FILED

JUL 25 2012

MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

RANDEE PARSONS and PEGGY PARSONS, Plaintiffs - Appellants, v. SISTERS OF CHARITY OF LEAVENWORTH HEALTH SYSTEMS INC., a Kansas corporation; et al., Defendants - Appellees.	No. 11-35693 D.C. No. 1:10-cv-00047-RFC MEMORANDUM*

Appeal from the United States District Court
for the District of Montana
Richard F. Cebull, Chief District Judge, Presiding

Argued and Submitted July 11, 2012
Seattle, Washington

Before: REINHARDT, KLEINFELD, and M. SMITH, Circuit Judges.

Plaintiffs-Appellants appeal from an order granting summary judgment in favor of Sisters of Charity of Leavenworth Health Systems, Inc., BlueCross

* This disposition is not appropriate for publication and is not precedent except as provided by 9th Cir. R. 36-3.

BlueShield of Kansas City, and BlueCross BlueShield of South Carolina. We have jurisdiction under 28 U.S.C. § 1291. We review the grant of summary judgment de novo. Johnson v. Buckley, 356 F.3d 1067, 1071 (9th Cir. 2004).

The benefit plan declined to cover Randee Parsons for participating in a clinical trial for autologous bone marrow transplant (ABMT) with Dr. Richard Burt because the trial was "experimental and investigational," and therefore not covered by the plan. We need not decide whether the district court should have reviewed the denial of coverage de novo or for abuse of discretion, or what law applies, because regardless, there is no genuine issue of fact as to whether this ABMT procedure was "experimental and investigational" under the plan.

A procedure is experimental and investigational under the plan if it: (1) has not received required final approval to market from appropriate government bodies; (2) is one about which the peer-reviewed medical literature does not permit conclusions concerning its effect on health outcomes; (3) is not demonstrated to be an established alternative; (4) has not been demonstrated to improve net health outcomes; or (5) is one in which the improvement claimed is not demonstrated to be obtainable outside the experimental and investigational setting.

Here, the procedure has only been approved by the FDA for the clinical trial phase. It has not received FDA final approval. The only legible peer reviewed literature submitted, coauthored by Dr. Burt, discusses a "pilot study" of twelve patients, and says a "randomized study will be needed to confirm the efficacy of this therapy." In his deposition, Dr. Burt stated that he had not yet completed the randomized trial. No improvements have been obtained, so far as the record shows, outside the experimental and investigational setting. The consent form signed by Randee Parsons describes this as an experimental procedure.

Accordingly, the Parsons failed to raise a genuine issue of material fact that this procedure is not experimental and investigational under the plan. The remaining arguments lack any outcome-changing force.

AFFIRMED.