IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

Jerry Whitley, as Personal Representative of the Estate of Carol Whitley, Plaintiff, v. Carolina Care Plan, Inc., Defendant.	)	C/A NO. 3:06-257-CMC **OPINION AND ORDER**

Through this action, Plaintiff, Jerry Whitley ("Mr. Whitley" or "Plaintiff") seeks a determination that Defendant, Carolina Care Plan, Inc. ("Plan"), abused its discretion when it denied his deceased wife's claim for coverage of certain medical procedures. The matter is currently before the court on Mr. Whitley's motion to strike the declaration of the Plan's medical director, Edward D. Hutt, M.D. ("Dr. Hutt"), Dkt No. 26, as well as for a decision on the merits based on the parties' written submissions. *See* Dkt No. 9 (Joint Certification agreeing to resolution based on the joint stipulation and cross memoranda for judgment).

The parties filed cross-memoranda in support of judgment on September 29, 2006, and October 2, 2006. Dkt No 24 & 25.[1] Both filed responsive memoranda ("Replies") on October 10, 2006. Dkt No. 27 & 28. In addition, on October 3, 2006, Mr. Whitley filed a motion to strike the declaration of Dr. Hutt, which the Plan relied on in its memorandum in support of judgment. Dkt No. 26. The Plan filed an opposition to the motion to strike on October 20, 2006. Dkt No. 29. Finally, Plaintiffs filed a notice of supplemental authority on October 23, 2006. Dkt No. 30.

[1] The substantive memoranda rely on the extensive evidentiary record filed on August 29, 2006, as Dkt No. 14-17. This administrative record is sequentially numbered and is referred to herein with the prefix "AR" followed by page number(s) (*e.g.*, AR pp. 1-25).

For the reasons set forth below, the court strikes the affidavit of Dr. Hutt. The court further finds that the Plan abused its discretion in denying benefits. The court, therefore, finds that Plaintiff is entitled to judgment in his favor on the claim for benefits. The court will defer entry of judgment, and resolution of Plaintiff's request for attorneys' fees, to allow Plaintiff to address the Fourth Circuit's recent decision relating to the same. *See Carolina Care Plan, Inc., v. McKenzie*, Slip Op. No. 05-2060 (4th Cir. October 23, 2006). Briefing on this issue shall be as set forth at the conclusion of this order.

APPLICABLE LAW AND STANDARD OF REVIEW

It is undisputed that the benefits at issue are provided under an employee benefit plan governed by the Employee Retirement Income and Security Act, 29 U.S.C. § 1001 *et seq.* ("ERISA"). Mr. Whitley's claim for benefits is, therefore, pursued solely under 29 U.S.C. § 1132(a)(1)(B).

It is also undisputed that the Plan's benefits determination is subject to a modified abuse of discretion standard of review. *See, e.g.,* Dkt No. 25 at 5-6 (Plan's memorandum); *McKenzie*, Slip Op. at 5-7. Under the basic abuse of discretion standard of review, the court is required to uphold the administrator's decision if it is reasonable, even if the court would have come to a different conclusion had it considered the matter independently. *See Ellis v. Metropolitan Life Ins. Co.*, 126 F.3d 228, 232 (4th Cir. 1997). A decision is reasonable if it is "the result of a deliberate, principled reasoning process and if it is supported by substantial evidence." *Id.* at 232 (quoting *Brogan v. Holland*, 105 F.3d 158, 161 (4th Cir. 1997)).

The modified abuse of discretion standard of review applies when the decision-maker is operating under a conflict of interest, such as when a for-profit insurance company is both the funder

and decision-maker. *See McKenzie*, Slip Op. at 5-7 (finding standard applicable even where relatively minor expense is involved). Under this standard, the court reduces the degree of deference to the extent necessary to neutralize any untoward influence resulting from the conflict of interest. *Id.*, Slip. Op. at 5.

Numerous factors are considered in "determining the reasonableness of a fiduciary's discretionary decision,." *Booth,* 201 F.3d at 342-43. These include:

> (1) the language of the plan; (2) the purposes and goals of the plan; (3) the adequacy of the materials considered to make the decision and the degree to which they support it; (4) whether the fiduciary's interpretation was consistent with other provisions in the plan and with earlier interpretations of the plan; (5) whether the decisionmaking process was reasoned and principled; (6) whether the decision was consistent with the procedural and substantive requirements of ERISA; (7) any external standard relevant to the exercise of discretion; and (8) the fiduciary's motives and any conflict of interest it may have.

Id. See also McKenzie, Slip Op. at 6-7 (quoting same).

As these criteria reveal, the plan language is the starting point. *Id.* ("[a]s with any interpretation of a contractual trust document, we begin by examining the language of the Plan"). This is because "ERISA demands adherence to the clear language of the employee benefit plan." *White v. Provident Life Accident Ins. Co.*, 114 F.3d 26, 28 (4th Cir. 1997). "When an ERISA plan vests discretion in an administrator who also insures the plan, reasonable exercise of that discretion requires that the administrator construe plan ambiguities against the party who drafted the plan." . *McKenzie,* Slip Op. at 9.

MOTION TO STRIKE

The motion to strike relates to the sworn declaration of Dr. Hutt, who serves as the Plan's Medical Director. Hutt Decl. ¶ 1. Dr. Hutt asserts that he is "familiar with the decision to deny the

claim . . . .because [he] reviewed the claim at the time it was made." Hutt Decl. ¶ 2. He then explains the Plan's reliance on the HAYES rating system[2] to deny Mr. Whitley's claim as experimental, investigational or unproven. Hutt Decl. ¶ 3-5 & 9. He also provides his interpretation of the evidence and explains that the initial denial was based on his own application of the HAYES rating system to this interpretation. Hutt. Decl. at 6-7.

In addition, Dr. Hutt addresses why he believes the two independent reviews obtained by the Plan (both favorable to coverage of the claim) should not result in a ruling in Mr. Whitley's favor. Dr. Hutt asserts that both reviews are irrelevant as they addressed only whether the treatment was "medically appropriate," not whether it fell within the Plan's Experimental Exclusion. This characterization of the two reports is incorrect as one of the two was obtained by the Plan for the sole and express purpose of addressing whether the service fell within the Experimental Exclusion. In concluding that the treatment at issue did not fall within this exclusion, this review (referred to in the remainder of the order as the "Peer Review") addressed each of the relevant Plan criteria. The other review was obtained as part of a transplant evaluation (referred to herein as the "URN-Review" or "URN Specialized Physician Review"). In concluding that Mrs. Whitley was not a good transplant candidate at the time of the review, the URN-Reviewer also addressed some of the criteria relevant to application of the Plan's Experimental Exclusion.

Thus, neither report was limited to the question of "medical appropriateness" of the treatment and both bear directly on the Experimental Exclusion. Dr. Hutt does not otherwise address these

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[2] As discussed in the remainder of this order, the Plan has consistently relied on a rating from Winifred S. HAYES, Inc., as its basis for denying the claim as experimental, investigational or unproven. The particular report relied on was published in February 2003 and was obtained by the Plan in October 2004 from the HAYES website. The published report is referred to herein as the "HAYES Report." The rating in that report is referred to as the "HAYES Rating."

independent reviews on their merits. Dr. Hutt's attempt to discount these reports would, therefore, bear little weight even if his declaration was considered.[3]

In any case, nothing in Dr. Hutt's declaration explains what information was provided to and considered by the third-level grievance panel. This is the body which rendered the Plan's final decision. While there is strong evidence that this body, as well as the panel before it, may have deferred unduly to Dr. Hutt's opinion, it remains that: (1) it is the decision of the final grievance panel which is actually at issue; and (2) nothing in Dr. Hutt's declaration aids the court in understanding what information that panel considered.[4]

Dr. Hutt's declaration is dated October 2, 2006. The final denial letter was written, and the record closed, almost a year earlier on October 28, 2005. Thus, Dr. Hutt's declaration clearly is not part of the record relied on by the Plan in making its benefit decision. Rather, it seeks to explain that decision with information not contained in the record.

There is no suggestion that the Plan advised Mr. Whitley of its intent to rely on such a declaration before it was filed with the Plan's memorandum in support of judgment. Indeed, all evidence is to the contrary as evidenced by the parties' July 26, 2006 Joint Certification which

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[3] The Plan asserts in its opening memorandum that, in reaching "his" decision to deny benefits, "Dr. Hutt reviewed and especially relied on" thirteen specifically listed excerpts from a URN-Specialized Physician Review and abstracts culled from a HAYES research update (discussed *infra* as "HAYES Update"). Dkt 25 at 13-15. Dr. Hutt's declaration contains no statements which would support either assertion. Hutt does not, in fact, even refer to the HAYES research update or the abstracts contained therein. His only reference to the URN-Specialized Physician Review is the cursory discounting of it as discussed above.

[4] As discussed in the remainder of this order, it is clear that Dr. Hutt made the decision to deny the first-level appeal and had direct input as to the second. As to the third-level appeal, the evidence of his input is less direct. Nonetheless, his opinion as to the controlling nature of the HAYES Rating was provided to the third-level grievance panel in a manner which likely had a strong, if not determinative, influence on the outcome of the final appeal.

provided the following assurances:

> a. The parties certify that they conferred on July 25, 2006 with respect to the matters contained in the Specialized Case Management Order.
>
> b. There are currently no issues raised by the Joint Stipulation on which the parties are not in agreement.
>
> *c. No parties object to the procedure for disposition of the action proposed by the Joint Stipulation.*
>
> *d. The parties confirm that they exchanged all documents on which any party intends to rely for resolution of the action.*

Dkt No. 9 (Joint Certification – emphasis added). The procedure to which the parties indicated agreement is set forth, in part, below:

> 5. If the matter is not resolved by mediation, the parties shall, within sixty (60) days after the conference addressed in Paragraph 2 above, file cross-memoranda in support of judgment with respect to all benefits claims governed by ERISA. The Joint Stipulation shall be filed at the same time. Each party shall have five (5) days thereafter to file an optional reply. These memoranda should follow the form of Local Rule 7.05. *All references in memoranda shall be to the consecutively-numbered page of the attachments to the Joint Stipulation.* In its discretion, the court may order a hearing. Unless so ordered, the court will decide the ERISA benefits issues upon the record before it without a hearing. Motions for summary judgment need not be filed. *Any party objecting to the court disposing of the case on the Joint Stipulation must file an objection with or prior to the filing of the joint certification required by Paragraph 2 of this order.*

Dkt No. 7 (original emphasis deleted – above emphasis added).

The parties, thereafter, filed their joint stipulation (with attached administrative record) on August 29, 2006. Dkt No. 14-17. This extensive record does not include Dr. Hutt's declaration which, as noted above, was not prepared until over a month after the administrative record was compiled and exchanged and long after the Plan's final denial of Plaintiff's claim. Thus, Dr. Hutt's declaration is clearly not part of the administrative record to which the parties agreed to limit their reliance in their July 2006 joint certification.

As suggested above, the critical difficulty with consideration of Dr. Hutt's declaration is that it is not a part of the administrative record. While supplementation of the record might, in some instances, be appropriate, it would only be appropriate if proper notice was given of the intent to rely on the additional evidence. Under the procedures of this court, that notice should have been given prior to the filing of the Joint Certification which occurred on July 26, 2006.

Had the Plan provided notice of its intent to rely on testimony of Dr. Hutt, the court would first have determined whether to allow that testimony. If the court determined that such testimony should be allowed, it would likely have allowed Plaintiff to depose Dr. Hutt as to his full role in the decision-making process. That deposition might, in turn, have led to the deposition of other Plan representatives to test the veracity of Dr. Hutt's testimony.

To the extent any of these depositions related to communications with third parties, the court would, upon request, have considered whether to allow Plaintiffs to designate opposing witnesses to address the same communications. Likewise, to the extent the testimony was in the nature of expert witness testimony (the reasonableness of relying on the HAYES Rating), a counter-expert would most likely have been allowed. In addition, the usual expert witness disclosure requirements would have applied.

None of the decisions detailed above was ever made because the Plan gave no notice of its intent to rely on Dr. Hutt's testimony until his declaration was filed with Defendant's memorandum in support of judgment.[5] Under these circumstances, it would be decidedly unfair to allow the Plan to rely on Dr. Hutt's declaration.

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[5] In opposing to the motion to strike, the Plan refers to several cases which have allowed expansion of the record under relatively unusual circumstances. Nothing in the Plan's memorandum, however, supports allowing such expansion *when not timely sought*. Under the procedures applied in this district, that would be no later than upon the filing of the joint stipulation.

For all of the reasons set forth above, the court grants Mr. Whitley's motion to strike Dr. Hutt's declaration.

DECISION OF THE COURT ON SUBSTANTIVE CLAIMS

After examining the administrative record, joint stipulation, and parties' memoranda, the court enters the following Findings of Fact and Conclusions of Law pursuant to Rule 52(a) of the Federal Rules of Civil Procedure. To the extent that any findings of fact represent conclusions of law, or vice-versa, they shall be so regarded.

FINDINGS OF FACT

OVERVIEW

The claims at issue in this action involve implantation of a left ventricle assist device (LVAD). This implantation was performed at Duke University Medical Center ("Duke") on October 11, 2004, and resulted in charges in the amount of $369,775.75.

The patient, Carol Whitley ("Mrs. Whitley" or "member"), is now deceased.[6] The claim is, therefore, pursued on behalf of Mrs. Whitley's estate by the estate's personal representative, Jerry Whitley ("Mr. Whitley").

The final denial was based on two related grounds, both of which are advanced as denial reasons in this action. First, the Plan maintained that "LVAD *for destination therapy* was considered by [the HAYES rating system] to be experimental at the time of the service." The Plan, therefore, denied coverage under a plan exclusion for experimental, investigational, or unproven services ("Experimental Exclusion"). AR p. 3 (emphasis added). Second, the Plan maintained that it was

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[6] The Plan uses the term "member," rather than the ERISA terms "participant" or "beneficiary" to refer to Mrs. Whitley and to other individuals covered under its policies The court will use the same terminology in this order.

not informed of the intent to implant an LVAD *for destination therapy* until after the procedure was completed. The Plan concedes, however, that it had approved other significant heart treatment, apparently including high-risk bypass surgery and preparation for a possible heart transplant. AR p. 3 (December 14, 2005 letter from Plan summarizing reasons for denial–emphasis added).[7]

The purpose of the implant ("for destination therapy") was critical to the denial.[8] This is because use for other purposes (*e.g.*, "as bridge to transplant") would not have been considered experimental, investigational, or unproven under the HAYES Report on which the Plan relied. *See supra* n. 2 and *infra* at 19 (explaining HAYES Report).

The HAYES Report on which the Plan relied was published in February 2003, nineteen to twenty months before Mrs. Whitley's surgery. At some point between Mrs. Whitley's surgery and December 14, 2005, a period of seventeen months, the published HAYES Rating was changed. *See* AR p. 3 (December 14, 2005 letter from Plan representative conceding that, as of that date, "LVAD for destination therapy is no longer considered experimental or investigational by Hayes"). Neither party has provided the court with the date of that change. The record is also silent as to what studies or other evidence was considered by HAYES when it ultimately did change the relevant rating.

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[7] The Plan has consistently relied on the Experimental Exclusion in its various denials. Its reliance on the alleged lack of notice has been sporadic.

[8] The term "destination therapy" refers to implantation of the LVAD as a permanent treatment which, according to the literature, may extend life by several years before a new implant is needed. "Bridge to transplant," by contrast, refers to implantation only pending an intended heart transplant. The line between the two goals of treatment is not, however, always clear. This is because a patient who is not a transplant candidate due to correctable or controllable conditions (*e.g.*, obesity and diabetes), may become a transplant candidate after implantation of the LVAD.

RELEVANT PLAN TERMS

1. Notice Term. The Plan provides as follows regarding notification for services received from Network Providers such as Duke.[9]

> Notification Requirements
>
> We require notification before you receive certain Covered Health Services. In general, Network providers are responsible for notifying us before they provide these services to you. Your Provider cannot bill you for these services if they fail to notify Us.

AR pp. 874-75.

After noting the member's duty to provide notice before receiving certain health services from non-Network Providers, the Plan document encourages confirmation that "services from non-Network Providers" are covered "because in some instances, certain procedures may not meet the definition of a Covered Health Service and are therefore excluded" or may fall within an exclusion such as the "Experimental, Investigational or Unproven Services exclusion." *Id.*

2. Coverage of Transplant Services[10]

The Plan document provides that it covers "Transplantation Services" as follows:

> Covered Health Services for the following organ and tissue transplants when ordered by a Network Physician. Transplantation services must be received at a Designated Facility. Benefits are available for the transplants listed below when the transplant

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[9] It is undisputed that Duke is a network provider. Thus, if denial rested solely on a failure of notification, the real parties in interest might be Duke and the Plan, rather than Mr. Whitley and the Plan, because Duke would be precluded from charging Mrs. Whitley or her estate for the service. The denial, however, rested on dual grounds. In any case, the Plan does not challenge Mr. Whitley's standing as the real party-in-interest.

[10] The transplant provisions are relevant because Mrs. Whitley was transferred to Duke because she was under consideration for a heart transplant. *See* AR p. 27 (October 4, 2004 letter to MUSC). Her initial care at Duke was, therefore, reviewed under the provisions applicable to transplant candidates.

meets the definition of a Covered Health Service, and is not an Experimental, Investigational or Unproven Service:

• • •

• Heart transplants.

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Notify Us

We have specific guidelines regarding Benefits for transplant services. Contact us at the telephone number on your ID card for information about these guidelines. You and your Network Physician must notify us as soon as the possibility of a transplant arises (and before the time a pre-transplantation evaluation is performed at a transplant center). If you do not notify us, and if the transplantation services are not performed at the Designated Facility, you will be responsible for paying all charges, and no Benefits will be paid.

AR p. 890.

3. Exclusion for Experimental, Investigational or Unproven Services[11]

The policy excludes coverage for:

Experimental, Investigational or Unproven Services Health services and associated expenses for Experimental, Investigational or Unproven Services, treatments, devices and pharmacological regimens except for health services which are otherwise Experimental, Investigational or Unproven that are deemed to be, in our judgment, Covered Health Services under (Section 1: What's Covered - - Benefits). The fact that an Experimental, Investigational or Unproven Service, treatment, device or pharmacological regimen is the only available treatment for a particular condition will not result in Benefits if the procedure is considered to be Experimental, Investigational or Unproven in the treatment of that particular condition.

AR p. 893. The two Plan definitions discussed below govern the scope of this exclusion.

4. Relevant Definitions

"Covered Health Service(s) – those health services provided for the purpose of preventing, diagnosing or treating a Sickness, Injury or their symptoms.

. . .

A Covered Health Service must meet each of the following criteria:

• It is supported by national medical standards of practice.

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[11] For ease of reference, the court refers to this exclusion as the "Experimental Exclusion."

• It is consistent with conclusions of prevailing medical research that demonstrate that the health service has a beneficial effect on health outcomes and are based on trials that meet either the following designs:

- Well-conducted randomized controlled trials. (Two or more treatments are compared to each other, and the patient is not allowed to choose which treatment is received).

- Well-conducted cohort studies. (Patients who receive study treatment are compared to a group of patients who receive standard therapy. The comparison group must be nearly identical to the study treatment group.)

• It is a cost-effective method and yields a similar or better outcome to other available alternatives.

• It is a health care service or supply described in (Section 1: What's Covered - - Benefits) as a Covered Health Service, which is not excluded under (Section 2: What's Not Covered - - Exclusions).

Decisions about whether to cover new technologies, procedures and treatments will be consistent with conclusions of prevailing medical research, based on well-conducted randomized trials or cohort studies, as described.

AR p. 922.

"Experimental, Investigational or Unproven Services – medical, surgical, . . . or other health care services, technologies, supplies, treatments, procedures, drug therapies or devices that, *at the time we make a determination regarding coverage* in a particular case, are determined to be any of the following:

- Not approved by the U.S. Food and Drug Administration (FDA) to be lawfully marketed for the proposed use and not identified in the American Hospital Formulary Service or the United States Pharmacopoeia Dispensing Information as appropriate for the proposed use.

- Subject to review and approval by any institutional review board for the proposed use.

- The subject of an ongoing clinical trial that meets the definition of a Phase 1, 2, or 3 clinical trial set forth in the FDA regulations, regardless of whether the trial is actually subject to FDA oversight.

- A service that does not meet the definition of a Covered Health Service. If

> you have a life-threatening Sickness or condition (one which is likely to cause death within one year of the request for treatment) we may, in our discretion, determine that an Experimental, Investigational or Unproven Service meets the definition of a Covered Health Service for that Sickness or condition. For this to take place, we must determine that the procedure or treatment is promising, but unproven, and the service uses a specific research protocol that meets standards equivalent to those defined by the National Institutes of Health.

AR p. 924 (underlining in original, italics added).

Summary of the Administrative Record.

October 4, 2004. Mrs. Whitley was initially admitted to the Medical University of South Carolina (MUSC). On October 4, 2004, MUSC requested approval from the Plan to perform a heart transplant. AR p. 145. The Plan promptly notified MUSC that it would not provide coverage for the requested transplant because MUSC was not a network provider. The Plan indicated, however, that the services could be performed by Duke, as it was a "network provider under the transplant benefit through United Resource Networks" (URN). AR p. 27 (October 4, 2004 letter to MUSC).[12]

Mrs. Whitley was, therefore, transferred to Duke for evaluation and treatment. It is undisputed that the Plan gave approval for the transfer to Duke and for Duke to perform a transplant evaluation and some other heart related treatment, though precisely what was approved is in dispute. *See, e.g.,* AR p. 3 (December 14, 2005 letter from Plan summarizing history of claim and stating that the "Plan approved the CABG to be done at Duke because of the complexity of the specific case and we were informed it could not be performed at MUSC"); AR p. 9 (October 12, 2004 computer entry

[12] In later letters, the Plan indicates that Mrs. Whitley was transferred from MUSC to Duke because MUSC was unable or unwilling to perform a high risk coronary artery bypass graft ("CABG"). *See* AR p. 3 (January 14, 2005, letter from Plan acknowledging approval of a CABG to be performed at Duke). A CABG is not, however, mentioned in the October 4, 2004 correspondence. An October 7, 2004 record from Duke does, however, mention an intent to explore "possible revascularization." AR p. 153.

indicating Mrs. Whitley received a "two vessel CABG yesterday, and placement of LVAD . . . to bridge the pt until she gets a heart transplant"); AR p. 222 (October 13, 2004 computer entry expressing concern as to purpose for which LVAD was implanted–discussed *infra*).

October 7-13, 2004. Mrs. Whitley was transferred to Duke on October 6, 2004. AR p. 216. By October 9, 2006, the transplant cardiologist reviewing her case, Carmelo A. Milano, M.D. ("Dr. Milano"), had determined that Mrs. Whitley was not a good transplant candidate, at least not at that time. AR pp. 7-8 (October 9, 2004 report by Dr. Milano finding Mrs. Whitley to be a "poor candidate for revascularization" and a "suboptimal candidate for cardiac transplantation"). This determination was based on Mrs. Whitley's obesity and diabetes with neuropathy. Dr. Milano, therefore, suggested implantation of a "destination left ventricle assist device" as the best treatment option. *Id.* Dr. Milano noted, nonetheless, that Mrs. Whitley could become a transplant candidate if she modified her weight. AR p. 8.

Plan's records of communications, October 6-13, 2004. The following undated record made by Lisa Hardin, RN, a representative of the Plan, appears to have been made around the time of Mrs. Whitley's admission to Duke.

> This 57 year old female was transferred from MUSC via ambulance to Duke University Medical Center. She had a cath at MUSC which showed three vessels 100% occluded and the only functioning vessel is the ramus. *At MUSC they wanted to transplant her*, but MUSC is not a center for excellence and they cannot do a transplant. She is on the heart pump at this time. *MUSC could not do the "high risk CABG" being contemplated.* They [missing words] . . .nd heparin. Trying to wean ballon pump, cardiac surgery. I spoke to Dr. Hutt at length about this and he said that this should be paid in network because the service could not be offered at MUSC. I have asked to have faxed clinicals sent to me in the am. *I spoke with Julia at Duke and I told her that if this case came down to transplant that it would go under her transplant benefit.* She verbalized an understanding.

AR p. 211-13 (print outs of the screens in the record appear to be partial print outs which, when

reconciled, still leave some gaps).[13]

Another screen, which includes a date of October 6, 2004, indicates receipt of faxed clinicals from Duke. This entry, also by Lisa Hardin, gives the following information: "57 year old s/p inferior STEMI with cardiogenic shock. Other [history] includes DM. She was transferred here from MUSC. She has transplant evaluation done 10/06/2004. See evaluation case." AR. p. 214.

Other screens appear to be a continuation or modification of this screen, and include additional detailed clinical information, AR pp. 217-19. These screens reveal that the Plan was informed that the patient was 100% occluded in three vessels, and that Duke would "discuss *possible* revascularization" and, "in the meantime, will have transplant meet the patient." *Id.* (emphasis added). This screen then states:

> *Poor coronary targets*. If IABP comes out, would do cardiac MRI for viability. *Transplant workup in progress*. On admission this mbr was in cardiogenic shock. Notified Paula of receipt of clinicals and day auth through 10/11/2004. Requested an update at this time. *Dr. Hutt aware of this situation and agrees*.

AR p. 217-19 (emphasis added).[14]

The computer entry dated October 7, 2004, states:

> Additional clinicals received an[d] reviewed. *Pt was evaluated by cardiac surgery and they have decided to proceed with a CABG on Monday*. Centro 1 line placed today for venous access. Requested an update on Tues[day] post CABG to let me

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[13] Lisa Hardin ("Hardin"), is a nurse reviewer who appears to have been the primary individual in charge of handling this claim. Her entries also frequently bear the initials "lh/rn."

[14] The section of the administrative record in which these records appear also contains duplicates of the screens referenced in the Plan's December 2005 letter (discussed *infra*). That letter, however, refers only to the October 7 and 12 computer entries. *See* AR p. 215 (identical to AR p. 6); AR p. 220 (identical to AR p. 9). Other similar screens in this section of the record, also not mentioned in or attached to the January 2005 letter, are discussed in the remainder of the text (relating to dates October 13-21).

know how the pt is doing.

AR p. 6 (signed "lh/rn"– emphasis added).

The next entry is dated October 12, 2004, the day after the surgery. This entry states:

> Clinical update received from Carolyn at Duke . . . . Pt underwent a two vessel CABG yesterday, and *placement of LVAD. . . . . The left ventricular assistance device is placed to bridge the pt until she gets a heart transplant.*

AR p. 9 (signed "lh/rn").

The next computer entry reflects a phone conversation between Hardin and a Duke representative on October 13, 2004. This entry reads as follows: "Call received from Carolyn at Duke and she said that this *mbr is NOT on the transplant list. She is to have the LVAD for the remainder of her life.* I notified Michelle Griffin at URN and Hetal Joshi, CCS." AR p. 221 (emphasis added).[15]

In a notation made several hours later, Hardin wrote: "I have discussed this case at length with Dr. Hutt since I have been notified of this mbrs *LVAD for destination*." AR p. 222. She then wrote: "Additional comments: *We ran a Hayes report (at the request of Dr. Hutt) since the LVAD was placed for destination rather than as a bridge to transplant as we originally thought.* According to Hayes, LVAD to destination is a [text ends abruptly – no other page completes]." AR p. 222 (emphasis added).[16]

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[15] This computer entry is generally consistent with an October 13, 2004 notation on Mrs. Whitley's chart which indicates that a representative of Duke spoke with the Plan's transplant insurance case manager on that date, advising the case manager that a destination LVAD had been performed after determining that Mrs. Whitley was not a candidate for transplant at that time. Nonetheless, the Duke notes indicate an intent to reconsider if weight and diabetes were later controlled. AR p. 164. The latter point is, however, missing from Hardin's report of the communication.

[16] The Plan apparently obtained the same HAYES Report twice, on October 13 and 14, 2004. *See* AR pp. 304-06 (dated10/13/04) & AR pp. 17-18 (dated 10/14/04).

Duke Evidence Regarding October 6-11 Communications. In a November 22, 2004 letter, Duke representative Joseph W. Robbins states that he and one other Duke representative had numerous conversations with Lisa Hardin between October 6, 2006 and October 11, 2006, in which the placement of an LVAD was approved. AR 180-81 (discussed below by date of letter). He further states that he was told by the Plan representative to do whatever was necessary to save the patient's life.

October 14-18, 2004. In a letter dated October 14, 2004, Dr. Hutt wrote to Dr. Milano asking that Mrs. Whitley's "entire medical record inclusive of preoperative, intraoperative and post operative notes and transplant evaluation" be sent to him by facsimile "no later than" the following day. AR p. 166. The Plan again obtained a copy of the HAYES Report on October 14, 2004 (HAYES Report discussed *infra*). Duke forwarded the records as requested.[17]

On October 15, 2004, Hardin had a conversation with a Duke representative. Hardin reports the conversation as follows:

> Call received from Carolyn case manager at Duke. We are still awaiting the clinicals to be faxed in. Still in ICU [condition and current treatment described]. Anticipate being in unit for the weekend. *Left Carolyn a message that I cannot authorize any more days until Dr. Hutt receive[s] the clinicals and decides if this is experimental or investigational.*

AR p. 224 (emphasis added). This appears to be the first notice to Duke of the Plan's position that

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[17] An October 15, 2006 computer entry by Hardin states:

> Faxed clinicals were received from Michelle Griffin, our URN coordinator as Duke thought that she was the case manager for this case. She forwarded them to me. I gave them to Dr. Hutt. He still does not have the transplant evaluation and operative reports. I sent a letter on behalf of Dr. Hutt requesting the records so he can make a benefit decision.

AR p. 223. Duke apparently resent the records to the Plan via facsimile on October 18, 2006. *See* AR pp. 167-74 (records sent via facsimile).

the treatment was experimental. No concern as to the adequacy of Duke's prior notice is mentioned.

Hardin's next computer entry is on October 18, 2004, and reflects that she received a call "from Carolyn the case manager [at Duke] as well as the LVAD coordinator wanting to know the benefit decision and that they were quite anxious to find out an answer to the case." AR p. 227-29. Hardin later returned the call (apparently speaking to another individual "Laura") to advise that the records were available and "that the medical director was to review them today." This individual asked "what criteria Dr. Hutt was going by that determined this an 'investigational/experimental' procedure as [M]edicare pays for it." Hardin states:

> I told her Hayes as criteria, and she wanted a copy of it to review. I faxed her the criteria and a reply was received that the fax did go thru. *I called Dr. Hutt back today at 4:55 p.m. and he said he still had not yet had time to review the notes I scanned to him. Will check with him again first thing in the am to see what his answer is.*

AR pp. 228-29 (emphasis added).

October 19, 2004. On October 19, 2004, the Plan denied coverage based its conclusion that the use of the LVAD for destination therapy was experimental or investigational under the terms of the Plan. AR p. 28 (October 19, 2004 letter signed for Dr. Hutt by L. Hardin, RN). In this denial letter, directed to Dr. Milano, the Plan quotes the exclusion for "Experimental, Investigational, or Unproven Services" then states:

> The use of the LVAD began on October 11, 2004, which is a non-covered service. Therefore, we will not be covering any service beyond this date. I have included a copy of the information we used to make this decision. If you should have any questions you may contact me at [phone number provided].

AR p. 28 (the referenced attachments are not included at this point in the record but apparently consisted of copies of the HAYES Report for LVAD discussed below).

The Plan's October 19, 2004 denial letter does not suggest any concern regarding lack of notice. It does, on the other hand, explain that the patient can file a grievance challenging the denial.[18]

HAYES Report. The Plan has consistently relied solely on the rating found in the HAYES Report from Winifred S. HAYES, Inc., as its basis for denying the claim under the Experimental Exclusion. The particular report relied on reflects a publication date of February 2003, and was obtained by the Plan on October 13 and 14, 2004. This specific report is referred to herein as the HAYES Report. The rating of LVAD provided in that report is referred to as the HAYES Rating.

The HAYES Report gives the LVAD an A rating for "use as a bridge to cardiac transplantation," and a B rating for "use as a bridge to recovery" for patients meeting certain specific criteria (the "bridge to recovery" criteria are inapplicable to Mrs. Whitley). As to use as a "permanent destination therapy," the HAYES Report provides a C rating and includes the following explanation:

> C – For LVAD use as permanent destination therapy for patients with end-stage CHF who are not eligible for transplantation and in whom no return of cardiac function is anticipated. This Rating is based on early but promising findings and reflects the limited treatment options available for these patients.

AR p. 17. This Report explains that a "C" rating indicates "Investigational and/or experimental. The data on this procedure are promising but inconclusive regarding safety and/or efficacy. There is no clear medical consensus regarding its safety and/or efficacy." AR p. 18.

October 20, 2004. On October 20, 2004, the Plan obtained an online search update relating to the LVAD rating through the HAYES Inc. website ("HAYES Update"). AR pp. 122-143

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[18] The record contains numerous copies of this letter. One appears immediately following a facsimile cover sheet to Dr. Milano from Lisa Hardin which indicates that four additional pages are attached. AR pp. 302. The pages which follow suggest that Dr. Milano was provided with the HAYES Report on which the Plan relied then and relies now, including a November 2001 "HAYES Alert" which describes as "promising" a then-recent "REMATCH" study reported in the New England Journal of Medicine, 2001. AR pp. 304-06.

(repeated at AR 484-505). The search covered the period January 2004 though October 2004, and retrieved sixty-two articles for which abstracts covering twenty-five pages were provided. AR p. 122-43 (although the cover page indicates there are 25 pages, only 22 are included in the record). The abstracts are described as covering "retrospective studies, case reports, small and large patient group case series and review articles." AR p. 484. Under "Anticipated Impact," this document states: "The search findings *will trigger a review* of the existing HAYES Medical Technology Directory Report." *Id.* (emphasis added).

Despite the significant number of abstracts revealed, and the warning that the search would lead to a review of the then-current rating, there is no indication that the Plan ever considered the content of this Update. For example, there is no mention of the HAYES Update in any letter or internal record, other than Hardin's notation that she was forwarding the HAYES Update to Hutt. AR p. 346. Neither are there any marks on the printout of the HAYES Update which would suggest that any of the numerous abstracts were reviewed. There is no other evidence which would suggest that Dr. Hutt, or any other decision-maker at the Plan, ever reviewed or considered the HAYES Update.[19] Further, there is no evidence that these materials were provided to either the second or third-level grievance panels.

There are also two records of phone conversations from October 20 and 21, 2004. While both relate to the Plan's intent to deny coverage under the Experimental Exclusion, neither refers to the Hayes Update.

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[19] The Plan argues that Dr. Hutt considered and relied on selected abstracts within the HAYES Update in concluding that LVAD for destination therapy remained experimental at the time of Mrs. Whitley's surgery. This claim is wholly without evidentiary support, with or without consideration of Dr. Hutt's disallowed declaration. *See supra* n. 3 (noting that Update is not mentioned in Dr. Hutt's declaration).

The earlier record indicates that Carolyn from Duke called Hardin with a patient update on October 20, 2004. After providing the update, Carolyn asked "if she still needed to call in updates if the case is not covered." AR p. 230 (the screen appears to cut off the final portions of the notes). The same record indicates that Hardin "left a message for Dr. Hutt to let me know if any of the MD's at Duke had called him today." *Id.*

The phone record from October 21, 2004, also written by Hardin, states:

> I spoke with Dr. Hutt and he stated that he spoke with Dr. Milano on a peer to peer review. He states that Dr. Milano was quoting an article from 2001 [[20]] and Dr. Hutt states the latest is from 2003 in which Hayes still calls destination therapy a "C" rating, which [is] experimental and investigational. I notified Carolyn UR nurse that the md's talked and that the decision remains as non covered from CCP. . . .

AR p. 231 (the screen appears to cut off the final portions of Hardin's notes).

October 26, 2004. On October 26, 2004, various Duke physicians wrote a letter "To Whom It May Concern," with the express purpose of "document[ing] the medical necessity for the transplant procedure." AR pp. 309-10. This letter provides a detailed description of Mrs. Whitley's current condition and prior treatments, but acknowledges that she would only be a transplant candidate "when her weight can be modified." The letter is signed by one nurse and two doctors, including Dr. Milano. AR. p. 310. The letter, plus numerous attachments related to Mrs. Whitley's medical condition, were transmitted by facsimile on October 28, 2004 to the Plan (attention Lisa Hardin). AR pp. 308-28.[21]

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[20] The HAYES Alert which the Plan obtained contemporaneously with the HAYES Report refers to a 2001 article published in the New England Journal of Medicine. That article addressed the "REMATCH" study and appears to be the article referenced in this discussion.

[21] By the time this letter was written, Duke was aware that the Plan had denied coverage because the LVAD was placed for destination therapy rather than as a bridge to transplant. Thus, the statements in and purpose of this letter might be viewed with some skepticism. On the other

November 3, 2004. On November 3, 2004, the Plan received, via facsimile, a Specialized Physician Review prepared on behalf of the United Resource Network ("URN"). This Review addresses, expressly, whether Mrs. Whitley is a suitable transplant candidate. This extensive report ("URN-Review") contains the following headings: I. Clinical Summary; II. Disease Treatment Statement; III. Literature Review; IV. Alternatives; and V. Community Standard. The last three sections address the propriety of use of the LVAD as destination therapy as an alternative to a heart transplant. AR pp. 88-91.

The URN-Review was prepared by a physician who specialized in cardiac transplantation. The following discussion is of particular relevance:

> The patient is now 2 ½ weeks after implantation of a HeartMate XVE Left Ventricular Assist Device for destination therapy. *This is a FDA approved and Medicare reimbursed procedure following the landmark REMATCH Trial (published in the New England Journal of Medicine) which evaluated destination therapy left ventricular assist device treatment versus medical therapy for end stage heart failure.*
>
> In patients [who] present as [Mrs. Whitley] did with refractory heart failure, non graftable coronary artery disease and inability to wean from inotropes and intraaortic ballon pump, *appropriate therapy does include consideration for long term implantable [LVAD] therapy.* However, once this is accomplished, the patient has a two to three year life expectancy on the device pending untoward complications. This time can be used in selective individuals to optimize their clinical status for transplantation. The longer she remains on the HeartMate device without untoward clinical events, the better condition she would be in for eventual cardiac transplantation . . . . . At the present time, in light of her BMI, and the recent insertion of Heartmate, there does not appear to be a medical indication to list her for transplantation.

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hand, the statements within the letter are wholly consistent with all medical records: that the LVAD was implanted with knowledge that it might ultimately be solely for destination purposes, but with the hope that Mrs. Whitley might reduce her weight and become a transplant candidate. *See, e.g.*, AR p. 106 (minutes relating to an October 13, 2004 meeting which included Dr. Milano and other Duke representatives and which states, as to Mrs. Whitley "Not a [transplant] candidate at this time; . . . would reconsider [transplant] if pt reaches WT goal of 155 lbs.").

AR p. 90 (emphasis added). Under a section titled "Literature Review," this reviewer states:

> The REMATCH Study clearly has documented that the mechanical support is superior to medical therapy in patients suffering from end stage heart failure. Extrapolation of this data to the acute setting is still in its infancy, although . . . the decision to proceed with destination therapy at an early time in this patient appears to be medically warranted.

AR p. 91.

Under "Alternatives," the reviewer states: At the present time, this reviewer feels that continuing the patient's original plan of LVAD destination therapy is the most prudent one." He recognizes, nonetheless, that transplantation could be reconsidered if Mrs. Whitley is able to achieve "full physical rehabilitation and . . . minimize her weight issues and optimally control her diabetes." AR p. 91.

The reviewer also addresses community practice in his geographic area (Washington, DC). In this regard, he states: clinical studies would be consistent with the placement of the HeartMate [LVAD] acutely in this setting. However, decisions regarding options of cardiac transplantation would be deferred until better management of her weight and diabetes could be obtained." *Id.*

November 4, 2004. On November 4, 2004, the Plan again wrote Dr. Milano, indicating that the question of the propriety of the LVAD implant and transplant candidacy had been referred to Dr. Babos, Medical Director from URN (United Resource Network), who, in turn, requested a third party review by an outside medical specialist reviewer. *See* AR p. 29-30 (letter to Dr. Milano from Dr. Hutt, signed on his behalf by Hardin); URN-Review (discussed above). The Plan states that the reviewer agreed that transplantation was not appropriate *at the present time.* It also concedes that the reviewer concluded "*that continuing the patient's original plan of LVAD destination therapy is the most prudent one*" and noted that, with weight loss and control of her diabetes, the patient might

become a transplant candidate. AR p. 29 (quoting reviewer, emphasis added). *See also* AR 331-32 (additional copy of letter to Dr. Milano from Dr. Hutt).

The Plan relied on this URN-Review in concluding that it would not cover any transplantation services. It also restated, in the same letter, that it would not cover the LVAD for destination therapy based on the Experimental Exclusion. As to this exclusion, the Plan expressly stated that it relied on the HAYES rating system. *Id.* The Plan did not discuss the significant support for coverage of the LVAD as destination therapy found in the URN-Review.

As with the Plan's earlier denial letter, this letter makes no reference to any concern regarding notice. Neither is there any reference to notice in Dr. Hutt's email directing that the denial letter be written.[22] The letter was copied to Mrs. Whitley.

November 22, 2004. On November 22, 2004, Joseph W. Robbins wrote the Plan on behalf of Duke. AR pp. 180-81 (listing department as Transplant Financial Services). The letter states that its purpose "is to formally appeal the denial . . .for the insertion of a left ventricular assistance device into Carol Whitley for the treatment of end-stage heart disease." Robbins states as follows regarding his earlier communications with the Plan:

> On October 6, 2004[,] the Transplant Financial Coordinators at Duke verified the insurance coverage with Carolina Care Plan and got case management involved. The

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[22] At 10:45 on November 4, 2005, Dr. Hutt emailed Hardin directing her to write the above letter. This email states:

> The answer to placing her on the transplant list is NO.
> The decision to use the LVAD for destination in the setting of this acute MI with heart failure is not supported by the literature or any current, past, or future proposed clinical trials and is therefore experimental and investigational. Her therapy at Duke is not a CCP covered benefit. Lisa, write up such a denial letter and send it to all relevant parties.

AR p. 333 (emphasis added).

> Transplant Financial Coordinator, Julia B. Holden and I were both *told by the case manager, Lisa Hardin, that basically anything we needed to do to save the patient was approved. According to Lisa she consulted with the Medical Director to confirm any services required to save the patient were approved.* A left ventricular assistance device and transplant evaluation were mentioned specifically. It was further *confirmed by Lisa that an LVAD and transplant evaluation were approved at that time.* We were also told that a transplant network, United Resource Network, had to be accessed.
>
> *I confirmed again on Friday 10/8/04 that the LVAD and transplant evaluation were approved.* On Saturday 10/9/04, Dr. Milano saw the patient and concluded that the patient needed to lose weight before proceeding with transplant. He also concluded that the [LVAD] was needed as soon as possible. He refers to the LVAD as a "destination vad" and then goes on to say that if the patient modified her weight, she could become a transplant candidate. I confirmed again on Monday 10/11/04 that the LVAD and transplant evaluation were approved. On that day, Dr. Milano inserted the LVAD.

AR pp. 180-81 (emphasis added–continuing to discuss patient's progress toward and possible eventual transplant candidacy, and related "bridge to transplant" nature of the procedure).

December 1, 2004. On December 1, 2004, the Plan wrote to Joseph Robbins at Duke acknowledging receipt of a grievance. The letter indicates a response will be provided within thirty days of the Plan's November 29, 2004 receipt of the grievance and further assured Robbins that: "Individuals with no prior involvement in your case will make a decision on your grievance." AR p. 385.

December 10-28, 2004 – Peer Review. On or about December 10, 2004, the Plan referred the question of whether LVAD for destination should be treated as experimental to a third party peer reviewer ("Peer Reviewer"). In his December 22, 2004 response, the Peer Reviewer, a cardiologist, notes that the Plan documents exclude coverage for "experimental, investigation or unproven" services, but responds "No" to the following inquiry:

> Based on all information reviewed, including the Hayes Rating and the definition of experimental investigational or unproven services outlined in the member's Benefit

> Handbook, would placement of the Left Ventricular Assistance Device for "destination therapy" be considered an investigational and/or experimental device?

AR p. 32 (dated December 22, 2004). He also answers "Yes" to the following question: "Based on all information reviewed does the member have benefits for a Left Ventricular Assistance Device?"

In support of the above conclusions, the Peer Reviewer states that the HeartMate LVAD procedure in question did not meet any of the four criteria listed [in the Handbook] for non-coverage." AR p. 33. He addresses each of these criteria as follows:

> * FDA Approval - LVAD placement is approved by the FDA for all applications from acute failure to wean from bypass after heart surgery, to bridge to transplantation, to destination therapy.
>
> * IRB approval needed . . . The procedure did not require review or approved informed consent by The Duke Institutional Review Board.
>
> * The procedure was not part of an ongoing clinical trial.
>
> * The procedure is not listed as a non-covered service in the benefit handbook.

AR p. 33.

The Peer Reviewer also discusses the "results of the REMATCH study published in the NEJM in 2001": which he stated "clearly document the survival benefits of destination LVAD support over medical therapy in patients suffering from end stage heart failure." AR p. 33.

After applying these standards to Mrs. Whitley's situation, the Peer Reviewer states "LVAD support and ultimate permanent or 'destination' therapy is currently being done in similar patients with FDA-approved devices and justified by data such as presented in the REMATCH study."

The Peer Reviewer criticizes the Plan's reliance on HAYES as follows:

> The [Plan] has based its determination . . . on the Hayes rating system. . . . This ["C" rating] of LVAD therapy was published about two years ago (February 2003) and does not take into account the large clinical experience in LVAD support which has occurred to date. (Annals of Thoracic Surgery. 2004, April; 1321-7 and Surgical

Clinics of North America 2004. Feb; 91-123.) This improved durability of LVAD systems as well as decreased incidence of complications would justify a higher rating than C for current applications of this technology.

AR p. 33.

In explaining his ultimate conclusion that the LVAD should be covered, the Peer Reviewer states that this particular use of LVAD was approved by the FDA and covered by Medicare. He also notes that, although the LVAD was designated as destination therapy in the medical records, Mrs. Whitley's use of the LVAD might well allow her to improve sufficiently to be a good transplant candidate. AR p. 34. This report is dated December 22, 2004, and was apparently faxed to the Plan on December 28, 2004.[23]

First-level Grievance

December 22-29, 2004–On December 22, 2004, Mr. Whitley wrote to Dr. Hutt summarizing the events leading to Mrs. Whitley's transfer to Duke and her medical care there. AR pp. 22-24. In this letter, Mr. Whitley asserts that he understood that a transplant was still under consideration when the LVAD was placed, but would be dependent on Mrs. Whitley losing thirty pounds. Mr. Whitley questions the HAYES Rating and notes that Duke was the developer of the LVAD and that Duke, along with FDA, Medicare and Medicaid as well as other insurers do not deem the LVAD

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[23] The REMATCH study relied on by the Peer Reviewer was, apparently, considered by HAYES prior to publication of its February 2003 Report. *See supra* n. 20 (discussing HAYES Alert discussion of 2001 REMATCH study). The HAYES Report could not, however, have considered reports of clinical experience or other studies or events post-dating publication of its February 2003 Report and preceding Mrs. Whitley's October 2004 surgery. As revealed by the HAYES Update, there wre sixty-two abstracts of such studies and reports in the first ten months of 2004 alone. Among the critical events post-dating the February 2003 HAYES Report is broadened FDA approval. As to FDA approval, the "HAYES Alert" states: "*The three LVAD systems currently cleared for market by the [FDA] are indicated for long-term use only as a bridge to transplantation.*" AR p. 65 (emphasis added). The above-quoted peer review as well as the URN-Review discussed earlier in this order, by contrast, address a more recent and broader FDA approval covering, *inter alia*, use of the LVAD for destination therapy.

investigational or experimental. He asks that the letter be treated as notice of a formal appeal. AR p. 24.

The Plan acknowledged receipt of Mr. Whitley's grievance by letter dated December 28, 2004, promising a response within thirty days. The letter advises Mr. Whitley that he (on his wife's behalf) may submit additional written materials in support of the grievance and that his wife may have a representative appointed to assist in presenting the grievance. The letter further assures him "*that individuals with no prior involvement in your case will make a decision on your grievance.*" AR p. 175 (emphasis added). This letter is signed by Valerie Keller of the Compliance Department.

On December 29, 2004, Dee Goodman, the Plan's Grievance Coordinator, wrote to Robbins at Duke advising him that Duke's grievance, received on November 29, 2004, remained in the review process. This letter states that a decision would be issued by January 12, 2005. AR p. 191.

January 3-14, 2005.

Plan records indicate a phone call was either made or received on January 3, 2005, relating to the Peer Review. The full notation reads as follows: "I adv per d. goodman peer reviewer has recommended approval . . . but this needs to be reviewed by dr. hutt and to pls give it til jan 12." It is not clear if the person on the other end of this call was Mr. Whitley or a Duke representative. The next two calls listed, however, are calls from a Duke representative on January 18 and 19 to check on the status of the claim. These are followed by a call from the Plan to Duke on January 20 advising that the denial would be upheld.[24]

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[24] AR p. 199 (January 18 notation stating: "prov called back to check on status of grievance. Adv I will contact Grievance department and give him a call back."); AR p. 199 (January 19 notation stating: "prov joe r . . .cal[l]ed back to speak to someone in grievance. supervisor Kim B took the call and advised the prov that she will have renee bouye call him back."); AR p. 199 (January 20 notation stating: "called prov back after speaking with renee in compliance. rec'd [voice mail] left msg indicating the denial was upheld based on the procedure being experimental and not approved

Mr. Whitley maintains that he called the Plan on January 14, 2005, to inquire regarding appointment of a representative. He asserts that he was told that the Plan had recommended that the disputed claim be paid and that he did not need to provide any further support for his claim. *See* AR p. 429 (Mr. Whitley's July 15, 2005 letter to Plan–discussed *infra*).

The record also contains a handwritten notation on a copy of the Plan's December 28, 2004 letter which appears to be notes of such a call made by Mr. Whitley during January 2005.[25] The Plan has no contemporaneous records of a call from Mr. Whitley, unless it is the January 3, 2005 call referenced above.

January 19, 2005. The Plan denied Mr. Whitley and Duke's first-level grievances on January 19, 2005. This denial relies on both the lack of notice and the experimental exclusion. AR p. 25-26. The letter is signed by Dee Goodman, Grievance Coordinator.

As regards the Experimental Exclusion, the denial letter first quotes the Plan exclusion language (though not the controlling definitions), then states that the Plan "rel[ies] on the HAYES rating system" which had given the LVAD a C rating. AR p. 25. Neither the URN-Review nor the Peer Review are mentioned.

As to lack of notice, and this is the Plan's first reliance on that ground, the Plan asserts that the "Medical Director reviewed your medical records and determined that we did not receive notification from you or the hospital requesting services for the [LVAD]." AR 25. The letter does not,

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by the FDA. advised that a formal letter will be forthcoming detailing the decision. advised that renee will be available to answer any additional questions he should have. left my contact number.").

[25] As discussed below (addressing July 2005 appeal letter), the notation refers to a January 3, 2005 call. This suggests either that Mr. Whitley may be referring to a conversation with someone else who had called the Plan on January 3, 2005 (possibly a Duke representative), or that the notation refers to his own call on January 3, 2005.

however, address the November 22, 2004 letter from Robbins (written on behalf of Duke) in which he detailed repeated conversations with Hardin and asserted that the Plan, through Hardin, provided an essentially "blanket" approval for whatever needed to be done to save the patient's life. Neither is there any record which suggests what evidence the Medical Director (Dr. Hutt) relied on in deciding, if he did so decide, that Robbins was untruthful in his letter as it related to notice.

What evidence is available as to Dr. Hutt's reasoning for the denial is found in an email string and suggests that he did not even consider the notice issue. *See* AR pp. 42-44. Moreover, this evidence suggests that Dr. Hutt made only a cursory decision to affirm the denial based predominantly on a desire to move the process to the next level, rather than to consider the merits of the grievance *Id.* (responding to inquiries as to how to handle the grievance:"*Let's send it out denied as experimental and handle any other re-review on the appeals side if it comes to that.*").[26]

This email string also discloses that Dr. Hutt was, effectively, the sole decision-maker on this grievance. As he was the initial decision-maker, this is obviously contrary to assurances the Plan gave Mr. Whitley and Duke (Robbins) in its letters acknowledging receipt of their grievances. In short, Dr. Hutt affirmed his own earlier decision, based solely on the summary HAYES Report Hardin obtained

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[26] This exchange was apparently prompted by a January 18, 2005 inquiry from the provider as to the status of the grievance. After confirming that this was "the LVAD case," Renee Bouye wrote Donald Pifer, Vice President of Network Management stating that "In our meeting, Dr. Hutt said he wanted to send this back out. I asked him about it the other day and he said he wanted to send it back out but I have heard nothing else. Do we really need to send this back out or can we just respond as a benefit issue?" Noting that the denial was based on the HAYES rating and an experimental exclusion, she notes "We are days away from missing our TAT by a month. Please advise." Pifer forwarded the email to Dr. Hutt asking "what do you suggest?" *Dr. Hutt replied: "Let's send it out denied as experimental and handle any other re-review on the appeals side if it comes to that."* AR p. 43 (emphasis added–quoted in text of order). The exchange between Pifer and Bouye which follows agrees to "handle this as a benefit" issue and states that the Grievance Coordinator will be told to deny as experimental and based on the HAYES rating of "C or D." *No mention of a notice concern appears anywhere in these email exchanges.*

on October 13 and 14, 2004. In doing so, he disregarded the information and opinions offered by the URN-Review and Peer Review.

The denial letter advises Mr. Whitley of the right to receive copies of criteria and documentation relied on by the Plan.[27] It also advises him of the member's right to file a second-level grievance. AR p. 25-26.

Second-level Grievance

July 2005. On July 15, 2005, Mr. Whitley filed a second-level grievance. AR pp. 428-31. In this detailed letter, Mr. Whitley states that after he received the Plan's December 28, 2004 letter:

> I called Carolina Care Plan on January 14, 2005, and requested information regarding the appointment of a representative and the procedure for submission of additional data . . . . I was told that Carolina Care Plan had recommended payment for my wife's treatment related to the LVAD. I was also told that Carolina Care Plan was waiting on additional materials sent from Duke . . . and as soon as that occurred, I would be notified in writing of the . . . Plan's decision, which I understood would be approved coverage for the LVAD procedure and all related medical costs.
>
> I also asked a Carolina Care Plan representative if I was wasting time and energy submitting additional data relating to the LVAD. The . . . representative again assured me that the LVAD procedure was covered and that Carolina Care Plan did not require additional information regrading the LVAD. . . . I relied on these assurances and did not submit additional data because the representative told me . . . that the procedure had been approved . . . .

AR p. 429. Mr. Whitley then describes his subsequent receipt of the January 19, 2005 denial letter and his understanding of pre-surgery communications between Duke and the Plan.[28]

Three exhibits appear to have been attached to this letter. AR pp. 432-37. Among the attachments was a copy of the Plan's December 28, 2004 letter which bears the following handwritten

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[27] From the record, it appears that the Plan may have attached its two letters to Dr. Milano as well as the October 4, 2004 letter to MUSC. AR pp. 27-30. There is, however, no indication that either the URN-Review or Peer Review were provided.

[28] Mr. Whitley's understanding of these communications would, of course, be second-hand information.