers of rotation of the hip, knee, or ankle or visual information like anatomical landmarks.

Registration

Registration refers to the ability of relating images (*i.e.* x-rays, CT, MRI or patients' 3-D anatomy) to the anatomical position in the surgical field. Early registration techniques required the placement of pins or "fiduciary markers" in the target bone, which required an additional surgical procedure. More recently, a surface-matching technique can be used in which the shapes of the bone surface model generated from preoperative images are matched to surface data points collected during surgery.

Tracking

Tracking refers to the sensors and measurement devices that can provide feedback during surgery regarding the orientation and relative position of tools to bone anatomy. For example, optical or electromagnetic trackers can be attached to regular surgical tools, which can then provide real time information of the position and orientation of the tools' alignment with respect to the bony anatomy of interest.

effects. There is nothing in this section that indicates the purpose of further studies or clinical trials.

Trials showing positive results are discussed in the section of the Medical Policy labeled "Anthroplasty (total hip [THA] and total knee [TKA])," which states as follows:

> It is proposed that computer-assisted surgery improves the alignments of the various components of THA and TKA. Ideally, one would like controlled trials comparing the long-term outcomes, including stability and recuperation rates. Intermediate outcomes include the percentage of implants that achieve a predetermined level of acceptable alignment.

The available studies cited in the Medical Policy "have consistently shown that computer-assisted navigation is associated with improved postoperative alignment along several different axes." Nonetheless, because the published studies reported immediate outcomes rather than the "ideal" long-term outcomes, the Medical Policy concludes that there is "inadequate scientific data to permit conclusions regarding whether the improvement in alignment associated with computer-assisted navigation will result in significant clinical improvement in patients undergoing TKA."

The court concludes that the plan administrator's interpretation is not a fair reading of the plan. The Medical Policy upon which the plan administrator relied does not support the conclusion that the computer-assisted musculoskeletal surgical navigational orthopedic procedure is investigational under paragraph B. The plan administrator's determination is inconsistent with the published data, the description and purpose of the navigation system as an information system, and the lack of federal regulations requiring such studies.

Because the supporting data in Medical Policy #00179 does not clearly fit either prong of

its own definition of "investigational," the administrator's interpretation is inconsistent with a fair reading of the plan and is not legally correct. Accordingly, the administrator failed to discharge its duties to process the claim solely in Welch's interest and, thereby, abused its discretion in denying payment for the computer-assisted musculoskeletal surgical navigation procedure.

Accordingly, there are no disputed issues of material fact, and Welch is entitled to judgment as a matter of law that the computer-assisted musculoskeletal surgical navigation procedure is covered under the plan. Welch's motion for summary judgment is granted, and HMOLA's cross motion for summary judgment is denied.

New Orleans, Louisiana, this 20 day of October, 2009.

**MARY ANN VIAL LEMMON**
**UNITED STATES DISTRICT JUDGE**