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IN THE UNITED STATES DISTRICT COURT

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FOR THE DISTRICT OF ARIZONA

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Michael J. Boldon,

No. CV06-02818-PHX-NVW

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Plaintiff,

**FINDINGS OF FACT AND
CONCLUSIONS OF LAW IN SUPPORT
OF PRELIMINARY INJUNCTION**

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vs.

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Humana Insurance Company; Cutter
Aviation Group Medical Plan
Administrator,

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Defendants.

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Pending before the court are Plaintiff's Complaint (Doc. # 1) and Application for Temporary Restraining Order and Preliminary Injunction (Doc. # 2). At issue is whether Defendant Humana Insurance Company ("Humana") should be required to provide coverage for Plaintiff's prescribed medical treatment under the Employee Retirement Income Security Act ("ERISA"). The court makes the following findings of fact and conclusions of law:

I. Findings of Fact

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A. The Parties

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Plaintiff Michael J. Boldon ("Boldon") is a 54-year old employee of Cutter Aviation, Inc. Since January 1, 2005, Boldon has been enrolled in the Cutter Aviation Group Medical Plan ("Plan"), a participating provider option plan ("PPO") that provides medical benefits to Cutter Aviation employees. Defendant Humana is the administrator, insurer, and payer of benefits under the Plan.

1 **B. Baldon's Condition**

2 In May 2006, Baldon was diagnosed with advanced unresectable hepatocellular
3 carcinoma ("HCC"), a rare form of terminal liver cancer with four stages of progressing
4 severity. HCC is considered an "orphan disease" because only approximately 16,000
5 patients are diagnosed with HCC in the United States each year. Patients who do not receive
6 treatment for HCC survive anywhere from three months to four years following diagnosis.
7 Baldon also has hepatitis-C and is HIV positive.

8 Due to the size of his tumor and his HIV status, Baldon was advised in July 2006 that
9 he is not eligible for liver transplantation at the Banner Good Samaritan Liver Disease Center
10 ("Banner") in Phoenix, Arizona. In August 2006, the Liver Transplant Clinic at the
11 University of California at San Francisco Medical Center ("UCSF") similarly declined to
12 offer the procedure in light of Baldon's use of narcotics and cigarettes, his tumor's size, and
13 evidence from a CT scan performed on August 23 "consistent with" the conclusion that his
14 HCC had metastasized. Doc. # 38, Exhibit 3 at 6.

15 Contrary to the UCSF CT scan's indication of possible metastasis, the report from a
16 CT scan subsequently performed at Banner on September 11, 2006, did not mention any
17 signs of metastasis. Additional blood and imaging tests conducted at Banner on December
18 12, 2006, also showed no signs of metastasis.

19 **C. The Recommended Treatment**

20 In September 2006, Baldon's physician at Banner, Kevin S. Hirsch, M.D. ("Dr.
21 Hirsch"), a board-certified interventional radiologist, recommended treating Baldon's
22 advanced HCC with yttrium-90 radioembolization using TheraSphere Y-90. TheraSphere
23 treatment involves the intra-arterial delivery of glass microspheres of the radioactive element
24 yttrium-90 to the site of a patient's liver tumor and is performed at Banner on an outpatient
25 basis. An initial administration of TheraSphere generally costs over \$100,000. Subsequent
26 administrations cost approximately \$20,000 each.

27 TheraSphere was recommended to Baldon for the purpose of prolonging and
28 improving the quality of his life. His only alternative is chemoembolization, a form of

1 treatment that is less likely to extend his life expectancy and more likely to produce adverse
2 side effects. If Boldon does not receive TheraSphere treatment in the near future, it is
3 probable that he will lose his life relatively prematurely.

4 **D. The Status of the Treatment**

5 In March 2000, the Center for Devices and Radiological Health of the United States
6 Food and Drug Administration ("FDA") approved TheraSphere for commercial distribution
7 under the FDA's humanitarian device exemption. This exemption permits a company to
8 distribute a medical device commercially without a scientifically rigorous demonstration of
9 effectiveness when the number of patients expected to benefit from the device is fewer than
10 4,000 per year. The FDA's approval notice permits TheraSphere to be used "for radiation
11 treatment or as a neoadjuvant to surgery or transplantation in patients with unresectable
12 hepatocellular carcinoma (HCC) who can have placement of appropriately positioned hepatic
13 arterial catheters." Joint Exhibit # 16 at 3-4. The FDA's approval was

14 based on the results of a randomized, controlled clinical trial
15 involving 70 persons with colorectal cancer metastatic to the
16 liver, 34 of whom received [floxuridine] chemotherapy (control
17 group), and 36 of whom received [floxuridine] plus
18 [microspheres]. Two of the patients receiving [floxuridine] plus
19 [microspheres] had a complete response, and 16 had a partial
20 response. By comparison, one patient receiving [floxuridine]
21 alone achieved a complete response and seven had a partial
22 response. There is a statistically significant delay of time to
23 progression of the disease in the group treated with [floxuridine]
24 plus [microspheres], when compared with the group treated with
25 [floxuridine] only. Joint Exhibit # 19 at 1.

26 Since obtaining FDA approval, TheraSphere has become a common, if not standard,
27 treatment for HCC. TheraSphere is available in 29 cancer treatment centers across the
28 United States. Since 2004, the National Comprehensive Cancer Network has included
TheraSphere treatment in its clinical guidelines for unresectable primary liver cancer.
TheraSphere is also fully reimbursable under Medicare and Medicaid, and is covered by
insurance plans provided by Aetna, CIGNA, and several Blue Cross/Blue Shield companies.
Dr. Hirsch has personally treated approximately 30 HCC patients with TheraSphere since
April 2005.

1 In total, thirteen Phase I and Phase II clinical studies have been conducted on
2 TheraSphere. Phase I studies tested the proper administration and dosage for the treatment.
3 Phase II studies, in contrast, tested whether TheraSphere is effective against HCC. One
4 randomized, controlled trial specifically compared the efficacy of TheraSphere and the
5 common chemotherapy drug floxuridine among 70 cancer patients. All of these studies were
6 discussed in peer-reviewed medical journals, and all of them concluded that TheraSphere is
7 a relatively safe and effective treatment for advanced-stage unresectable HCC. Due in large
8 part to the rarity of HCC, Phase III trials have not been conducted to compare TheraSphere
9 to alternative treatments among large populations of patients.

10 E. The Scope of Boldon's Coverage

11 The Cutter Aviation Group Medical Plan covers the "services of a radiologist."
12 However, the Plan does not cover the provision of "[a]ny drug, biological product, device,
13 medical treatment, or procedure which is *experimental, or investigational or for research*
14 *purposes.*" Joint Exhibit # 1 at 52. In the Plan's Glossary, "experimental or investigational
15 of for research purposes" is defined as

16 a drug, biological product, device, treatment or procedure that
17 meets any one of the following criteria, as determined by *us*:

- 18 ● Cannot be lawfully marketed without the final
19 approval of the United States Food and Drug
20 Administration (FDA) and which lacks such final
21 FDA approval for the use or proposed use, unless
22 (a) found to be accepted for that use in the most
23 recently published edition of the United States
24 Pharmacopeia-Drug Information for Healthcare
25 Professional (USP-DI) or in the most recently
26 published edition of the American Hospital
27 Formulary Service (AHFS) Drug Information, or
28 (b) identified as safe, widely used and generally
accepted as effective for that use as reported in
nationally recognized peer reviewed medical
literature published in the English language as of
the date of service; or (c) is mandated by state
law;
- Is a device required to receive Premarket
Approval (PMA) or 510K approval by the FDA
but has not received a PMA or 510K approval;
- Is not identified as safe, widely used and
generally accepted as effective for the proposed
use as reported in nationally recognized peer

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- reviewed medical literature published in the English language as of the date of service;
- Is the subject of a National Cancer Institute (NCI) Phase I, II or III trial or a treatment protocol comparable to a NCI Phase I, II or III trial, or any trial not recognized by NCI regardless of phase; or
- Is identified as not covered by the Centers for Medicare and Medicaid Services (CMS) Medicare Coverage Issues Manual, a CMS Operational Policy Letter or a CMS National Coverage Decision, except as required by state or federal law. Joint Exhibit # 1 at 94.

The Plan concludes with the following language:

DISCRETIONARY AUTHORITY

With respect to paying claims for benefits or determining eligibility for coverage under a policy issued by Humana, Humana as administrator for claims determinations and as ERISA claims review fiduciary, shall have full and exclusive discretionary authority to: 1) interpret plan provisions, 2) make decisions regarding eligibility for coverage and benefits, and 3) resolve factual questions relating to coverage and benefits. Joint Exhibit # 1, Notices at 2.

F. The Denial of Coverage

In September 2006, Dr. Sankara Atman Sidat-Singh (“Dr. Sidat-Singh”), a former family practitioner now employed as the medical director for Humana’s Commercial Segment in Arizona and Colorado, reviewed Dr. Hirsch’s recommendation of TheraSphere treatment for Boldon. Following an internal Humana guideline that describes TheraSphere as “experimental/investigational,” Dr. Sidat-Singh denied coverage. The guideline on which Dr. Sidat-Singh relied states:

Humana members would **NOT** be eligible under the Plan for intrahepatic yttrium-90 microsphere therapy. This technology is considered experimental/investigational as it is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language. Joint Exhibit # 15.

This guideline was in turn based on two medical literature summaries provided to Humana by a private industry consultant. Neither of these summaries express the conclusion that ThereSpere treatment for HCC is experimental or investigational as defined in the Plan or in general medical usage. The literature summaries instead note that, as of May 2006, there

1 are “no randomized controlled trials that compare[] the efficacy of alternative treatment
2 options to those of intrahepatic arterial yttrium-90 microsphere therapy.” Joint Exhibit # 16
3 at 1; *see also* Joint Exhibit # 17. The literature summaries also note that all of the clinical
4 studies on TheraSphere concluded that it is “relatively safe, well-tolerated, and effective for
5 advanced stage unresectable HCC.” *Id.*

6 Dr. Sidat-Singh’s decision to deny coverage was not based on Boldon’s medical
7 record. Because Humana had previously determined that TheraSphere is
8 “experimental/investigational,” Humana did not accord him the authority to make an
9 independent determination concerning coverage for Boldon’s treatment. Nor was Dr. Sidat-
10 Singh familiar with TheraSphere treatment or the Plan provision on which he based the
11 denial of coverage. Dr. Sidat-Singh has never performed TheraSphere treatment, consulted
12 with other physicians about the treatment, or read any literature on TheraSphere other than
13 the internal Humana guideline. Dr. Sidat-Singh also did not review the UCSF report
14 indicating possible evidence that Boldon’s cancer had become metastatic.

15 Following Dr. Sidat-Singh’s application of the guideline, Humana sent a letter to
16 Boldon on September 26, 2006, denying coverage for his prescribed treatment. This denial
17 was based on a “physician review” and Plan provision # 213100, which excludes coverage
18 for “[a]ny drug, biological product, device, medical treatment, or procedure which is
19 *experimental, or investigational or for research purposes.*” Doc. # 4, Exhibit 3 at 160.

20 Dr. Hirsch responded on September 26, 2006, by submitting an appeal of the denial
21 of benefits to Humana’s Expedited Appeals Department. In the appeal, he argued that
22 Humana’s decision was unwarranted because TheraSphere is an effective and widely
23 accepted treatment for Boldon’s condition. While the appeal was pending, Humana retained
24 the Medical Review Institute of America, Inc. (“Review Institute”), to provide an
25 independent review of the denial of coverage. Finding the medical literature insufficient to
26 reverse Humana’s decision, the Review Institute stated:

27 The studies on TheraSphere suggest that based on limited data,
28 the treatment may prolong survival as compared with known
survival characteristics of liver cancer patients based on Okuda

1 staging. However, none of the studies to date have involved a
2 statistically meaningful study group or have employed rigorous
3 study designs involving randomization to chemotherapy versus
4 [TheraSphere] or blinding of observers, and nearly all expert
reviewers conclude there is a need for these randomized, well
designed studies to determine the efficaciousness of
[TheraSphere] as a palliative measure. Joint Exhibit # 19 at 2.

5 Again explaining that TheraSphere is considered to be “experimental/investigational,”
6 Humana denied the expedited appeal in a letter dated October 3, 2006. The October 3 letter
7 stated that the denial of benefits

8 was based on the information provided to the Medical Review
9 Institute of America, Inc., an external review agency, whom
[sic] determined that the studies conducted for the TheraSphere
do not validly prove the efficaciousness of the treatment.

10 Additionally, based on the limited data, the treatment may
11 prolong survival as compared with known survival
12 characteristics of liver cancer patients based on Okuba staging.
13 However, none of the studies to date have involved a
statistically meaningful study group or have employed rigorous
study designs involving randomization to chemotherapy. *Id.*

14 Humana attached to this letter a copy of the internal guideline on which Dr. Sidat-Singh
15 relied in denying coverage.

16 Dr. Hirsch submitted a second expedited appeal to Humana’s Independent Review
17 Organization on October 10, 2006, repeating that the denial of benefits was unwarranted
18 because TheraSphere is effective and widely accepted as a treatment for HCC. In response
19 to this second appeal, the Arizona Department of Insurance retained Permedion, an
20 independent medical review organization, to review Boldon’s claim. Permedion
21 subsequently concluded that “TheraSphere treatment for unresectable hepatocellular
22 carcinoma is experimental/investigational.” Doc. # 49, Exhibit 4 at 2. The Permedion
23 reviewer, a individual certified as a specialist in hematology and oncology, explained the
24 basis for this conclusion as follows:

25 TheraSphere . . . is indicated by the [FDA] for radiation
26 treatment or as a neoadjuvant treatment to surgery or
27 transplantation in patients with unresectable Hepatocellular
28 Carcinoma. Based on a review of the peer reviewed medical
literature it is noted that there are no Phase III randomized
clinical trials that show Yttrium 90/TheraSphere is more
effective than or as effective as conventional, standard of care,

1 treatment. This enrollee has not had any surgery or a
2 transplantation, nor is he a candidate for a transplant, so he does
3 not qualify under the conditions that TheraSphere is a
neoadjuvant treatment.

4 There is published peer-reviewed medical literature regarding
5 the technical success and clinical outcomes of TheraSphere.
6 These small Phase II randomized trials; [sic] however, fail to
7 show convincingly that subjects on trials are able to exhibit a
8 defined benefit.

9 Treatment with TheraSphere is not the generally accepted
10 standard of practice, nor does it appear to represent the best
11 practice for this enrollee. There is no demonstrated scientific
12 evidence that TheraSphere will improve his overall health
13 outcome. Further clinical investigation and evaluations with
14 larger controlled clinical trials is recommended. *Id.*

15 In substance, both the Review Institute and Permedion found the lack of Phase III trials to
16 preclude a finding of efficaciousness despite the evidence of safety and efficaciousness from
17 the limited trials noted in the literature.

18 In light of the denial of coverage, Banner Good Samaritan Medical Center has told
19 Boldon that its staff cannot proceed with TheraSphere treatment. Because Boldon lacks
20 sufficient financial resources to pay for TheraSphere treatment on his own, the treatment will
21 not be administered unless the requested injunction is entered.

22 TheraSphere is identified as safe, widely used and generally accepted as effective for
23 the treatment of HCC, as reported in nationally recognized peer-reviewed literature published
24 in the English language.

25 **II. Conclusions of Law**

26 "A preliminary injunction may issue when the moving party demonstrates either (1)
27 a combination of probable success on the merits and the possibility of irreparable harm; or
28 (2) that serious questions are raised and the balance of hardships tips in its favor." *Faith Ctr.*
Church Evangelistic Ministries v. Glover, 462 F.3d 1194, 1201-02 (9th Cir. 2006) (internal
quotation marks omitted). These formulations are not different tests but rather "two points
on a sliding scale." *Id.* at 1202. The "greater the relative hardship to the moving party, the
less probability of success must be shown." *Mircosystems, Inc. v. Microsoft Corp.*, 188 F.3d
1115, 1119 (9th Cir. 1999).