Comptroller General
of the United States

United States General Accounting Office
Washington, DC 20548

Decision

Matter of: Novartis Pharmaceuticals Corporation; Parke-Davis--Costs

File: B-281681.8; B-281681.9

Date: August 24, 1999

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Sharif T. Dawson, Esq., Defense Supply Center Philadelphia, Defense Logistics Agency, for the agency.
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DIGEST

General Accounting Office will not recommend that protester be reimbursed costs of filing and pursuing protest of alleged solicitation deficiencies following agency corrective action, where protest arguments were not clearly meritorious.

DECISION

Novartis Pharmaceuticals Corporation and Parke-Davis request that we recommend that they be reimbursed the costs of filing and pursuing their protests challenging the terms of solicitation SP0200-99-R-1502, issued by the Defense Supply Center Philadelphia (DSCP), Defense Logistics Agency, for HMG-CoA Reductase Inhibitors.

We deny the requests.

BACKGROUND

The solicitation, issued on October 23, 1998, contemplated the award of one or two fixed-price national contracts for HMG-CoA Reductase Inhibitors (cholesterol-lowering drugs, commonly referred to as statins) for use in the Department of Defense's formulary programs and military treatment facilities. The solicitation initially provided that proposals would be evaluated based on two factors of equal importance, cost-efficacy and past performance. (The solicitation provided for calculation of the cost-efficacy of any particular statin through a mathematical formula that considers both the drug's annual cost per patient and the

efficacy of the statin in lowering cholesterol.) In the event that proposals were rated essentially equal after application of these two factors, the solicitation provided for consideration of the effect of the statin on the incidence of fatal and non-fatal myocardial infarctions (MIE); if the proposals then were still essentially equal, the inconvenience of switching patients to the contracted statins would be considered. RFP (Oct. 23, 1998) at 29-33. On December 1, 1998, DSCP issued amendment No. 0002 to the solicitation, which (1) elevated MIE from its tie-breaker status to an evaluation factor, and (2) made the technical factors significantly more important than cost. As amended, the solicitation stated as follows:

> Award will be made to the offeror(s) whose proposal contains the combination of those criteria (set forth below) offering the best overall expected value . . . . In aggregate, the technical factors are significantly more important than cost or price. . . . In achieving this objective, the following evaluation factors will be considered and are listed in descending order of importance:
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> Cost-Efficacy
> Evidence of effect on incidence of fatal and non-fatal myocardial infarctions
> Past Performance

RFP amend. No. 0002, at 29.

On December 9, Novartis protested to our Office that the solicitation as amended was ambiguous as to the basis for award, unclear as to how the agency would calculate MIE, and unduly restrictive of competition due to limitations on the types of evidence of effectiveness the agency would consider. DSCP amended the solicitation on December 16 (amendment No. 0006) to (1) delete the statement that the technical factors would be significantly more important than cost in the evaluation and to provide instead simply that the factors are "listed in descending order of importance," and (2) address the alleged ambiguity with respect to the MIE calculation.[1]

On December 29 Parke-Davis, and on December 30 Novartis, protested that competition was unreasonably restricted due to consideration of only MIE under the second evaluation factor to the exclusion of other favorable outcomes, and due to the definition of acceptable MIE evidence. DSCP amended the solicitation on January 11 and January 14, 1999 (amendment Nos. 0007 and 0008) in an effort to respond to these protests. Finally, on February 11, the agency amended the solicitation (amendment No. 0009) to provide for consideration of favorable

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[1]The solicitation as amended continued to provide for consideration of the inconvenience of switching patients to the contracted statins in the event that proposals otherwise were essentially equal after application of the above factors.

cardiovascular outcomes other than reducing MIE and to broaden the definition of acceptable evidence.

Meanwhile, on December 3, DSCP amended the solicitation (amendment No. 0003) to delete the solicitation option pricing provisions and to substitute an economic price adjustment (EPA) clause. On December 29 Novartis, and on January 19 Parke-Davis, protested to our Office that the EPA clause improperly used a contractor's Federal Supply Schedule (FSS) prices as the economic indicator for the purpose of calculating price adjustments under the contract. In addition, Parke-Davis questioned the requirement in the EPA clause that the contractor submit (at the time of final invoice for each contract period) a written representation that the amounts invoiced under the contract reflected all price decreases required by the EPA clause. RFP amend. No. 0003, EPA Clause, at 9. Although continuing to maintain that the EPA clause was valid, DSCP then amended the solicitation (amendment No. 0010) on February 19 to delete the clause.

On February 22, Novartis and Parke-Davis requested that we recommend reimbursement of the costs of filing and pursuing their protests. (On March 2, we dismissed the protests as academic because of the agency's corrective action.) Novartis and Parke-Davis assert that, since their protests were clearly meritorious and the agency's corrective action occurred after it had filed agency reports disputing the protest arguments, the corrective action was unduly delayed so as to warrant our recommending the recovery of protest costs.

STANDARD FOR RECOVERY OF COSTS

Under the Competition in Contracting Act of 1984 (CICA), our Office may recommend recovery of costs where we find that an agency's action violated a procurement statute or regulation. 31 U.S.C. § 3554(c)(1) (1994). Our Bid Protest Regulations provide that we may recommend that a protestor recover its costs of filing and pursuing a protest where the contracting agency decides to take corrective action in response to a protest. 4 C.F.R. § 21.8(e) (1999). This does not mean that costs are due in every case in which an agency decides to takes corrective action; rather, we will recommend that a protester recover its costs only where an agency unduly delayed its decision to take corrective action in the face of a clearly meritorious protest. Baxter Healthcare Corp.--Entitlement to Costs, B-259811.3, Oct. 16, 1995, 95-2 CPD ¶ 174 at 4-5. Thus, as a prerequisite to recovery of costs where a protest has been settled by corrective action, the protest not only must have been meritorious, but also must have been clearly meritorious, i.e., not a close question. Id.; GVC Cos.--Entitlement to Costs, B-254670.4, May 3, 1994, 94-1 CPD ¶ 292 at 3. Here, we conclude that the protests were not clearly meritorious so as to warrant recovery of protest costs.

MIE

Novartis and Parke-Davis asserted in their protests that the evaluation scheme with respect to MIE was restrictive of competition because it failed to account for positive outcomes other than MIE, and limited evidence of MIE to studies published in peer-reviewed medical journals. The protesters contended that the evaluation scheme failed to consider that different statins can produce various positive outcomes which aid in illuminating a particular statin's overall value, and that there is other relevant and reliable evidence of positive outcomes besides studies published in peer-reviewed medical journals. According to the protesters, the agency's evaluation scheme improperly favored statins which had been on the market for a relatively long period of time.

Where an agency has deliberated and reached a considered judgment concerning a medical policy, we do not believe that it is appropriate for our Office to review that policy or judgment under our bid protest function. Hoechst Marion Roussel, Inc., B-279073, May 4, 1998, 98-1 CPD ¶ 127 at 5; Pfizer, Inc., B-277733, Oct. 27, 1997, 97-2 CPD ¶ 119 at 2-3; Pfizer, Inc., B-276362, June 6, 1997, 97-1 CPD ¶ 205 at 6. In choosing to include MIE as an evaluation factor, DSCP determined that MIE provided a useful and effective gauge for assessing a statin's ability to produce a clinically desired outcome; the agency found that MIE is an important factor that provides greater confidence that a statin will produce a desired, favorable outcome and that, unlike some other possible outcomes, it is a relatively uniformly defined and measured outcome such that it facilitates valid comparisons between studies. Contracting Officer's Report (B-281681), Jan. 12, 1999, at 8; Contracting Officer's Report (B-281681.3, B-281681.4), Jan. 12, 1999, at 3-4. In addition, DSCP determined to limit evidence of MIE to studies published in peer-reviewed medical journals on the basis that the peer-review process provides a greater assurance about the reliability and validity of the conclusions in a study (which is likely to have been performed and/or paid for by a drug's manufacturer). Contracting Officer's Report (B-281681.3, B-281681.4), Jan.12, 1999, at 5-6.

While reduction in the incidence of fatal and non-fatal MIE is not the only positive outcome that a particular statin may produce, and studies published in peer-reviewed medical journals are not the only evidence of MIE, they were the outcome and evidence the agency--in its considered medical judgment--deemed necessary to satisfy its medical needs. The protesters' disagreement with DSCP's decision would not provide a basis to review the agency's medical judgment. Thus, the protests in this regard were not clearly meritorious and did not warrant recovery of protest costs.[2]

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[2]The protesters also objected to the fact that the solicitation provided for the agency to evaluate a statin more favorably if at least one study showed that the statin produced a statistically significant reduction in MIE; the protesters asserted that this provision overlooked clinically significant outcomes. DSCP explained that the

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OTHER PROTEST GROUNDS

As noted above, the protesters raised two additional general challenges to the solicitation. First, in its December 9 protest, Novartis contended that amendment No. 0002 introduced an ambiguity into the solicitation with respect to the evaluation scheme. Specifically, as subsequently explained in its comments on the administrative report, Novartis argued as follows:

> Amendment No. 0002 . . . converted MIE from a tie-breaker to a separate evaluation factor, without indicating how this new factor [would] relate to the integrated cost/technical trade-off inherent [in] the best value determination that the Agency would make when it evaluated cost-efficacy. As amended, the Solicitation gave no indication as to how MIE (a purely non-price factor) would be weighed against the integrated assessment of cost and technical merit conducted under the cost-efficacy evaluation factor. That is, the Solicitation provided no mechanism for calculating an overall technical score including MIE which could then be weighed against price.

Novartis Comments, Feb. 1, 1999, at 3. DSCP, on the other hand, maintained that the solicitation was clear on its face as to the basis for award: the cost figure derived from the cost-efficacy calculation (the annual drug cost per patient successfully treated so as to attain their cholesterol-lowering goal) would be considered with the other evaluation factors, MIE and past performance, in descending order of importance (as provided for by amendment No. 0006), and a cost-technical tradeoff then would be made using these factors. Contracting Officer's Report (B-281681), Jan. 12, 1999, at 4-5.

Second, in their protests of the EPA clause added by amendment No. 0003, Novartis and Parke-Davis generally asserted that an EPA clause using a contractor's FSS prices as the economic indicator for the purpose of calculating price adjustments was improper because the clause was not one of the three general types of EPA clauses listed in Federal Acquisition Regulation (FAR) § 16.203-1, and was

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solicitation did not differentiate between clinical and statistical significance, but instead simply provided that the agency would evaluate more favorably a clinical outcome--reduction in MIE--that is statistically significant. Contracting Officer's Report (B-281681.3, B-281681.4), Jan. 12, 1999, at 7-9; RFP, Oct. 23, 1998, at 33 and amend. No. 0007. The agency's determination as to the type of evidence of MIE that was important for evaluation purposes was a matter of medical judgment that we will not review. Hoechst Marion Roussel, Inc., supra, at 5. Thus, the protesters' arguments in this regard were not clearly meritorious so as to warrant recovery of protest costs.

inconsistent with the concepts underlying that provision. Further, because the EPA clause allegedly was improper, the protesters asserted, it did not furnish a basis for the exercise of option years under the contract. In addition, Parke-Davis challenged the requirement in the EPA clause for the contractor to submit a written representation that the amounts invoiced under the contract reflected all price decreases required by the EPA clause, on the basis that this was not one of the representations and certifications authorized under FAR §§ 12.301(b)(2) and 52.212-3 when acquiring commercial items.

In response to the protests, DSCP maintained that the EPA clause was unobjectionable because it was in fact consistent with the types of EPA clauses described in FAR § 16.203-1. Further, DSCP noted that it had received approval for a class deviation from the requirements of FAR § 16.203-1. Contracting Officer's Report (B-281681.6), Feb. 3, 1999, at 3-4. In addition, the agency contended that the limitation in FAR § 12.301(b)(2) on required representations and certifications when acquiring commercial items concerned only solicitation provisions, not contract clauses, and thus did not apply to the contract requirement challenged by Parke-Davis. FAR §§ 52.101(a), 52.212-3; Contracting Officer's Report (B-281681.6), Feb. 3, 1999, at 8-9.

As noted above, we will only recommend reimbursement of costs where the agency's corrective action was both unduly delayed and taken in response to a clearly meritorious protest. Baxter Healthcare Corp.--Entitlement to Costs, supra, at 4-5. Our Office did not resolve these additional protest grounds, and the agency has not conceded that its actions violated procurement statutes or regulations; in this regard, the mere fact that an agency has taken corrective action does not establish that a statute or regulation was violated. Spar Applied Sys.--Declaration of Entitlement, B-276030.2, Sept. 12, 1997, 97-2 CPD ¶ 70 at 5; Network Software Assocs., Inc.--Request for Declaration of Entitlement to Costs, B-250030.4, Jan. 15, 1993, 93-1 CPD ¶ 46 at 3. Regardless of whether our Office would have ultimately sustained or denied these protest grounds--a matter not for resolution in the context of a cost claim--we do not view the issues as clearly meritorious, and therefore do not recommend that costs be paid.

The requests are denied.

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of the United States