Comptroller General
of the United States

Washington, D.C. 20548

Decision

Matter of: Hoechst Marion Roussel, Inc.

File: B-279073

Date: May 4, 1998

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DIGEST

1. Solicitation for various dosages of a drug is improper where the solicitation fails to realistically state agency's estimated requirements for the various dosages; prohibits vendors from offering larger dosages of the drug, although agency concedes that doing so would lead to cost savings and agency has an identified need for the larger dosages; and the solicitation reflects an intent to modify the contract after award, on a sole-source basis without adequate justification, to add the larger dosages.

2. Agency properly may seek offers for different formulations of a drug under a single solicitation, and make a single award based on low price, where the agency determines that any of the available formulations will meet its requirements; agency's medical judgment regarding the relative efficacy of the different formulations is not appropriate for review within the context of a bid protest.

3. General Accounting Office will not consider protest that solicitation requirement violates Federal Healthcare Anti-Kickback Act, because the Act provides for obtaining advisory opinions on such matters from the Secretary of Health and Human Services, and those opinions are binding on the parties seeking the Secretary's opinion.

DECISION

Hoechst Marion Roussel, Inc. (HMR) protests the terms of request for proposals (RFP) No. M5-Q1-98, issued by the Department of Veterans Affairs (VA) for sustained action (administered once daily) Diltiazem, a calcium channel blocker used primarily in the treatment of hypertension. HMR argues that the RFP

improperly permits VA to make a post-award sole-source modification of the resulting contract to include dosage strengths and package sizes not subject to evaluation during the acquisition.[1] HMR also maintains that the RFP fails to provide for consideration of the competing products' relative efficacy in connection with the agency's technical evaluation, and improperly calls for the winning vendor to bear the cost of recalibrating VA's automatic drug dispensing equipment.

We sustain the protest.

The RFP contemplates the award of a single requirements-type contract for all of VA's requirement for Diltiazem for a base year and four 1-year options. This drug is currently available under multiple-award Federal Supply Schedule (FSS) contracts (the three potential competitors each have an FSS contract for Diltiazem). VA currently dispenses some 23 million doses of Diltiazem per year in varying strengths and, depending on the vendor, the product is commercially available in 120, 180, 240, 300 and 360 milligram (mg.) dosages. Pursuant to VA's national formulary program, the agency seeks to establish, through the current procurement, a single, nationwide supplier of Diltiazem to ensure the availability and consistency of the drug, and to take advantage of volume-based pricing.

For evaluation and award purposes, the RFP provides that price and past performance will be considered, with price more important. The contract line items are divided among several dosage strengths and package sizes (for example, 120 mg. dosages available in 30, 90 and either 1,000 or 5,000 dose packages), and the RFP provides that an aggregate price for each offer will be arrived at by adding the cumulative total of the proposed prices for all contract line items. The RFP further provides that some, but not all, of the commercially available dosage strengths will be evaluated for award purposes, specifically, that only 120, 180 and 240 mg. dosages will be evaluated. As for other available strengths, the RFP provides:

> If additional strengths are available, they should be included in the offer, however they will not be made part of the evaluation process. Any additional strength may be added after award by mutual agreement through negotiation between the contractor and Government. Furthermore, any commercially offered packaging sizes should be made available to the Government after award.

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[1]HMR's protest originally included several allegations relating to the way in which the agency was to evaluate different package sizes in arriving at the offerors' aggregate pricing for award purposes. In its report to our Office, VA explained that it had issued an amendment to clarify and correct this aspect of the RFP. HMR did not further pursue its contentions in its comments, and we deem those arguments abandoned. TMI Servs., Inc., B-276624.2, July 9, 1997, 97-2 CPD ¶ 24 at 4 n.3.

VA states that it has a known requirement for higher dosages (specifically 300 mg. and 360 mg. dosages), and will meet that requirement either through a single, large pill under the terms of the above provision (if the contractor manufactures larger pills), or with a combination of lower dosage pills (if the contractor manufactures only the three lower dosages). VA explains that it has limited the RFP to only the lower dosage strengths because these are common to all three of the prospective vendors, and maintains that this will foster broader competition, since only one firm manufactures the full range of dosage strengths (i.e., up to 360 mg.).

DOSAGE REQUIREMENTS

HMR alleges that the solicitation does not accurately reflect the agency's needs and that any modification under the provision quoted above will constitute an improper sole-source award to the successful contractor for dosage strengths that were not evaluated. For example, HMR has a 300 mg. dosage available, and the intervenor in this protest, Forest Pharmaceuticals, has 300 and 360 mg. dosages available. HMR maintains that, since the agency has a clearly-defined need for these larger dosages, it must state its requirement in the RFP and procure them competitively, rather than on a sole-source basis by means of the modification provision.

When issuing a solicitation for a requirements-type contract, agencies are required to include realistic estimates of the total quantities of goods or services being procured. Federal Acquisition Regulation § 16.503 (a)(1). Where a solicitation lacks realistic estimates, firms cannot prepare bids or offers that reflect the agency's actual, anticipated needs, and the agency cannot determine whether award to one firm versus another will result in the lowest possible cost to the government. Beldon Roofing & Remodeling Co., B-277651, Nov. 7, 1997, 97-2 CPD ¶ 131 at 7.

Here, the record shows that VA has a known requirement for approximately 1.7 million 300 mg. strength dosages, and 33,000 dosages at the 360 mg. strength. These estimates are based on historical data showing the dosages prescribed during the preceding year for outpatient use, and VA does not contest that this represents a realistic estimate of its requirement for these higher strengths. Rather than include estimates for these dosage requirements and allow offerors alternatives to meeting the requirements (e.g., offer combinations of 120 mg. and 180 mg. dosages to meet the 300 mg. requirement, or offer a 300 mg. dosage if available), the agency increased the estimated quantity for 180 mg. dosages by 3.4 million dosages to cover needed 300 mg. dosages. Moreover, by accounting for the requirement for 300 mg. dosages in terms of 180 mg. dosages, the RFP's quantity estimates overstate the agency's actual requirement for 180 mg. dosages by approximately 566,000

dosages.[2] Because of this unrealistic estimate, offerors will be proposing to supply dosages that the agency may not order.

The agency argues that its approach maximizes competition and will ensure that VA obtains the lowest prices. The record, however, does not support the agency's position. Under the Competition in Contracting Act, solicitations shall "include restrictive provisions or conditions only to the extent necessary to satisfy the needs of the executive agency or as authorized by law." 41 U.S.C. § 253a(a)(2) (1994). Rather than increasing competition, the agency's approach of allowing offerors to propose only smaller dosage pills constitutes a restrictive provision that appears to lack any basis in the agency's needs. The solicitation precludes firms such as the protester from proposing larger dosage pills to satisfy the need, whose existence the agency concedes, for larger dosages.

Moreover, there is no basis to believe that this restriction will ensure that VA obtains the lowest prices. Indeed, VA concedes that prescribing single 300 and 360 mg. dosage pills might be more cost effective than prescribing smaller dosage pills in combination. For example, the protester's FSS price for its large dosage pill is lower than the price for a combination of its smaller dosage pills. Allowing offerors to propose only small dosage pills may mean that manufacturers of the larger dosage pills, such as the protester, are precluded from offering their lowest possible price in the course of the competition, and the contract thus may be awarded at other than the lowest possible cost to the government. Including the larger dosages in the evaluation would not prevent any firm from competing--indeed, competition could be increased, if firms are allowed to offer either a single pill or a combination of pills to meet the larger dosages--and including the larger dosage pills in the evaluation may result in a cost saving to the agency. Since the reasons offered by the agency for not allowing offerors to propose larger dosage pills do not demonstrate that this restriction is necessary to satisfy the needs of the agency, we conclude that the restriction is improper.

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[2]The agency increased the estimate of 180 mg. dosages by 3.4 million to account for its requirement of 1.7 million 300 mg. dosages. This, however, overstates the agency's need by 60 mg. per 300 mg. dosage (180 x 2 = 360, rather than 300). On the other hand, the agency represents in its legal memorandum that, where a 300 mg. dosage is required, it could prescribe a combination of one 120 mg. pill and one 180 mg. It follows that the agency will either be prescribing 360 mg. where only 300 are required (if two 180 mg. pills are prescribed), or that the RFP in fact inaccurately overstates VA's requirement for 180 mg. dosages by 566,666 pills (1,700,000 x 60 mg. / 180 mg. = 566,666) (if one 180 mg. and one 120 mg. pill are prescribed). If the latter is the case, the RFP understates the agency's requirement for 120 mg. pills.

Our conclusion in this regard is reinforced by the RFP provision allowing for a post-award contract modification in the event that the awardee manufactures higher strength dosages. This provision demonstrates that the agency already anticipates a need for the larger dosage pills, and thus lacks any basis for precluding offerors from proposing prices for those pills. The agency's recognition of the need for the larger pills establishes another defect in the agency's procurement strategy, as set out in the solicitation: the agency apparently intends to modify the contract after award to add items (the larger dosage pills) that were not subject to the competition originally obtained. An agency may not properly competitively award a contract with the intention of materially modifying it after award; such a modification would be tantamount to an improper sole-source award. Falcon Carriers, Inc., B-232562.2, Jan. 30, 1989, 89-1 CPD ¶ 96 at 4.

In sum, we conclude that the dosage requirements provisions of the RFP do not realistically state the agency's requirements, impose a restriction not necessary to satisfy the agency's needs, and reflect the intent to modify the contract on a sole-source basis after award.

DIFFERENCES IN EFFICACY

HMR contends that the RFP's evaluation scheme fails to provide for an assessment of the differences in the efficacy among the three prospective offerors' products. According to the protester, the three drugs have important medical differences arising from the fact that each firm formulates its product differently. HMR contends, for example, that there are differences in the absorption rate of the three products, and that there is a so-called "food effect" that changes the absorption rate of one of the products. HMR argues that the evaluation scheme should take these clinical differences into account, and that the agency has not produced a medical study or other adequate medical evidence to show that its conclusion regarding the therapeutic equivalence of the three drugs is reasonable. In support of its position, HMR has submitted a forthcoming study that it maintains shows that there are potential clinical differences in the offerors' products.

Where an agency has deliberated and reached a considered judgment concerning a medical policy, we do not believe that policy or judgment is appropriate for review under our bid protest function. Pfizer, Inc., B-277733, Oct. 27, 1997, 97-2 CPD ¶ 119 at 2-3. This includes the need for, and accuracy of, evidence supporting the agency's medical judgments. Id. at 3 n.3. The record shows that VA's Pharmacy Benefits Management and Medical Advisory Panel (MAP) reviewed the three drugs in question to determine whether any one of the three manufacturers could be selected as VA's primary formulary for Diltiazem. The MAP concluded that the sustained action Diltiazem products available were therapeutically equivalent for contracting purposes. The record also contains affidavits executed by two doctors who participated in the MAP review. The first agrees with the MAP's conclusion that any one of the three available drugs could be placed on the national formulary,

and that the difference between them lies solely in the release mechanism employed. The second doctor states that the differences between the three drugs are not clinically significant, and will not induce important side effects. The record thus shows that VA considered the therapeutic comparability of the three drugs, concluded that any one of the three would be satisfactory for the agency's purposes and found that, while there were differences in the three products, none was significant for the agency's purposes. While the protester disagrees with the agency's conclusion, we will not review the agency's considered medical judgment.

FEDERAL HEALTHCARE ANTI-KICKBACK ACT

The RFP calls for the contractor to bear the cost of recalibrating VA's automatic pill dispensing equipment. (The equipment must be recalibrated to accommodate each manufacturer's unique pill size and shape.) HMR contends that this requirement violates the Federal Healthcare Anti-Kickback Act, 42 U.S.C.A. § 1320a-7b(b) (West Supp. 1998). According to HMR, payment of the cost of recalibrating the machines could constitute a prohibited remuneration under the terms of the Act.

The statutory and regulatory scheme at issue provides for the Secretary of Health and Human Services (HHS) to issue advisory opinions regarding whether a given arrangement constitutes a violation of the Act's substantive provisions, and those advisory opinions are binding on the Secretary and the parties requesting the opinion. 42 U.S.C.A. § 1320a-7d(b)(4)(A). Detailed regulatory procedures exist for requesting and obtaining such advisory opinions, 42 C.F.R. pt. 1008 (1997), and determinations regarding what constitutes "prohibited remuneration" are specifically among the matters subject to the Secretary's review. 42 U.S.C.A. § 1320a-7d(b)(2)(A); 42 C.F.R. § 1008.5(a)(1).

Congress envisioned the Secretary of HHS as the government's centralized source for information and guidance concerning application of the Act's fraud provisions:

> Providers want to comply with the fraud and abuse statute, but many are unsure of how the statute affects them. These providers should be able to receive guidance from the government regarding financial arrangements. Little or no guidance is currently provided because there are no regulations and only insufficient safe harbors.
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> The Secretary shall issue written advisory opinions regarding (i) what constitutes prohibited remuneration . . . . Advisory opinions shall be binding as to the Secretary and the party requesting the opinion.

H.R. Rep. No. 104-496, at 84-85 (1996), reprinted in 1996 U.S.C.C.A.N. 1884-85.

Where, as here, Congress has vested oversight and guidance authority in a particular federal official or agency, our Office will not consider protests involving issues which are properly for review by that official or agency, especially where the determinations of the federal official or agency are binding on the parties. Mississippi State Dep't of Rehabilitation Servs., B-250783.8, Sept. 7, 1994, 94-2 CPD ¶ 99 at 3-4. Given the comprehensive nature of the regulatory and statutory scheme that exists for obtaining advisory opinions regarding application of the Act, and in light of the binding nature of the Secretary's opinions, we decline to consider this aspect of HMR's protest. This is a matter that the protester instead should address to the Secretary, through the procedures outlined in the governing regulations.

RECOMMENDATION

In view of the foregoing, we recommend that the agency amend the RFP to state VA's estimated requirements for all dosages, rather than permitting offerors to propose only the three smaller dosages. As indicated above, the agency may, if consistent with its needs, allow offerors to satisfy the requirements for larger dosages by offering either single large dosage pills or multiple small dosage ones. We also recommend that HMR be reimbursed the cost of filing and pursuing its protest, including reasonable attorneys' fees. 4 C.F.R. § 21.8(d)(1) (1997). The protester should submit to the agency its certified claim for those costs, detailing the time spent and the expenses incurred, within 60 days of receiving this decision. 4 C.F.R. § 21.8(f)(1).

The protest is sustained.

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