

excluded from coverage under the Plan. Having exhausted her administrative remedies through EIP, Antonelli now appeals EIP's denial of coverage to this court pursuant to S.C. Code Ann. § 1-11-710(C) (2005), § 1-23-380 (Supp. 2007), and § 1-23-600(D) (Supp. 2007). Antonelli challenges EIP's decision as being unsupported by the relevant medical evidence in the record and based on flawed medical evidence. Upon review of this matter, EIP's decision to deny coverage of ADR for Antonelli is reversed.

II. PROCEDURAL HISTORY

Upon Antonelli's request for pre-authorization from BCBS, the nurse conducting the initial review recommended approving coverage. BCBS's in-house medical director, Dr. Ashby Jordan, a pediatrician by training, then sought an opinion from a service known as National Medical Review, an organization that provides insurance companies with opinions regarding benefit plans. Dr. Daniel Benson, a board-certified orthopedist of the National Medical Review, found that ADR was investigational based solely on a portion of Antonelli's medical records and without reference to her treating physician's documents or the applicable Plan language. Dr. Jordan then adopted Dr. Benson's report and denied coverage.

On appeal to the Committee, Antonelli submitted an affidavit of Dr. Johnson, her treating physician and board-certified orthopedic surgeon; a statement from Dr. Steven Poletti, a board-certified orthopedic surgeon; a report issued by the United States Food and Drug Administration ("FDA") regarding a Phase III clinical trial conducted regarding the Charité artificial disc ("FDA/Dupuy Study"); and other medical literature.² The Committee denied coverage, finding that ADR was investigational because it determined that (1) peer-reviewed medical literature does not permit conclusions concerning its effect on health outcomes; (2) the Charité disc has not been demonstrated to be as beneficial as established alternatives; and (3) the Charité disc has not been demonstrated, to a statistically significant level, to improve net health outcomes. (See R. at 83-88) (EIP Appeals Committee Health Appeal Final Determination Letter). In making these findings, the Committee relied upon: (1) Dr. Benson's opinion; (2) a February 2005 report from BCBS's Technology Evaluation Center ("TEC Assessment"); and (3) a report by Winifred S.

² Pursuant to 2006 S.C. Act No. 387, the ALC's review of EIP determinations is appellate under the standard of review set forth in § 1-23-380(A)(5). Unlike most cases that this court reviews in its appellate capacity, however, no evidentiary hearing takes place before the agency. The Committee conducts a paper review of EIP's initial coverage determination, which is also made without an evidentiary hearing.

Hayes, Inc., a company that provides synopses of clinical evidence regarding various medical treatments ("Hayes Brief"). (See *id.* at 87).

III. ISSUE

Did EIP err in finding that ADR is investigational and therefore excluded from coverage under the Plan?

IV. STANDARD OF REVIEW

As set forth above, this matter is before the ALC in its appellate jurisdiction pursuant to S.C. Code Ann. § 1-11-710(C), § 1-23-380, and § 1-23-600(D). Accordingly, the Administrative Procedures Act's standard of review governs this appeal. See S.C. Code Ann. § 1-23-380(A) (Supp. 2007); see also Byerly Hosp. v. S.C. State Health & Human Servs. Fin. Comm'n, 319 S.C. 225, 229, 460 S.E.2d 383, 385 (1995). The standard used by appellate bodies, including the ALC, to review agency decisions is provided by S.C. Code Ann. § 1-23-380(A)(5). See S.C. Code Ann. § 1-23-380(B) (Supp. 2007) (directing Administrative Law Judges to conduct appellate review in the same manner prescribed in Section 1-23-380(A)). This section provides:

The court may not substitute its judgment for the judgment of the agency as to the weight of the evidence on questions of fact. The court may affirm the decision of the agency or remand the case for further proceedings. The court may reverse or modify the decision [of the agency] if substantial rights of the appellant have been prejudiced because the administrative findings, inferences, conclusions, or decisions are:

- (a) in violation of constitutional or statutory provisions;
- (b) in excess of the statutory authority of the agency;
- (c) made upon unlawful procedure;
- (d) affected by other error of law;
- (e) clearly erroneous in view of the reliable, probative, and substantial evidence on the whole record; or
- (f) arbitrary or capricious or characterized by abuse of discretion or clearly unwarranted exercise of discretion.

S.C. Code Ann. § 1-23-380(A)(5) (Supp. 2007).

A decision is supported by "substantial evidence" when the record as a whole allows reasonable minds to reach the same conclusion reached by the agency. Bilton v. Best Western Royal Motor Lodge, 282 S.C. 634, 321 S.E.2d 63 (Ct. App. 1984). Further, substantial evidence means that a decision will not be set aside simply because reasonable minds may differ on the judgment. Lark v. Bi-Lo, 276 S.C.130, 276 S.E.2d 304 (1981). Substantial evidence is not a

mere scintilla of evidence, nor the evidence viewed blindly from one side of the case, but is evidence that, considering the record as a whole, would allow reasonable minds to reach the conclusion the agency reached in order to justify its action. Hargrove v. Titan Textile Co., 360 S.C. 276, 289, 599 S.E.2d 604, 611 (Ct. App. 2004). The fact that the record, when considered as a whole, presents the possibility of drawing two inconsistent conclusions from the evidence does not prevent the agency's finding from being supported by substantial evidence. Id.; Waters v. S.C. Land Res. Conservation Comm'n, 321 S.C. 219, 467 S.E.2d 913 (1996); Grant v. S.C. Coastal Council, 319 S.C. 348, 461 S.E.2d 388 (1995). However, § 1-23-380(A)(5) requires the reviewing tribunal to consider not only the amount of evidence, but also the quality of that evidence; it must be both "reliable" and "probative," as well as "substantial." See S.C. Code Ann. § 1-23-380(A)(5).

It is helpful to note that the standard of review in this case is analogous to the standard used in cases arising under the federal Employee Retirement Income Security Act ("ERISA"). See, e.g., Bynum v. Cigna Healthcare of N.C., Inc., 287 F.3d 305 (4th Cir. 2002) (holding that an insurer's decision could be overturned if "a coverage decision is unreasonable" and the insurer "abused its discretion."); see also Booth v. Wal-Mart Stores, Inc. Assocs. Health & Welfare Plan, 201 F.3d 335, 342 (4th Cir. 2002); Feder v. Paul Revere Life Ins. Co., 228 F.3d 518, 522 (4th Cir. 2000). Accordingly, although not binding, ERISA case law provides guidance in analyzing the issue before the court.

V. DISCUSSION

A. Applicable Plan Language

The parties agree that the issue of coverage in this case is controlled by the Plan language contained in Article 9, which provides:

No benefits will be provided under any Article of this Plan for any service, supply or charges for the following

G. Any surgical or medical procedures determined by the medical staff of the Third Party Claims Processor with appropriate consultation, to be experimental or investigational or not accepted medical practice. Experimental or investigational procedures are those medical or surgical procedures, supplies, devices, or drugs, which at the time provided, or sought to be provided:

1. Are not recognized as conforming to accepted medical practice in the relevant medical specialty or field of medicine; or

2. The procedures, drugs or devices have not received final approval to market from appropriate government bodies; or
3. Are those about which the peer-reviewed medical literature does not permit conclusions concerning their effect on health outcomes; or
4. Are not demonstrated to be as beneficial as established alternatives; or
5. Have not been demonstrated, to a statistically significant level, to improve the net health outcomes; or
6. Are those in which the improvement claimed is not demonstrated to be obtainable outside the investigational or experimental setting.

(R. at 54-55).

B. Evidence Relied Upon by EIP

In denying coverage, EIP relied upon three specific pieces of evidence in the Record: (1) the opinion of Dr. Benson; (2) the TEC Assessment; and (3) the Hayes Brief.

1. Dr. Benson's Opinion

Antonelli argues that EIP erred in relying upon Dr. Benson's opinion because his finding that ADR is "investigational" was not based upon the applicable Plan criteria. The court agrees. The portion of Dr. Benson's opinion regarding the investigational status of ADR states in its entirety: "[T]he question is whether the CHARITE disc is investigational. Yes, it is. There are no larger peer reviewed studies that have proven efficacy and long term outcomes. The scientific evidence does not currently permit conclusions concerning the effect of the technology and health comes [sic]." (R. at 170) (Fax from National Medical Review dated Dec. 15, 2005).

Dr. Benson's letter does not indicate whether he was applying the proper Plan criteria or definition of "investigational." The word "investigational," left undefined, is ambiguous. See Pirozzi v. Blue Cross-Blue Shield of Va., 741 F. Supp. 586, 589-90 (E.D. Va. 1990) (noting in the ERISA context that the terms "experimental" and "clinical investigative" are ambiguous when they do not define the quantum or type of evidence required to demonstrate that the treatment is not experimental, the test that should be used to evaluate the treatment, or the threshold of statistical success in terms of cure). Accordingly, the fact that Dr. Benson did not use the applicable Plan definition of "investigational" when providing his opinion on that point

renders that evidence objectively unreliable for the purpose of determining coverage under the Plan.³

EIP argues that Dr. Benson did not need to use the applicable Plan definition of “investigational” to render an opinion because that issue is a question of law for the court. This argument misapprehends the nature of EIP’s inquiry. Whether a particular procedure is “investigational” under the specific terms of a plan document can be a question of law or a question of fact. See, e.g., Hendricks v. Cent. Reserve Life Ins. Co., 39 F.3d 507, 512-13 (4th Cir. 1994) (ERISA). “Whether a form of treatment is experimental or investigative can be answered on at least two levels.” Id. When the issue turns on contract interpretation, it is a question of law; however, when it is based upon whether a medical procedure meets a contract’s definition on facts presented and the opinion of experts, it is a question of fact. Id. Here, where both components are at issue, it is a mixed question of law and fact. An expert’s opinion as to the factual aspects of this determination is unhelpful, and therefore not probative, if it does not address the relevant criteria. See Rule 702, SCRE (“If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise.”).

It is also unclear whether Dr. Benson reviewed the FDA/Dupuy Study. In fact, Dr. Benson does not mention FDA approval anywhere in his opinion. Dr. Benson vaguely refers to “peer-reviewed studies” and “scientific evidence,” but he does not specify what resources he referenced in coming to his conclusion.⁴ There is no indication that Dr. Benson reviewed any of the relevant medical literature. Dr. Benson concludes that “[t]here are no larger peer reviewed studies [of the disc] that have proven efficacy and long term outcomes.” (R. at 170). However, he does not articulate a measurable standard for what would constitute a “larger” study or what criteria might be used to establish a study as a “larger” one.⁵

³ By contrast, Dr. Johnson’s medical opinion, which was part of the information considered by EIP, specifically addressed the question in terms of the Plan criteria.

⁴ Additionally, Dr. Benson admits he did not have Antonelli’s updated MRI to review. (See R. at 170).

⁵ It follows that Dr. Jordan’s opinion is likewise unreliable. Dr. Jordan’s finding that ADR is experimental cannot constitute reliable, probative evidence upon which EIP can rely because it is clear from his report that he made no independent judgment about the investigational status of ADR, but rather merely relied upon the opinion of Dr. Benson. In addition, Dr. Jordan is a pediatrician and not a specialist in orthopedics.

Thus, because Dr. Benson did not render his opinion in the context of the applicable Plan criteria and because his report does not specify the sources or literature he considered, the court finds that EIP erred in relying on his opinion in finding that ADR was investigational and therefore excluded from coverage.

2. TEC Assessment

Antonelli argues that the BCBS TEC Assessment relied upon by EIP does not constitute reliable and probative evidence that ADR is investigational under the Plan criteria. Again, the court agrees.

TEC Assessments are documents prepared by members of the BCBS Association's Technology Evaluation Center and reviewed by the BCBS Association's Medical Advisory Panel, comprised of various physicians located across the country. See BCBS, Technology Evaluation Center, <http://www.bcbs.com/betterknowledge/tec/medical-advisory-panel.html> (last visited Jan. 29, 2008).⁶ Generally, courts have diverged on their consideration of TEC Assessments as evidence in insurance benefits cases. Compare Bucci v. Blue Cross Blue Shield of Conn., Inc., 764 F. Supp. 728 (D. Conn. 1991) ("Defendant's reliance on the TEC is not valid . . ."); and Pirozzi, 741 F. Supp. at 591 ("[T]he [TEC Assessment] criteria are not part of the Plan and the Plan nowhere states that the Blue Cross criteria are determinative of a treatment's experimental status . . .") with Martin v. Blue Cross & Blue Shield of Va., 115 F.3d 1201 (4th Cir. 1997) (upholding denial of benefits for high-dose chemotherapy and peripheral stem-cell rescue as being experimental based in part on TEC Assessment); Evans v. Blue Cross and Blue Shield of S.C., 834 F. Supp. 887 (D.S.C. 1993) (upholding denial of benefits for radial keratotomy based in part on TEC Assessment); and Glauser-Nagy v. Med. Mut. of Ohio, 987 F. Supp. 1002 (W.D. Ohio 1997) (denying preliminary injunction for pre-approval for high-dose chemotherapy and peripheral stem-cell rescue based in part on TEC Assessment that indicated that procedure was investigative or experimental).

⁶ A court may take judicial notice of information on a website. See Hall v. Virginia, 385 F.3d 421, 424 n.3 (4th Cir. 2004) (taking judicial notice of information published on the Virginia Division of Legislative Services website); Renaissance Greeting Cards, Inc. v. Dollar Tree Stores, Inc., 405 F. Supp. 2d 680, 684 n.9 (E.D. Va. 2005) (stating that information on a commercial website is appropriate for judicial notice under Fed. R. Evid. 201).

Thus, it is clear that in determining whether to provide coverage, EIP cannot blindly accept the statements or conclusions of a TEC assessment.⁷ Rather, it must carefully evaluate the probative value and reliability of a TEC assessment with regard to a particular treatment or procedure. For example, as with any other piece of evidence, EIP should consider such factors as whether the purpose of the TEC assessment is sufficiently analogous to the question at hand so it assists EIP in arriving at its conclusion, whether the criteria utilized by the TEC assessment are helpful in applying the criteria specified in the Plan, and whether the TEC assessment properly applies the stated criteria.

Here, the court finds that EIP erred in relying on the TEC Assessment. TEC assessments are used to determine whether a particular medical technology improves health outcomes such as “length of life, quality of life, and functional ability,” BCBS, Technology Evaluation Center Criteria, <http://www.bcbs.com/betterknowledge/tec/tec-criteria.html> (last visited Jan. 29, 2008), and not whether that technology is investigational, nor whether any insurer should provide coverage for that procedure. Additionally, as Antonelli points out, although the criteria discussed in the TEC Assessment are similar to the Plan criteria, the language is not identical.

Moreover, the TEC Assessment in this case is internally inconsistent in its findings regarding ADR. For example, as to the efficacy of the procedure, the TEC Assessment states on the one hand that “[c]urrent evidence supporting the effectiveness of artificial vertebral disc is insufficient,” but then asserts that “[t]he Charité artificial disc had a success rate of 63%, compared to a success rate of 53% for BAK fusion” It further recognizes that no other artificial discs “have better or more rigorous evidence of efficacy.” (R. at 189). The TEC Assessment then concludes that “the reported success rate shows that the artificial disc is *not inferior* to the BAK [fusion]” Id. (emphasis added).

In addition, the TEC Assessment appears in several instances to apply a more rigorous standard than that mandated by either the Plan or the TEC Assessment itself. As stated above, the TEC Assessment specifically concludes that ADR is *not inferior* to fusion. This statement compels the conclusion that ADR is at least *as beneficial as* fusion – the criterion stated in the Plan. The TEC Assessment states that the 63% success rate of the disc (compared to 53% for fusion) shows that the disc “is not inferior” to fusion, but does “not [show] that it is *better*” than

⁷ In addition, the TEC Assessment contains disclaimer language that it is to be used “solely for informational purposes,” and it should not be interpreted to suggest that BCBS or the TEC Program “discourages any particular treatment, procedure, or service” (R. at 189).

fusion. *Id.* (emphasis added). The TEC Assessment adds that the fact that the trial “did not show statistically significant *superiority*” to fusion is a “concern.” *Id.* (emphasis added). These conclusions implicitly mandate a demonstration of the superiority of ADR to spinal fusion, rather than utilizing the applicable Plan criterion – or even the stated TEC criterion – that requires merely that ADR be “as beneficial as” the established alternative.

Similarly, the TEC Assessment appears to misapply the Plan requirement that ADR “improve the net health outcomes.” In construing similar language in another plan, at least one court has noted that this criterion simply requires that the patient be better off with the treatment or procedure than without it. See Johnson v. Blue Cross & Blue Shield of Ala., Inc., 457 F. Supp. 2d 1288, 1314 & n.166 (N.D. Ala. 2006), vacated following settlement on appeal by Johnson v. Blue Cross & Blue Shield of Ala., Inc., 489 F. Supp. 2d 1290 (N.D. Ala. 2007); see also Chapman v. Anthem Health Plans of N.H., Inc., 2005 WL 1123949, *1 (D.N.H. 2005) (unpublished decision stating that “improvement in health outcomes” means “the beneficial effects outweigh any harmful net effects”).

These courts’ construction of “improve the net health outcomes” is startlingly similar to TEC’s own website’s stated interpretation of that language. The TEC website explains that, to improve the net health outcomes, “[t]he technology’s beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.” BCBS, Technology Evaluation Center Criteria, <http://www.bcbs.com/betterknowledge/tec/tec-criteria.html> (last visited Jan. 29, 2008). However, the TEC Assessment at issue conjoins this criterion of “improv[ing] the net health outcome” with that of being “as beneficial as any established alternatives,” indicating that the TEC Assessment applies the same analysis to both. (See R. at 190, 202) (discussing the two criteria together); (R. at 197) (listing as the assessment question: “Does artificial disc replacement . . . improve health outcomes . . . compared with fusion or other treatments?”). Such a construction is contrary to the plain language of TEC’s own stated definition.

In relying on the TEC Assessment for its finding that ADR did not improve health outcomes, EIP similarly misapplied the Plan criterion. It adopted the TEC Assessment’s misapplication, which (as stated above) is inconsistent with the plain language of the Plan criterion requiring only that ADR be “as beneficial as” – not superior to – fusion. Such a construction of the words “improve the net health outcomes” renders this criterion meaningless, as it is redundant to the Plan’s separately stated “as beneficial as” criterion that does call for a

comparison to established alternatives – in this case, fusion. See Goodman v. Resolution Trust Corp., 7 F.3d 1123, 1127 (4th Cir. 1993) (“Contract terms must be construed to give meaning and effect to every part of the contract, rather than leave a portion of the contract meaningless or reduced to mere surplusage.”); Medlin Constr. Group, Ltd. v. Harveya, 449 F.3d 1195, 1200 (Fed. Cir. 2006) (a reasonable contract interpretation must “assure that no contract provision is made inconsistent, superfluous, or redundant”); cf. Gregory v. S.C. Democratic Executive Comm., 271 S.C. 364, 247 S.E.2d 439 (1978) (stating that a statute is not to be interpreted so that a particular phrase becomes “redundant and meaningless”). In other words, unlike the TEC Assessment’s analysis with regard to this criterion (“improve the net health outcomes”), the Plan language does not invite a comparison to the accepted alternatives – an exercise already mandated by a different Plan criterion (that the treatment “be as beneficial as established alternatives”). Thus, in relying on the TEC Assessment, EIP erred in construing the Plan criterion that ADR “improve the net health outcomes” to (1) require, yet again, a comparison to fusion, and (2) require superiority to fusion.

Applying the “improve the net health outcomes” Plan criterion properly, the evidence in the record viewed as a whole overwhelmingly shows to a statistically significant level that patients are better off with ADR than without it. See Johnson, 457 F. Supp. 2d at 1314 & n.166; Chapman, 2005 WL 1123949, at *1. Medical literature shows that with ADR, “full flexibility and motion is restored and the natural integrity and design of the spine is maintained.” (R. at 116-17). Disc replacement allows a patient’s spine to “maintain its normal range of motion” and “reduc[es] or eliminat[es] the risk of degeneration in adjacent segments of the spine.” (R. at 124). In addition, the Spine Arthroplasty Society found that “both the patients’ pain and functional scores improved significantly after surgery.” (R. at 123). The disc “is intended to maintain the normal movement between the vertebral bodies and prevent them from collapsing (and thereby irritating or damaging the nerve root) by maintaining the disc space height between the bones.” (R. at 125). The FDA/DePuy study found that “those patients implanted with the Charité disc improved or maintained their range of motion” (R. at 117). In addition, artificial discs “preserve the mobility of the patient’s adjacent discs” Id. Patients with the disc enjoy “[i]mprovements in range of motion, disc space height and less subsidence.” (R. at 127). Thus, EIP erred in finding that ADR had not been demonstrated to improve net health outcomes to a statistically significant level.

3. Hayes Brief

Antonelli argues that the Hayes Brief relied upon by EIP does not constitute reliable and probative evidence that ADR is investigational under the Plan criteria. The court agrees.

The criterion used by the Hayes Brief is whether ADR is "more efficacious" than fusion. (R. at 182). However, as previously discussed, the Plan only requires *equal* effectiveness. Therefore, the Hayes Brief does not employ the same criterion as the Plan. Notably, the Hayes Brief, like the TEC Assessment, contains a disclaimer stating that it "is not to be used as the sole basis for determining coverage policy." *Id.* In Whitley v. Carolina Care Plan, Inc., No. 3:06-257-CMC, 2006 WL 3827503, slip op. (D.S.C. Dec. 28, 2006), the District Court for the District of South Carolina held that an insurer's reliance upon a Hayes Brief alone to conclude that a particular procedure was "experimental" was an abuse of discretion for a number of reasons.⁸ The Hayes Brief in this case does not indicate whether it properly applied the Plan definition of "investigational" or even used that definition in rendering its opinion. Further, it is not clear what evidence was considered or referenced in forming the opinions found in the Hayes Brief. See Whitley, 2006 WL 3827503, at *32 ("While there is evidence that HAYES considers some of the same criteria as the Plan, it is far from clear that the HAYES Rating considers all of the same criteria and in the same way. Thus, it cannot fairly be said that the HAYES Rating is the equivalent of any one of the Plan's criteria or all of them."). For these reasons, the Hayes Brief does not constitute substantial evidence supporting EIP's decision.

C. Antonelli's Evidence

Dr. Johnson, Antonelli's treating physician and a board-certified orthopedic surgeon, submitted an affidavit in which he stated the following with regard to the Plan's definition of "investigational," as it relates to the Charité disc:

1. The disc is "widely accepted in the medical community and is increasingly being used"
2. The disc "has been implanted in thousands of patients worldwide . . . with proven safety and efficacy"
3. Typically a patient must sign an "informed consent" form when a procedure "is truly investigational." No informed consent was required here.
4. The disc has FDA approval.
5. "There are copious amounts of peer reviewed medical literature that conclude that the Charite artificial disc is a beneficial and effective treatment" In addition, the

⁸ EIP conceded at oral argument that the Hayes Brief alone would not constitute substantial evidence supporting its decision.

disc has been discussed numerous times in the peer-reviewed publication, The Spine Journal.

6. "There is ample evidence to show that the medical community has drawn conclusions regarding the beneficial effect of [ADR]" and the disc "has a most extensive clinical history with over seventeen (17) years of clinical experience with the current design in over 8000 patients in 30 countries worldwide."
7. The evidence shows that the disc would "be more beneficial than any alternative available"

(R. at 98-103).

Dr. Johnson's affidavit⁹ is supported by other evidence provided by Antonelli. First, the record contains extensive medical literature about the disc, including: (1) an online article appearing on the University of Pittsburgh Department of Neurosurgery's website entitled Neurosurgical Spine Services Division Charité Artificial Spine Disc Replacement, (R. at 116-17); (2) an online article appearing on the National Public Radio ("NPR") website entitled Artificial Disc Offers New Hope for Treating Back Pain, (R. at 118-21); (3) a discussion on the NPR program "All Things Considered," on May 10, 2005, wherein Dr. Scott Blumenthal, the "principal investigator" of the FDA study, stated, "[T]he Charite is a viable alternative to spinal fusion. And if you look at the comparison, even if they are equal, both operations have a good potential to reduce pain. One eliminates motion, and one preserves motion." (R. at 120); (4) two online articles found on Spine-Health.com's website entitled All About the Charité Artificial Disc: Now Approved for Use in the U.S., (R. at 122-23), and Spinal Disc Replacement with the CHARITÉ Artificial Disc, (R. at 124-25); and (5) a listing of news stories about the disc on Charité's website, (R. at 126). Additionally, Dr. Johnson discusses in his affidavit other peer-reviewed literature including: (1) numerous articles that have appeared in The Spine Journal, which is the official journal of the American Spine Society – an international and multi-disciplinary journal that publishes original, peer-reviewed articles on research and treatment related to the spine; (2) an article authored by Dr. Regis W. Haid and Dr. Vincent Traynelis entitled Artificial Discs – the Future is Bright, (see R. at 102); and (3) an article in the Journal of

⁹ The Respondent's contention that the record merely shows that there are conflicting medical opinions about whether or not the disc is investigational misapplies the Plan criteria and fails to consider all the reliable, probative data in the record as a whole. In addition to all of the other reasons discussed herein, the fact that other physicians may *disagree* with the peer-reviewed literature's conclusions or question its methodology does not mean that the procedure is investigational under the exclusionary language of the Plan. See, e.g., Bolden v. Humana Ins. Co., 466 F. Supp. 2d 1199, 1211 (D. Ariz. 2006) ("[E]ven 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 [meeting the Humana plan's requirement that the procedure be] 'generally accepted as effective.'").

Neurosurgery: Spine, which describes the technique for placement of the Charité disc, (see R. at 102). Moreover, EIP offered no peer-reviewed literature to counter Antonelli's position.¹⁰ Thus, the only peer-reviewed literature before this court is that offered by Antonelli, and that evidence clearly supports Antonelli's position.

Furthermore, the Charité disc was granted full FDA approval as of October 26, 2004, which was based upon the FDA/Dupuy clinical trial. This trial's objective was determining "whether the Charité artificial disc was any less safe or effective than the currently available spinal fusion surgery" Stephen Hochschuler, MD, and Paul McAfee, MD, All About the Charité Artificial Disc: Now Approved for Use in the U.S., (R. at 122). The results from that study showed the patients who received the disc were "no worse than patients treated with anterior lumbar interbody fusion." Id. (emphasis added).

As Dr. Johnson pointed out in his affidavit, (R. at 98-103), an indication of a procedure being considered "investigational" is whether it is being administered as part of a clinical trial, which requires informed consent. See Hendricks, 39 F.3d 507 (noting that the fact that the disputed procedure was part of clinical trial and informed consent was required supported the finding that the procedure was investigational or experimental); Martin, 115 F.3d 1201 (observing that the facts that informed consent was required and that the procedure was part of a Phase II clinical trial "strongly supports Blue Cross's conclusion that the procedure . . . was experimental or investigative"). The treatment in this case has already received government approval and will be administered in a normal hospital setting, not as part of a clinical trial.

VI. CONCLUSION

EIP denied coverage because it found that (1) the peer-reviewed medical literature does not permit conclusions concerning the effect of ADR on health outcomes; (2) ADR was not demonstrated to be as beneficial as the established alternative, spinal fusion; and (3) ADR has not been demonstrated, to a statistically significant level, to improve net health outcomes. (R. at 87). For all of the reasons discussed above, the court finds that EIP's decision to deny coverage

¹⁰ The term "peer reviewed" is not defined in the Plan; however, "peer review" generally means "a process by which something proposed (as for research or publication) is evaluated by a group of experts in the appropriate field." Miriam-Webster Online Dictionary (2008); Taber's Cyclopedic Medical Dictionary 1613 (20 ed. 2001) (defining "peer review" as "[t]he evaluation of the quality of the work effort of an individual by his or her peers. It could involve evaluation of articles submitted for publication of the quality of medical care administered by an individual, group, or hospital."). Notably, the Plan criterion on this point uses different language than that of the sources relied upon by EIP, which merely speak in terms of "scientific evidence" rather than "peer-reviewed literature." Thus, the sources that can be consulted for a determination as to this criterion are different from those used by EIP.

for ADR based upon these three criteria is clearly erroneous in view of the reliable, probative, and substantial evidence in the record as a whole. Furthermore, EIP misapplied the Plan criteria, causing its decision to be affected by error of law.

The Plan requires EIP to make six specific inquiries in determining whether a procedure is excluded because it is investigational.¹¹ EIP must consider whether the treatment has governmental approval.¹² The Charité disc does. EIP must also consider whether the peer-reviewed medical literature permits conclusions concerning ADR's effect on health outcomes. Here, the record is replete with conclusions regarding ADR's effect on health outcomes based upon peer-reviewed literature. The Plan also requires EIP to determine whether the procedure is demonstrated to be as beneficial as established alternatives. As noted above, the sources relied upon by EIP applied a more stringent standard, requiring superiority, and even the TEC Assessment itself found that ADR was "not inferior" to fusion. Finally, under the terms of the Plan, EIP must consider whether ADR has been demonstrated to a statistically significant level to improve health outcomes. Viewing the record as a whole, the evidence unquestionably shows that patients are better off with ADR than without it.

¹¹ EIP did not rest its decision on the ground that (1) the treatment is "not recognized as conforming to accepted medical practice in the relevant medical specialty or field of medicine"; or (2) the claimed improvement "is not demonstrated to be obtainable outside the investigational or experimental setting." (R. at 87).

¹² Although EIP did not expressly base its decision denying coverage on this criterion, its criticisms of the methodology of the FDA/DuPuy Study appear to implicitly rely on this criterion in that they seem to question whether the FDA *should have* approved the Charité disc. The Plan language, however, does not permit EIP to second-guess the FDA; it merely requires EIP to inquire whether the treatment *in fact has* government approval. Moreover, the court observes that the United States Court of Appeals for the Fourth Circuit has found that a Phase III clinical study is not a prerequisite to a treatment's non-investigational status. Wilson v. CHAMPUS, 65 F.3d 361, 365-66 (4th Cir. 1995) (ERISA). Thus, as the existence of a Phase III clinical trial has not been considered to be determinative as to whether a treatment should be deemed investigational, the court finds that EIP's criticisms of the FDA/DuPuy study miss the mark.

VII. ORDER

For all of these reasons, EIP's conclusions as to the investigational status of ADR were clearly erroneous when viewed in light of the reliable, probative, and substantial evidence in the record as a whole, and were affected by error of law. It is therefore

ORDERED that EIP's denial of coverage is reversed.

IT IS SO ORDERED.



PAIGE J. GOSSETT
Administrative Law Judge

January 29, 2008
Columbia, South Carolina

CERTIFICATE OF SERVICE

This is to certify that the undersigned has this date served this order in the above entitled action upon all parties to this cause by depositing a copy hereof, in the United States mail, postage paid, or in the Interagency Mail Service addressed to the party(ies) or their attorney(s).

This 29 day of January, 2008

By: Olivia Jones
Staff Counsel