UNITED STATES DISTRICT COURT

DISTRICT OF NEW HAMPSHIRE

Joanne Mulready,
Administratrix of the Estate of
James C. Mulready,
Plaintiff

v. Civil No. 98-45-SM

United States Office of
Personnel Management,
Defendant

O R D E R

Plaintiff Joanne Mulready, Administratrix of the Estate of James C. Mulready, brings this action to compel Defendant United States Office of Personnel Management ("OPM") to require Blue Cross and Blue Shield of Rhode Island ("Blue Cross-RI") to pay for cancer treatment provided to Mr. Mulready.[1] Both parties have filed motions for summary judgment.

Summary judgment is appropriate when the record reveals "no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). Neither party asserts that a genuine dispute as to any material fact exists, and both agree that the case is appropriate for disposition on summary judgment. The court's review is

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[1]Although plaintiff's complaint purports to seek a declaratory judgment pursuant to 28 U.S.C. § 2201, the relief requested is an order directing OPM to require Blue Cross to pay the disputed benefits. See 5 C.F.R. § 890.107 (1999) (providing for judicial review of OPM's denial of health benefits and limiting recovery to an order directing OPM to require the insurance carrier to pay the benefit).

limited to the record that was before OPM at the time it made the challenged decision. See 5 C.F.R. § 890.107(3).

Background

The Federal Employee Health Benefits Act, 5 U.S.C. §§ 8901 et seq., authorizes OPM to contract with private carriers to provide health insurance to federal employees under certain statutorily-described health benefits plans. See 5 U.S.C.A. §§ 8902, 8903 and 8903a (West 1996 and Supp. 1999). Mr. Mulready, a federal employee at the Portsmouth Naval Yard, was insured under such a plan, administered by the Blue Cross and Blue Shield Association (the Blue Cross and Blue Shield Service Benefit Plan or the "Plan").

In 1987, Mr. Mulready was diagnosed as suffering from Dukes B Stage rectal cancer. He underwent surgery and did well until the cancer recurred in 1992 or 1993. He had additional surgery and was treated with radiation and chemotherapy. The condition arose again in 1995, but because he had had the maximum dose of radiation, and standard chemotherapy had failed, his oncologist recommended passive care. By August, 1996, Mr. Mulready's tumor had doubled in size and he was referred to Dr. Harold J. Wanebo, Chief of Surgery at Roger Williams Hospital in Providence, Rhode Island, for pelvic perfusion treatment. Pelvic perfusion involves delivering high doses of chemotherapy locally to the pelvis. The procedure involves isolating the bloodstream

supplying the pelvic region, running the blood through a hemodialysis pump, and administering drugs into the bloodstream.

Because the procedure was to be performed in Rhode Island, Mr. Mulready sought precertification from Blue Cross-RI. By letter dated November 8, 1996, Blue Cross-RI informed Mr. Mulready that the procedure was excluded from coverage under the Plan because it was "experimental/investigational in nature." (R. at 68.) Dr. Wanebo and Dr. Dennis B. Hammond, Mr. Mulready's local oncologist, wrote to Blue Cross-RI requesting reconsideration of the denial of benefits. See 5 C.F.R. § 890.105(a)(1) (1999) (providing for reconsideration by the carrier). Dr. Wanebo wrote that pelvic perfusion was "the only option we are aware of that might produce significant regression of tumor as well as controlling his severe pain." (R. at 63.) By letter dated December 4, 1996, Blue Cross-RI again denied coverage, with the following explanation:

> The medical documentation was first reviewed by our Medical Director and externally by a surgical oncologist who confirms that high dose chemotherapy by way of pelvic perfusion with the intent to palliate pelvic pain in an individual who is otherwise unresectable [i.e., not a candidate for further surgery] is considered experimental.

(R. at 67.)

Mr. Mulready sought review of Blue Cross-RI's decision by OPM, and Drs. Wanebo and Hammond again wrote supportive letters on his behalf. See 5 C.F.R. § 890.105(e) (1999) (providing for OPM review of carrier's denial of benefits). Dr. Wanebo stated that his plan was to treat Mr. Mulready with pelvic perfusion "in

order to palliate and control [his] local disease." (R. at 61.) He also noted that "[b]oth Mr. Mulready and his wife understand that the technique is not a cure and they are not anticipating this as a goal." (R. at 62.)

Following its review of Mr. Mulready's appeal, OPM concluded that it could not find a contractual basis on which to require the Plan to pay for the proposed pelvic profusion therapy. OPM noted that its "medical consultant has reviewed all the documentation submitted to support Mr. Mulready's appeal and he has determined that pelvic perfusion therapy is an experimental/investigative procedure." (R. at 301.) OPM suggested that Mr. Mulready attempt to secure payment under the Plan's Flexible Service Option which provides benefits under certain conditions for procedures not expressly covered under the Plan. Blue Cross-RI, however, determined that benefits were not available under the Flexible Service Option for experimental/ investigational procedures.

Despite his inability to secure payment from Blue Cross-RI, Mr. Mulready underwent two pelvic profusion treatments, which he paid for with the help of his family and community. Mr. Mulready died in August of 1997.

By letter dated September 16, 1997, counsel for Mr. Mulready's estate requested that OPM re-open and reconsider Mr. Mulready's case based on new evidence. See 5 C.F.R. § 890.105(e)(5) (providing for re-opening of OPM case). Appended to the letter were a number of exhibits, including an excerpt

from a book published in 1997 and therefore not available to OPM at the time of its decision. OPM responded that the supplemental information did not warrant reversal of its decision, and this suit for judicial review of OPM's decision followed.

Discussion

The standard of review applicable to OPM's decision is supplied by the Administrative Procedure Act ("APA"). See Caudill v. Blue Cross and Blue Shield of North Carolina, 999 F.2d 74, 80 (4th Cir. 1993); Harris v. Mutual of Omaha Companies, 992 F.2d 706, 712 (7th Cir. 1993). Under the APA, the court may set aside OPM's decision if it was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C.A. § 706(2)(A) (West 1996). This standard requires the court to "consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971). The court cannot substitute its judgment for that of OPM, see Caudill, 999 F.2d at 80, or set aside OPM's decision because it is "unhappy with the result reached," Dubois v. United States Dep't of Agriculture, 102 F.3d 1273, 1284 (1st Cir. 1996) (internal quotation marks omitted). Nevertheless, the standard of review, while highly deferential, is not a "rubber stamp." Id. at 1285.

Plaintiff argues that the reasoning behind OPM's decision is not set forth with sufficient clarity to be upheld by the court. The Supreme Court has noted:

> [A] reviewing court, in dealing with a determination or judgment which an administrative agency alone is authorized to make, must judge the propriety of such action solely by the grounds invoked by the agency. If those grounds are inadequate or improper, the court is powerless to affirm the administrative action by substituting what it considers to be a more adequate or proper basis.

Securities and Exchange Comm'n v. Chenery Corp., 332 U.S. 194, 196 (1947). A court may, however, "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc., 419 U.S. 281, 286 (1974).

Like Blue Cross-RI, OPM concluded that the proposed pelvic perfusion treatment was not covered under the Plan because it was an experimental/investigational procedure. The Plan defines an investigational/experimental procedure as follows:

> A drug, device or medical treatment or procedure is experimental or investigational:
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> 1) if the drug or device cannot be lawfully marketed without approval of the U.S. Food and Drug Administration and approval for marketing has not been given at the time the drug or device is furnished; or
> 2) if reliable evidence shows that the drug, device or medical treatment or procedure is the subject of ongoing phase I, II, or III clinical trials or under study to determine its maximum tolerated dose, its toxicity, its safety, its efficacy, or its efficacy as compared with a standard means of treatment or diagnosis; or
> 3) if reliable evidence shows that the prevailing opinion among experts regarding the drug, device or medical treatment or procedure is that further studies or clinical trials are necessary to

> determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with a standard means of treatment or diagnosis.
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> Reliable evidence shall mean only published reports and articles in the authoritative medical and scientific literature; the written protocol or protocols used by the treating facility or the protocol(s) of another facility studying substantially the same drug, device or medical treatment or procedure; or the written informed consent used by the treating facility or by another facility studying substantially the same drug, device or medical treatment or procedure.

(R. at 49.)

OPM's medical consultant, Dr. James Vorosmarti, Jr., on whom OPM apparently relied in determining that the proposed treatment was experimental/investigational, did not reveal his reasoning in great detail. His complete written analysis consisted of the following note:

> The plan reviewer, an oncologist and a surgeon have all stated that pelvic perfusion therapy is an experimental/investigative procedure. After reviewing the abstracts presented and recent surgical, oncology + medical texts (none of which reference pelvic perfusion) I must arrive at the same opinion.
>
> Regional chemotherapeutic perfusion has been in use for colon cancer metasteses to the liver, head + neck skin cancer, etc. for about 30 years.

(R. at 220.) However, as Dr. Vorosmarti essentially concurred with the opinions of Blue Cross-RI's medical reviewers, the court finds that it can reasonably look to their reasoning to discern the grounds for OPM's decision. Cf. Harris, 992 F.2d at 712 (agreeing with district court that although OPM made no explicit factual findings, "the letter affirming the company's denial of benefits, together with . . . [a list of] the documents that were

before [OPM] for review, was sufficient record evidence to support [OPM's] determination).

Blue Cross-RI's Medical Director, Dr. Rosario Noto, wrote an appeal summary on November 19, 1996. Dr. Noto noted that "Dr. Wanebo has recommended pelvic perfusion as the only option that might produce significant regression of tumor as well as controlling [Mr. Mulready's] severe pain." (R. at 257.) Nevertheless, in analyzing whether the procedure was "experimental or investigational," Dr. Noto only discussed, and therefore presumably only considered, its use in controlling pain. Dr. Noto wrote:

> On review of twelve articles with reference to pelvic perfusion in various methods of administration (chemofiltration, balloon occlusion, closed circuit perfusion) there was not sufficient evidence to say that pelvic perfusion was superior to other methods of pain control in pelvic cancers. . . . None of the studies reviewed compared the efficacy of pelvic perfusion to conventional methods of pain management. It was therefore concluded that there was not sufficient evidence to consider the use of pelvic perfusion for pain palliation other than investigational at this time.

Id. The point is more clearly made in a letter from Blue Cross-RI's general counsel to Mr. Mulready's former attorney:

> I noted in your letter dated December 5, 1996 that you made the statement that this pelvic perfusion procedure is the only hope that Mr. Mulready has to again achieve remission and lead a productive life. It is my understanding that the pelvic perfusion procedure here is only being used to administer pain medication. The treatment is not curative but palliative.

(R. at 330.)

Mr. Mulready's treating physicians, however, plainly recommended the procedure not only as a means of controlling

pain, but also as a potential means of shrinking Mr. Mulready's tumor and obtaining remission. Concededly, pain control was likely a major anticipated result of the procedure. Dr. Wanebo informed Blue Cross-RI that "[i]n patients receiving this for palliative therapy, the primary effect is a significant reduction of pain which is the most incapacitating insult that these patients face." (R. at 63.) He continued, however, to advise that "[i]n addition, it produces an associated tumor regression in many though not all patients." Id. (emphasis added).

Although the treatment was expected to be palliative, and not expected to be a cure, part of the anticipated result included controlling tumor growth. Dr. Wanebo's office notes of November 5, 1996, state: "The only thing remaining is to provide palliation by pelvic perfusion - This will reduce pain + hopefully induce tumor regression. The perfusion can be repeated to maintain local tumor control." (R. at 276.) In a letter to Dr. Gary Friedman of Blue Cross-RI, Dr. Wanebo described the treatment as an alternative to radiation and resection, for which Mr. Mulready was clearly not a candidate, as a means of providing local control of the disease. He stated that the procedure "can produce tumor shrinkage as well as reduce or eliminate pelvic pain for a reasonable period of time i.e. similar to radiation." (R. at 272.)

The Supreme Court has recognized four specific instances in which an agency may be found to have acted arbitrarily and capriciously:

> Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). OPM's decision in this case falls within the second (and arguably the third) categories. With respect to the second category, OPM completely failed to consider whether pelvic perfusion for the purpose of inducing tumor regression and providing local tumor control (and attaining remission) constituted an experimental or investigational procedure as defined in the Plan. With respect to the third category, OPM based its decision on the premise that the treatment for which Mr. Mulready sought precertification was for the sole purpose of controlling pain, which appears to be directly contrary to the evidence OPM had before it. Thus, OPM's decision was necessarily arbitrary and capricious, since it did not consider an important aspect of the problem — the experimental/investigatory nature of the treatment related to tumor management.

Where the agency has failed to consider a relevant factor, the reviewing court should remand the case to the agency "for additional investigation or explanation." Florida Power & Light Co. v. Lorion, 470 U.S. 729, 744 (1985). The court generally may not make a de novo determination of the matter before it. Id.

Accordingly, the court remands this case to OPM for further review.

An additional point should be made. In determining whether the proposed procedure was experimental or investigational as defined by the plan, Dr. Noto reviewed the relevant literature and concluded that since none of the studies compared the efficacy of the proposed treatment (for the purpose of pain palliation) with that of standard pain treatment, the procedure had not been shown to be other than experimental or investigational. Dr. Noto probably reasoned that since there were no studies of relative efficacy, "further studies or clinical trials are necessary to determine . . . [the procedure's] efficacy as compared with a standard means of treatment or diagnosis," rendering the procedure experimental/investigational under the Plan.[2] (R. at 49.) Dr. Noto's approach was incorrect. As defined by the Plan, a procedure is experimental or investigational "if reliable evidence shows that the prevailing opinion among experts regarding the . . . procedure is that further studies or clinical trials are necessary . . . ." Id. (emphasis added). Dr. Noto's personal opinion regarding the need for further studies is of course not germane, given the Plan's definitions. It is also not "reliable evidence" as defined by the Plan The Plan states that "[r]eliable evidence shall mean only published reports and

[2]Actually, the record does not reveal whether Dr. Noto was aware of the Plan's definition of an experimental or investigative procedure.

articles in the authoritative medical and scientific literature" (as well as other forms of evidence not applicable here). Id. (emphasis added). Thus, the determination that further studies are necessary must be reflected in the authoritative medical and scientific literature.[3]

For similar reasons, the opinions Dr. Noto obtained from other physicians are not particularly germane either. Dr. James A. Edney wrote that it was his "opinion that high dose chemotherapy by way of pelvic perfusion with the intent to palliate pelvic pain in an individual who is otherwise unresectable would be considered experimental treatment." (R. at 256.) Another doctor wrote that he had consulted with a rectal surgeon and an oncologic surgeon and that they all agreed that "pain palliation . . . is not substantiated by significant literature to leave the realm of the investigative." (R. at 270.) Again, the personal opinions of these physicians are not "reliable evidence" as defined by the Plan. Nor do the personal opinions of physicians, such as Dr. Hammond and Dr. Paul H. Sugarbaker, who wrote supportive letters on Mr. Mulready's behalf (stating that pelvic perfusion was not experimental) constitute "reliable evidence" under the Plan. The court has relied on

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[3]The Plan's choice of language might create substantial difficulty in cases in which the contemplated procedure is so new and obviously experimental that the "authoritative medical and scientific literature" has not had an opportunity to declare it so. But this case does not seem to fall into that category, or, at least no one has argued that the plain language of the Plan should not govern what is and is not "reliable evidence" of the "prevailing opinion among experts" in this case.

those letters only to establish the purpose for which pelvic perfusion was recommended for Mr. Mulready. On remand, OPM must ensure that it considers only "reliable evidence" as defined by the Plan in determining whether the pelvic perfusion recommended was experimental or investigational in nature in this case.

Conclusion

For the foregoing reasons, defendant's motion for summary judgment is denied. Plaintiff's motion for summary judgment is granted to the extent that the court sets aside OPM's decision and remands for further administrative consideration, and is otherwise denied. OPM's decision is vacated and the case remanded to OPM for further consideration. The court will retain jurisdiction over the matter, but for administrative purposes only will close the case.

SO ORDERED.

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Steven J. McAuliffe
United States District Judge

July 15, 1999

cc: Lynmarie C. Cusack, Esq.
Gretchen Leah Witt, Esq.