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DECISION

THE COMPTROLLER GENERAL
OF THE UNITED STATES
WASHINGTON, D.C. 20548

[Protest of VA Refusal to Consider Proposal]

FILE: B-195827 DATE: March 31, 1980

MATTER OF: Cardiocare, a division of Medtronic, Inc.

DLG04248
DLG04259
AGC00989
DLG04261

DIGEST:

1. Determination that an award to particular firm would result in an organizational conflict of interest must be made by procuring activity, with which lies the responsibility for balancing Government's competing interest in preventing bias in performance of contract and awarding contract that will best serve Government's needs to the most qualified firm.

2. Agency policy of not contracting with manufacturers of cardiac pacemakers or their affiliates for followup monitoring is reasonable. Because the health and safety of the patient is critically affected, complete objectivity in performance of pacemaker monitoring contract is necessary.

Cardiocare, a division of Medtronic, Inc. (Cardiocare), protests the refusal of the Veterans Administration (VA) to consider the proposal it submitted under solicitation No. M2-Q70-79. The solicitation was for the monitoring of cardiac pacemakers implanted in VA hospital patients.

The protested solicitation was issued on March 15, 1979, by the VA's Marketing Division for Medical Equipment. Cardiocare soon thereafter submitted its proposal. However, the VA did not make a final decision to exclude Cardiocare until July 31, 1979. On that date, the VA's Director of Supply Service sent a letter to Medtronic, Inc., stating the following:

> "The proposal of Cardiocare has been carefully considered at various levels of the agency, including the Pacemaker Committee. It is our decision that we

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> continue our policy of not contracting for follow-up service on pacemakers with the manufacturers of these units. It is also our decision that the follow-up monitoring will be conducted by an independent agency which will give us an impartial assessment of the performance of pacemakers supplied by any and all vendors of pacemakers. We noted in Cardiocare's appeal that they offered some services which they contend we need and which were not offered by our contract. It is our decision that we did not want these services. Therefore, the argument of Cardiocare is not persuasive. They state that the purpose of pacemaker surveillance is to evaluate the patient and not the product. This view is not acceptable to the VA. It is our intention that the monitoring of the patient will be conducted by the physicians who are treating the patients on behalf of the Veterans Administration, not by a third party. Coincidentally, Cardiocare in previous representations emphasized the need for keeping surveillance over the pacemaker units, not the patient. Since their affiliation with your firm, they have switched their position to one of intent to monitor primarily the patient. Again I must emphasize that this latter is not the desire of the Veterans Administration."

Cardiocare states that it received the foregoing letter on August 10, 1979. By letter dated August 17, 1979, and received by us on August 20, 1979, Cardiocare protested the Director of Supply Service's decision.

Cardiocare contends that the VA's policy of having the monitoring and evaluation of the quality and performance of a pacemaker done by companies independent of the manufacturer violates the Federal Procurement Regulations (FPR). The company alleges that the VA negotiated the solicitation in a noncompetitive manner in making an award to Pacemaker Diagnostic Clinic of America (PDCA). Cardiocare emphasizes that FPR § 1-3.101(c) (1964 ed. amend. 194) provides that whenever property or services are procured by negotiation,

proposals shall be solicited from the maximum number of qualified sources. In applying its policy as a rigid rule Cardiocare asserts that the VA has foreclosed considerations such as quality of service and price in determining which companies should be awarded contracts. The company believes that, at the very least, physicians at each VA hospital should be able to choose the pacemaker monitoring systems they desire based on the factors of quality and price.

With regard to the Director of Supply Service's reasons given in support of the VA policy, Cardiocare claims that while pacemaker monitoring does disclose the quality of a pacemaker, the actual purpose of the monitoring is to evaluate the functioning of the heart and pacemaker as a system. According to Cardiocare, the monitoring service is merely a routine medical checkup for pacemaker patients and that in the vast majority of cases, the problems detected are not related to the quality of the pacemaker unit. Furthermore, in Cardiocare's opinion, the policy of barring any company associated with the manufacturer of a pacemaker is unwarranted here in view of Cardiocare's excellent record of providing unbiased and high quality service.

Cardiocare also asserts that there is absolutely no evidence which would imply that its relationship with Medtronic, Inc., would adversely affect the objectivity and accuracy with which it provides its pacemaker monitoring service. The company avers that as one of the largest pacemaker followup services in the world, it provides both 24-hour electrocardiogram monitoring and telephonic followup of pacemaker patients. Following telephonic transmission of a patient's electrocardiogram Cardiocare alleges that it analyzes and medically reviews, through a staff cardiologist, the EKG report. The report, including the underlying data, is then forwarded to the patient's physician. Cardiocare avers, then, that all the data necessary for evaluating the function of the pacemaker unit are available to the physician, since he receives an actual copy of the EKG strip. Therefore, Cardiocare believes that there is no validity to the VA's concern that Cardiocare might be motivated to misinterpret or fail to mention problems detected in Medtronic's pacemakers.

The VA declares that the Director of Supply Service's July 31, 1979, letter adequately sets forth its position in this matter. Nevertheless, the agency states that FPR § 1-3.101(c) is not applicable here because the method of procurement involves multiple-award contracting. Multiple-award contracts are in the nature of basic agreements as authorized by FPR § 1-3.410. The VA emphasizes that it was always its intention to arrange for multiple contracts and, although no award other than to PDCA has yet been made, potential contractors are being evaluated. In this regard, the VA states that it initially expected to contract with Cardiocare when the firm was "independent" from Medtronic but that after it was purchased or merged with Medtronic, Inc., Cardiocare no longer had the independent status which the VA required. In any event, the VA believes that because it contemplates multiple-award contracts, such competition as is required by the FPR will be obtained.

PDCA claims that the reasons which the VA has chosen not to contract for pacemaker monitoring services with any company which has a relationship with a pacemaker manufacturer are in the best interest of the Government and the VA patients themselves. In PDCA's opinion, the VA is rightfully concerned that the data which it obtains are independent data from a contractor who has no relationship with a pacemaker manufacturer and upon which data a high degree of reliance can be placed. With respect to Cardiocare's argument that it provides the underlying data to the physician, PDCA takes the position that a fundamental distinction must be made between the reports of the operation of a single pacemaker and the totality of data derived from the testing of numerous pacemakers. According to PDCA, the VA can detect trends in the operation of a particular make and model of pacemaker from an analysis of the latter type of data. PDCA urges that data analyzing numerous patients who have been tested must be collected and analyzed by an independent company in order to insure its validity.

We have recognized that procuring activities have a legitimate interest in protecting the Government from the bias that might result from awarding a contract to a firm having an organizational conflict of interest. See Planning Research Corporation Public Management Services, Inc., 55 Comp. Gen. 91 (1976),

76-1 CPD 202. At the same time, because it is a general policy of the Federal Government to allow all interested qualified parties an opportunity to participate in its procurement in order to maximize competition, unless there is a clearly supportable reason for excluding a firm, we recognize that a firm should not be excluded from competition simply on the basis of a theoretical conflict of interest. PRC Computer Center, Inc.; On-Line Systems, Inc.; Remote Computing Corporation; Optimum Systems, Inc., 55 Comp. Gen. 60 (1975), 75-2 CPD 35. Furthermore, the determination as to whether a sufficient possibility exists that an award to a particular firm would result in an organizational conflict of interest must be made by the procuring activity, with which lies the responsibility for balancing the Government's competing interest in (1) preventing bias in the performance of certain contracts which would result from a conflict of interest, and (2) awarding a contract that will best serve the Government's needs to the most qualified firm. See Planning Research Corporation Public Management Services, Inc., supra.

In this case, regardless of whether the monitoring service is characterized as keeping surveillance over the pacemaker units themselves or as checking the medical condition of the patient, it is clear that complete objectivity is necessary. Since the record shows that Medtronic, Inc., supplies 50 percent of the pacemakers used by VA, Cardiocare would be placed in the position of having to decide whether its parent company's pacemaker is adequate for VA patients if it were awarded a contract. Because the health of the VA patients is so directly involved, we believe that the VA's policy not contracting with pacemaker manufacturers is reasonable.

The protest is denied.

Milton J. Socolar

For The Comptroller General
of the United States