WO

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Michael J. Boldon, Plaintiff, vs. Humana Insurance Company; Cutter Aviation Group Medical Plan Administrator, Defendants.	No. CV06-02818-PHX-NVW **FINDINGS OF FACT AND CONCLUSIONS OF LAW IN SUPPORT OF PRELIMINARY INJUNCTION**

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

A. The Parties

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.

B. Boldon's Condition

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

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

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

C. The Recommended Treatment

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

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

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

D. The Status of the Treatment

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

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

Since obtaining FDA approval, TheraSphere has become a common, if not standard, treatment for HCC. TheraSphere is available in 29 cancer treatment centers across the 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.

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

E. The Scope of Boldon's Coverage

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

> a drug, biological product, device, treatment or procedure that meets any one of the following criteria, as determined by *us*:
>
> - Cannot be lawfully marketed without the final approval of the United States Food and Drug Administration (FDA) and which lacks such final FDA approval for the use or proposed use, unless (a) found to be accepted for that use in the most recently published edition of the United States Pharmacopeia-Drug Information for Healthcare Professional (USP-DI) or in the most recently published edition of the American Hospital Formulary Service (AHFS) Drug Information, or (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 bus 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

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

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

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

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

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

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

> staging. However, none of the studies to date have involved a statistically meaningful study group or have employed rigorous study designs involving randomization to chemotherapy versus [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.

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

> was based on the information provided to the Medical Review 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.
>
> Additionally, based on the limited data, the treatment may prolong survival as compared with known survival characteristics of liver cancer patients based on Okuba staging. 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.*

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

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

> TheraSphere . . . is indicated by the [FDA] for radiation treatment or as a neoadjuvant treatment to surgery or transplantation in patients with unresectable Hepatocellular 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,

> treatment. This enrollee has not had any surgery or a transplantation, nor is he a candidate for a transplant, so he does not qualify under the conditions that TheraSphere is a neoadjuvant treatment.
>
> There is published peer-reviewed medical literature regarding the technical success and clinical outcomes of TheraSphere. These small Phase II randomized trials; [sic] however, fail to show convincingly that subjects on trials are able to exhibit a defined benefit.
>
> Treatment with TheraSphere is not the generally accepted standard of practice, nor does it appear to represent the best practice for this enrollee. There is no demonstrated scientific evidence that TheraSphere will improve his overall health outcome. Further clinical investigation and evaluations with larger controlled clinical trials is recommended. *Id.*

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

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

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

II. Conclusions of Law

"A preliminary injunction may issue when the moving party demonstrates either (1) a combination of probable success on the merits and the possibility of irreparable harm; or (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).

A. Irreparable Harm

In this case, the requirement of irreparable harm is satisfied by the anticipated difference between treating Boldon's condition with TheraSphere and its only alternative: chemoembolization. Clinical studies on TheraSphere have unanimously found that it is an effective way to reduce tumor size and prolong the lives of HCC patients, and Dr. Hirsch specifically recommends TheraSphere as the best treatment for Boldon. Dr. Hirsch has concluded that TheraSphere is both more likely to prolong Boldon's life and less likely to produce negative side effects than chemoembolization. Because the benefits of treating Boldon with TheraSphere cannot be wholly replicated by the alternative, and because Boldon's loss of life expectancy and relative comfort could in no way be corrected, Humana's denial of coverage will cause irreparable harm. *Cf. Harris v. Blue Cross Blue Shield*, 995 F.2d 877, 879 (8th Cir. 1993) (finding irreparable injury when the plaintiff's insurance carrier denied coverage for treatment of a life-threatening illness); *Sluiter v. Blue Cross Blue Shield of Mich.*, 979 F. Supp. 1131, 1145 (E.D. Mich. 1997) (same).

The relatively severe nature of Boldon's harm would typically reduce the requisite level of probability for success on the merits. Humana argues, however, that a higher level of probability should be required because Boldon's mandatory injunction will effectively grant ultimate relief. The argument is persuasive. A "mandatory injunction goes well beyond simply maintaining the status quo *pendente lite* [and] is particularly disfavored." *Stanley v. Univ. of S. Cal.*, 13 F.3d 1313, 1320 (9th Cir. 1994) (internal quotation marks omitted). Thus, when a mandatory injunction is requested, "the district court should deny relief unless the facts and law clearly favor the moving party." *Id.*; *see also Neveux v. Webcraft Techs., Inc.*, 921 F. Supp. 1568, 1571 (E.D. Mich. 1996) ("In cases, such as here, where plaintiff seeks preliminary injunctive relief not to maintain the status quo but rather to alter it so that he receives essentially all of the relief to which he would be entitled after a successful trial on the merits, plaintiff must satisfy an even heavier burden of showing that [the factors affecting the propriety of relief] weigh heavily and compelling in [his] favor.") (internal quotation marks omitted).

Because the vast majority of TheraSphere's cost is incurred at the time of the first treatment and Boldon lacks the resources to pay for TheraSphere on his own, a preliminary injunction requiring Humana to provide coverage will effectively decide the entire case. The outcome of a trial held after an award of preliminary relief could be little more than symbolic: even if Humana wins, the cost of the treatment will have already been incurred and Boldon will be unable to compensate Humana for the expense. The requested injunction will issue, therefore, only if Boldon shows a probability of success on the merits that is the functional equivalent of proof sufficient for a final judgment on the merits.

The court has denied Humana's motion to consolidate the hearing on the preliminary injunction with a trial on the merits because the preliminary injunction hearing was held only ten days after the action was filed and there remain possibilities that future changes in circumstances might lead to a termination of TheraSphere treatment. However, the court has been presented with all the evidence that would be presented at trial, as Humana's counsel acknowledged. Therefore, though the requested injunction is preliminary in form, it is final in substance, with the opportunity for full presentation of material evidence attendant to a final injunction after trial on the merits.

B. Likelihood of Success on the Merits

A claims determination under an employee benefits plan governed by ERISA is by default subject to de novo review. *Kearney v. Standard Ins. Co.*, 175 F.3d 1084, 1089 (9th Cir. 1999). However, where the plan "unambiguously provide[s] discretion to [its] administrator" to interpret the terms of the plan and make final benefits determinations, the determination is reviewed for an abuse of discretion. *Abatie v. Alta Health & Life Ins. Co.*, 458 F.3d 955, 963 (9th Cir. 2006). "The plan administrator bears the burden of showing the plan gives it discretionary authority." *Ondersma v. Metro. Life Ins. Co.*, 2006 U.S. Dist. LEXIS 85460, at *2 (N.D. Cal. Nov. 16, 2006).

If plan language warrants de novo review, "[t]he court simply proceeds to evaluate whether the plan administrator correctly or incorrectly denied benefits" in light of all the evidence. *Abatie*, 458 F.3d at 963. However, if the language of the plan triggers review for

an abuse of discretion, three stages of analysis will remain. First, it must be determined whether the administrator in fact exercised its plan-authorized discretion in the course of denying the benefits. If the administrator did not, the denial may be reviewed de novo. *Id.* at 972.

Second, if the administrator both possessed and actually exercised discretion in denying benefits, the precise level of scrutiny with which to review the denial must then be determined. A denial of benefits should be reviewed with greater scrutiny if a plan gives discretion to an administrator that has a structural conflict of interest due to its status as both administrator and funding source. *Id.* at 965. Other factors to consider in determining the appropriate level of scrutiny include evidence of malice, self-dealing, "a parsimonious claims-granting history," inconsistent reasons for denial, inadequate investigation into a claim, failure to credit a claimant's reliable evidence, a history of denying "benefits to deserving participants by interpreting plan terms incorrectly or by making decisions against the weight of evidence in the record," and procedural irregularities. *Id.* at 968, 972. Unlike de novo review, review for an abuse of discretion is generally limited to the administrative record before the plan administrator at the time of its decision. *Id.* at 970.

Finally, after determining the appropriate level of scrutiny, that scrutiny must be utilized in deciding whether the administrator actually abused its discretion in denying coverage. "ERISA places the burden of proving an exclusion from coverage in an ERSIA-regulated welfare plan on the plan administrator." *Caffey v. Unum Life Ins. Co.*, 302 F.3d 576, 580 (6th Cir. 2002); *see also Fought v. Unum Life Ins. Co. of Am.*, 379 F.3d 997, 1007 n.4 (10th Cir. 2004). The administrator will have failed to satisfy this burden and accordingly abused its discretion if it construed a coverage exclusion in a fashion that "conflicts with the plain language of the plan." *Wallace v. Intel Corp.*, 2006 U.S. Dist. LEXIS 67693, at *26 (D. Ariz. Sept. 20, 2006).

1. The Language of the Plan

Humana has satisfied its burden of showing its own discretionary authority under the Cutter Aviation Group Medical Plan. The Plan states clearly and unequivocally that

"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." Doc. # 49, Exhibit 1, Notices at 2. This language plainly establishes that Humana, as the Plan administrator, has discretion to interpret the Plan and determination eligibility under its provisions. Accordingly, Humana's decision to deny coverage for Boldon's TheraSphere treatment may be reviewed under the abuse-of-discretion standard.

2. Whether Humana Exercised Discretion

Moving to the second stage of analysis under *Abatie*, Humana did not exercise discretion in denying coverage specifically for Boldon's treatment. Rather than freely evaluate Dr. Hirsch's recommendation for TheraSphere in order to determine whether coverage was warranted in the circumstances, Dr. Sidat-Singh simply followed a preexisting Humana guideline that categorically barred coverage for TheraSphere on the ground that it is "experimental/investigational." Given that Dr. Sidat-Singh had no authority to disregard this inflexible "guideline," the outcome of his review was effectively decided before he obtained a single document pertaining to Boldon's case. A decision made in these circumstances can hardly be deemed discretionary. *See* Black's Law Dictionary 499 (8th ed. 2004) (defining "discretion" as "the power of free decision-making").

Nor did Humana exercise discretion during any of Boldon's administrative appeals. The letter denying Boldon's first appeal simply provided a more thorough articulation of the basis for Dr. Sidat-Singh's initial denial and provided no indication that Humana had denied coverage in its discretion based on the particular facts of Boldon's claim. Humana confirmed that it was simply following a preexisting rule when it sent a copy of its internal guideline to Boldon as an attachment to the October 3 denial of coverage. Boldon is therefore entitled to a de novo decision–actually a first decision–by the court on any issue concerning his individual suitability for TheraSphere treatment.

If Humana is entitled to abuse of discretion review, it would be applied only to its categorical decision that TheraSphere is experimental or investigational for HCC treatment, which is the only decision Humana actually made. No post-*Abatie* precedent squarely addresses the proper locus of the discretionary decisionmaking that may trigger abuse-of-discretion review. However, the court need not decide whether Humana's global internal guideline is subject to abuse of discretion or de novo review because, as discussed below, even under the flexible abuse of discretion standard of *Abatie*, that categorical decision cannot survive a fair reading of the Plan language.

3. The Appropriate Level of Scrutiny

Two aspects of Humana's decision denying coverage for Boldon's TheraSphere treatment warrant a high level of scrutiny under the abuse-of-discretion standard. First, it is relevant to the extent of deference to be accorded to Humana's global decision that Dr. Sidat-Singh failed to consider the merits of Dr. Hirsch's recommendation in light of Boldon's specific condition and treatment options. Indeed, even if he had attempted to make such an individualized determination, he did not have expertise in the relevant field of medicine. Dr. Sidat-Singh, a former family practitioner, testified that he has never performed TheraSphere treatment, consulted with another physician about the treatment, or even read any literature on the topic. Compounding this problem is the fact that Dr. Sidat-Singh never reviewed the definition of "experimental/investigational" that is contained in the Plan Glossary. In these circumstances, he could not have possibly made a well-informed decision under the provisions of the Plan. Although Humana heard several appeals on Boldon's claim, there is also no indication that it ever considered the specific facts of Boldon's individual claim at any stage of the appeal process.

Similar conduct has previously been held to warrant a heightened level of scrutiny. *Daic v. Metropolitan Life Insurance Company*, 2006 U.S. Dist. LEXIS 74207 (D. Haw. Oct. 6, 2006), for example, involved a plaintiff who had been denied long-term disability benefits under a plan governed by ERISA on the ground that her condition did not preclude her from holding employment. In evaluating the denial of benefits, it was noted that some skepticism

was appropriate because the administrator did not thoroughly investigate the claim: although the administrator's physicians reviewed evidence concerning the plaintiff's condition, they did not examine the plaintiff in person. *Id.* at *24.

Second, a higher level of scrutiny is supported, even if only marginally, by the structural conflict of interest created by Humana's status as both the administrator of the Plan and its funding source. *See Abatie*, 458 F.3d at 965. This conflict creates an "incentive to pay as little in benefits as possible to plan participants because the less money the insurer pays out, the more money it retains in its own coffers." *Id.* at 966. In this case, there is no evidence of malice, self-dealing, or a parsimonious claims-granting history on the part of Humana. Independent review organizations also concurred with Humana's medical judgment. However, the conflict of interest created by Humana's dual role is "inherent" and must be given some weight "even if merely formal and unaccompanied by indicia of bad faith." *Id.* Thus, the fact that independent reviewers agreed with the judgment that TheraSphere is "experimental/investigational" cannot fully obviate the conflict of interest, *see Sherry v. Hartford Life & Accident Ins. Co.*, 314 F. Supp. 2d 714, 722 (N.D. Ohio 2004), particularly when there is no indication that the reviewers concurred with Humana's decision based on the precise language of the Plan, rather than on the meaning of "experimental/investigational" that is generally understood within the medical community. The conflict of interest will therefore be considered in determining whether Humana abused its discretion.

4. Whether Humana Abused its Discretion

Humana abused its discretion by denying coverage without demonstrating that the exclusion for "experimental/investigational" treatments applies to TheraSphere under the plain language of the Plan. *See Wallace*, 2006 U.S. Dist. LEXIS 67693, at *26. Humana considers TheraSphere treatment to be "experimental/investigational" because "it is not identified as safe, widely used and generally accepted as effective for the proposed use as reported in nationally recognized peer reviewed medical literature published in the English language." Doc. # 49, Exhibit 7 at 1; Joint Exhibit 1 at 94. This conclusion is based on two

literature summaries that Humana obtained from a medical industry consultant in May 2006. Yet those summaries do not support Defendant's conclusion. They simply observe that, while all Phase I and Phase II clinical studies on TheraSphere have concluded that it is "relatively safe, well-tolerated, and effective for advanced stage unresectable HCC," no Phase III trials have been conducted to compare its efficacy with that of alternative treatment options. Joint Exhibits # 16-17.

Humana also failed to demonstrate that the treatment fell short of the Plan's requirements for reported safety and effectiveness. The literature summaries on which Humana relied report that all thirteen clinical trials on the treatment found it to be "relatively safe, well-tolerated, and effective." Joint Exhibit # 17 at 2. These trials were discussed in nearly thirty peer-reviewed, professional medical journals, all of which are cited in the literature summaries that Humana used to inform its internal guideline. To the extent that the literature provided additional analysis on the treatment, it further supported the conclusion that TheraSphere is safe and effective. Moreover, even if some scientists hypothetically dispute the safety and efficacy of the treatment, Humana's policy exclusion does not apply so long as a treatment is identified in the literature as "generally accepted as effective." Doc. # 49, Exhibit 1 at 94. The existent peer-reviewed literature on TheraSphere amply satisfies this language.

Humana has also failed to show that TheraSphere is identified in the relevant literature as anything other than widely used. The reason is transparent: TheraSphere is available in nearly thirty cancer treatment centers across the United States. Since 2004, the National Comprehensive Cancer Network has included TheraSphere treatment in its clinical guidelines for HCC. TheraSphere is also fully reimbursable under Medicare and Medicaid, and it is covered by a series of major medical insurance carriers. Dr. Hirsch has himself treated approximately 30 patients with TheraSphere since April 2005. In these circumstances, the peer-reviewed medical literature would have little basis for concluding that TheraSphere is not widely used. Indeed, one peer-reviewed article suggested that TheraSphere is "rapidly being adopted in the medical community as an adjunctive

therapeutic tool in the management of primary and secondary liver malignancies." Riad Salem, *Radioembolization with 90Yttrium Microspheres: A State-of-the-Art Brachytherapy Treatment for Primary and Secondary Liver Malignancies*, J. Vascular Interventional Radiology 1251, 1251 (2006).

If Humana is arguing that TheraSphere is experimental or investigational because it is not "widely used" in relation to the size of the general public, it advances an unreasonable interpretation of the Plan language. The only sensible interpretation of the Plan is that a covered treatment must be identified in the relevant literature as widely used among the population of patients who suffer from the disease for which the treatment is designed. Because the burden is on Humana to show the applicability of its exclusion and Humana has failed to provide any evidence that TheraSphere is not widely used among HCC patients, the treatment cannot be deemed experimental or investigational on that basis.

Rather than demonstrate that TheraSphere is "experimental/investigational" under the plain language of the Plan, Humana denied coverage solely on the ground that TheraSphere has not been subject to Phase III comparative clinical studies involving large numbers of patients. That is the criticism voiced in the independent reports Humana endorsed as the basis for its universal finding that TheraSphere is "experimental/investigational." In making its decision on this basis, Humana imported a surprising, categorical requirement of Phase III trials that effectively excludes coverage for FDA-approved and otherwise safe, efficacious, and generally used treatments for orphan diseases. This was an abuse of discretion. Phase III trials typically require hundreds, if not thousands, of participating patients to demonstrate in a statistically meaningful manner the effectiveness of a treatment. Because orphan diseases by definition only involve a small number of patients, it is extremely difficult, if not impossible in many cases, to conduct Phase III trials involving patients with these diseases. The humanitarian device exemption recognizes this reality by waiving many of the FDA's rigorous clinical requirements for commercial distribution when a treatment will be utilized by fewer than 4,000 patients per year.

Despite its significant effect, the asserted requirement for Phase III clinical trials is by no means apparent from the text of the Plan. No language in the Plan's definition of "experimental or investigational" fairly discloses that treatments otherwise legal, safe, efficacious and generally used can be excluded solely on the ground that they have not been subjected to Phase III trials. With references to Phase I, II, and III clinical trials performed by the National Cancer Institute, various forms of FDA approval, and even a specific Medicare coverage manual, the Plan's definition of "experimental or investigational" clearly contained a high level of detail. Boldon had no reason to believe that those details were incomplete. Humana may not employ what amounts to a submerged requirement of Phase III trials when that exclusion cannot reasonably be anticipated from the text of the Plan. This approach is consistent with the doctrine of reasonable expectations, which requires an ERISA plan administrator to make exclusionary clauses "conspicuous, plain, and clear, placing them in such a fashion as to make obvious their relationship to other policy terms." *Saltarelli v. The Bob Barker Group Med. Trust*, 35 F.3d 382, 385 (9th Cir. 1994) (quoting *Nat'l Mut. Ins. Co. v. McMahon & Sons, Inc.*, 356 S.E.2d 488, 496 (1987)).

For these reasons, Boldon has shown a prospect of success equivalent to what would be required for a final injunction upon trial on the merits.

5. Current Suitability for the Treatment

Humana separately argues that the injunction request should be denied because, according to the report from the UCSF CT scan that Humana discovered during this litigation, Boldon's HCC has already metastasized. Humana reasons that if this information had been reviewed originally, coverage justifiably could have been denied under the Plan's exclusion for treatments that are not medically necessary because TheraSphere is ineffective and even harmful for patients with metastatic HCC. The argument is rejected.

Boldon is entitled original decision by the court on this issue, without deference to any decision Humana may wish to make. Humana made no effort, and indeed had no intention, to base its denial of coverage on Boldon's specific suitability for this treatment. Rather, Humana made a strategic decision to deny coverage for TheraSphere on the basis of a global

policy that disregards the medical circumstances of individual patients. In making that decision, Humana embraced the possibility that some valid, case-specific justifications for the application of its policy exclusions would remain unutilized. Humana's failure to make a decision, and to call for the specific medical evidence that would allow it to make a decision, leaves the matter for decision by the court.

The court has been advised this day by Boldon's attorney that tests conducted at Banner Hospital on December 12, 2006, lead Dr. Hirsch to conclude that Boldon's cancer has not metastasized and that he remains a suitable patient for TheraSphere treatment. To address the issue, the court will set a hearing on Monday, December 18, 2006, at 1:00 p.m. If Humana does not dispute Dr. Hirsch's opinion, it will advise the court promptly and the hearing will be vacated.

6. Bond

Because the injunctive relief is granted under the standard for final injunction after trial on the merits, no bond will be required of Boldon.

The relief shall be delayed until after December 22, 2006, to provide Humana an opportunity to seek a stay of the order from the Court of Appeals.

DATED this 13th day of December 2006.

Neil V. Wake
United States District Judge