Comptroller General
of the United States

Washington, D.C. 20548

Decision

Matter of: Pfizer, Incorporated

File: B-276362

Date: June 6, 1997

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DIGEST

In solicitation for blanket purchase agreement under Federal Supply Schedule contracts, agency decision to use only price and price-related evaluation factors is unobjectionable where, prior to issuance of solicitation, agency reasonably determines that competing drugs are essentially technically equal.

DECISION

Pfizer, Incorporated protests the evaluation criteria in a request for quotation (RFQ) for a blanket purchase agreement (BPA) issued by the Department of Veterans Affairs (VA) for a drug class referred to as long-acting alpha blockers. The solicitation was issued with evaluation criteria consisting only of price factors.[1] Pfizer argues that the agency should have included technical criteria to take into consideration certain allegedly meaningful differences in the competing drugs.

We deny the protest.

BACKGROUND

This RFQ was issued as part of a broader program underway at VA to standardize pharmaceuticals and medical/surgical items in order to achieve concentrated buying power. Since the Veterans Health Administration (VHA) expends approximately $1 billion on pharmaceuticals each year, the VA seeks to accomplish its "greater

[1]The solicitation was originally issued as a request for proposals and contained a section entitled "technical evaluation," which listed only price and price-related evaluation factors. In response to Pfizer's protest, the VA amended the solicitation to make it an RFP, to entitle it a "blanket purchase agreement quote," and to delete the reference to a technical evaluation.

goals of quality care, access, customer service and cost efficiency" by creating "national formularies" for various drugs.[2] In order to facilitate these goals, the VHA created a Pharmacy Benefits Management (PBM) section which, among other tasks, assists in the effort to create a national formulary. To assist the PBM, a 10-member medical advisory panel (MAP) was created. The MAP is composed of practicing VA physicians from various disciplines who serve 2-year terms. The pharmacologic treatment guidelines developed by the MAP provide guidance for standardized research-based care across the VA.

THE SOLICITATION

The long-acting alpha blockers which are the subject of this solicitation are used in the treatment of hypertension (HTN) and benign prostatic hyperplasia (BPH). There are only two manufacturers of these drugs: Pfizer, which manufactures doxazosin, and Abbott Laboratories, which manufactures terazosin; both companies have Federal Supply Schedule (FSS) contracts that encompass the drugs.

The RFQ was issued pursuant to Federal Acquisition Regulation § 13.202(c)(3) and a clause in the companies' FSS contracts in which they agree to enter into BPAs. See Intelligent Decisions, Inc., B-274626, B-274626.2, Dec. 23, 1996, 97-1 CPD ¶ 19 at 5, recon. denied, B-274626.3, May 15, 1997, 97-1 CPD ¶ ___. The RFQ, as originally issued, identified the VA's estimated volume in various doses of the drug.[3] The RFQ provided that, in exchange for lower drug prices than those provided in the FSS contracts, the VA would give the selected drug national formulary status. The firm receiving the BPA would be required to provide, at no additional cost, standard starter kits to facilitate conversion (switching) from the patient's current medication to the chosen one. The BPA was to last from award to the end of December 1997.

The solicitation provided that a BPA would be issued to the offeror meeting the RFQ's requirements, whose quote was most advantageous to the government and represented the best overall expected value. The VA reserved the right to cancel the RFQ if the overall advantage of the quotations received was minimal and provided no significant cost savings (i.e., relative to the extant FSS prices). The cost of switching was to be used in determining overall value only where there was

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[2]The term "national formulary" refers to the VA's selection of a limited number of common drug items for unrestricted use by any prescriber. The selection of drugs for the national formulary is designed to standardize the VA's care for patients throughout its national network of medical care facilities and to reduce costs.

[3]While Pfizer and Abbott both make 1 and 2 milligram (mg) doses, their larger doses differ. For example, Pfizer makes 4 and 8 mg doses while Abbott makes 5 and 10 mg doses. The revised solicitation provided separate blanks for the pricing of each manufacturer's individual doses.

merely a nominal pricing advantage of one quote over the other. Price was to be evaluated on the basis of a proposed aggregate price for all line items with additional consideration for scored tablets.[4] No other evaluation criteria were set forth.

Prior to the closing date, Pfizer submitted an offer and protested the terms of the solicitation, primarily arguing that the evaluation criteria were flawed. Since various alpha blockers are not identical, Pfizer presumed that the VA intended to consider the differences in a technical evaluation but had improperly failed to disclose in the solicitation how it intended to evaluate them. As noted above, after receiving the protest, the VA issued a revised version of the solicitation to make plain that it was an RFQ under which price was the only evaluation criterion. The VA also clarified the format for making price quotes and provided an example of how it would evaluate scored tablets. The revision set a new deadline for quotes. After receipt of the revised RFQ, Pfizer advised the VA that its original submission would remain unchanged.

DISCUSSION

Since the VA has made clear that price is the sole evaluation criterion, Pfizer's protest now focuses on differences between doxazosin and terazosin which it believes the agency should take into consideration in the evaluation. First, Pfizer notes that its drug has a longer "half-life" in the patient's body, allowing for uniform once-daily dosing, while Abbott's drug "is often" administered twice daily. Second, the initial dose of Pfizer's drug can be administered in the morning or evening, while it is recommended that the initial dose of Abbott's drug be taken at bedtime. Third, Pfizer believes that its current 70-percent market share will translate into relatively higher switching costs if Abbott's product is selected. Fourth, Pfizer's starter/titration packs (used to switch a patient from one drug to another) contain 5 weeks of medication, while Abbott's contain only 3 weeks, allegedly making Pfizer's packs more economical.

The determination of an agency's minimum needs and the best method of accommodating them is primarily within the agency's discretion. Premiere Vending, B-256437, June 23, 1994, 94-1 CPD ¶ 380 at 7. Agencies enjoy broad discretion in the selection of evaluation factors, and we will not object to the use of particular evaluation factors so long as the criteria used reasonably relate to the agency's needs. Id.

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[4]Scored tablets could be broken to provide multiple doses from a single tablet. The RFQ provided the estimated percentage usage of scored tablets and advised that only a small segment of the VA population used scored tablets.

The agency's Formulary Committee met in May 1996 to study a national formulary for alpha blockers. They reviewed three available drugs, including doxazosin and terazosin, and the conditions that these drugs could effectively treat (HTN and BPH).[5] The committee reviewed pharmacology, pharmacokinetics, precautions, toxicity, cost, and other issues related to the drugs. The committee study included a review of more than 20 articles and reports on the drugs' uses, effectiveness, and side effects. Some of these articles reported tests which directly compared doxazosin and terazosin and found them comparably, if not equally, effective and well tolerated in the treatment of HTN and BPH. The committee noted that either doxazosin or terazosin could be chosen as the only long-acting alpha blocker on the formulary.

In making its recommendations, the MAP reviewed the committee's report. The MAP looked at efficacy, safety/administration, pharmacy factors, and cost. As to efficacy, they found that both doxazosin and terazosin were effective for the management of HTN and BPH. As to safety/administration they noted that the first-dose side-effect could be reduced by initiating therapy with the lowest possible dose. They also noted that, while the pharmacokinetic profiles of the drugs differed, both were generally well tolerated by patients. The MAP found that both doxazosin and terazosin had long elimination half-lives, making once-daily dosing possible to enhance patient compliance. Since the MAP found doxazosin and terazosin equally efficacious and well tolerated, it recommended that cost be the basis for deciding which of the two drugs should be included on the national formulary.

We have reviewed the evaluations of the committee and the MAP, and it is clear that they are consistent with the product and test reports on which they were based. While the drug formulations solicited are not identical, the record makes clear that, after a detailed examination of product and test reports, the VA reasonably determined that the drugs are essentially equal for treatment of HTN and BPH. Under these circumstances, the agency determination that price should be the determinative factor is unobjectionable, and this determination obviated the need for inclusion of any technical factors in the evaluation scheme.

Pfizer also expresses concern over the manner in which the agency planned to evaluate switching costs and cost savings due to use of scored tablets. The record

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[5]The third drug, prazosin, is also manufactured by Pfizer. While effective in treating both HTN and BPH, it is approved by the Food and Drug Administration only for treatment of HTN. Prazosin is widely available in generic formulations, making it much less expensive than doxazosin and terazosin. Accordingly, prior to the issuance of this RFQ, the agency approved placement of prazosin on the national formulary. The BPA solicited here is for long-acting alpha blockers, a category that does not include prazosin.

reflects that the committee and the MAP observed that doxazosin appeared slightly more expensive than terazosin, but was available in scored tablets. However, they recognized that the patient's ability to split the tablets would have to be assessed to make this a cost savings issue. The committee and the MAP also recognized that the issue of switching costs needed to be taken into consideration since there was no literature to which to refer for recommendations on dosing conversions.[6]

The RFQ incorporated both of these recommendations. With regard to switching costs, the RFQ required that the firm holding the BPA furnish starter kits at no cost to the VA and provided for further evaluation of switching costs as a tie-breaker if the overall pricing advantage of one quote over the other was minimal.[7] The evaluation scheme also provided for evaluation of scored tablets. Since Pfizer's concerns were addressed by the agency in the MAP's review and in the evaluation scheme itself, we see no basis to conclude that the RFQ was flawed.

Pfizer next argues that the MAP's conclusions were questionable because its members did not include a urologist. Here, the MAP included nine doctors of medicine, all from different VA Medical Centers around the United States, who were specialists in internal medicine, neurology, psychiatry, pharmacology, geriatrics, nephrology, and emergency care. In view of the MAP's responsibilities to review drugs for treatment of various conditions, the absence of a urologist provides no basis to conclude that the MAP was unqualified. Moreover, the record reflects that the review regarding BPH was sent to the Chief of Urology for comment, and there is no evidence that the Chief had any disagreement with the MAP's conclusions or recommendations.

Pfizer also argues that the VA's intention to select a single alpha blocker for the national formulary violates its mission to "provide complete medical and hospital

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[6]Part of this lack of information appears to be due to adverse effects associated with the body's adjustment to the first dose of either drug. To alleviate this effect, initial doses of the drugs and switching are accomplished by starting the patient on the lowest possible dose of the new drug and "titrating" the doses upward until the optimal level is reached.

[7]The agency states that it could not quantify the actual costs of switching, but it believed that the savings through a BPA discount would outweigh those costs. Pfizer argues that this inability to quantify the value casts doubt on the evaluation scheme. However, Pfizer has submitted no evidence suggesting what this cost would be or how it could be quantified. Since it appears that the bulk of the switching costs would involve the cost of starter kits, which the firm receiving the BPA must provide at no charge to the VA, the VA reasonably decided to address switching costs only if the overall price difference between the quotes received was minimal.

service for the medical care and treatment of veterans." In Pfizer's view, the formulary should include sufficient variety to ensure that doctors can fully exercise their medical judgment. In this regard, Pfizer notes that the VA's Directive 10-95-065 states, as a matter of policy, that the process of standardizing medical supplies in VA did "not necessarily mean that VA would, or should, limit choice to a single product from a single source."

Pfizer's reliance on this statement in Directive 10-95-065 is misplaced. The Directive provides that "[w]here practicable, standardization will result in a single award contract for quality products." The Directive also gives the VA's National Acquisition Center (NAC), which issued the BPA solicitation, the responsibility to participate in product definition teams which would "determine whether it is in VA's best interest to award a single source contract or whether the degree of flexibility needed requires multiple similar products and/or suppliers." If flexibility were needed, the group would specify the types of different features required and recommend an optimum number of suppliers. Here, the NAC reviewed the findings of the committee and the MAP in preparing the solicitation. As discussed above, the MAP performed a detailed review of the alpha blockers doxazosin and terazosin and concluded that the two drugs were equally effective for the treatment of HTN and BPH and reasonably concluded that price factors should be the only discriminators for selecting the national formulary. The MAP's determination to utilize a single drug award reflects medical policies and judgments of the VA, an executive agency, the review of which is inappropriate for consideration under our bid protest function. Bristol-Myers Squibb Co., B-275277, Feb. 5, 1997, 97-1 CPD ¶ 60 at 9-10; IVAC Corp., 67 Comp. Gen. 531, 534 (1988), 88-2 CPD ¶ 75 at 4; Travenol Labs., Inc., B-215739; B-216961, Jan. 29, 1985, 85-1 CPD ¶ 114 at 3.

We further note that the VA explains that, where use of a drug which is not on the national formulary is required, there are procedures whereby the prescribing physician can obtain the appropriate medication. Since the award of the BPA will have no effect on existing FSS contracts, VA physicians can still order these medications.[8] Further the availability of another alpha blocker, prazosin, approved for treatment of HTN (but not BPH), will be unaffected by this BPA.

Finally, Pfizer contends, for the first time in its comments, that the issuance of a BPA at this time is irrational because the national formulary choice under the BPA will only be in effect until December 1997, at which time a new BPA may be competed, creating the potential for another medication switch. The duration of

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[8]Pfizer has also noted that Abbott's use of gelatin capsules for its drug may present religious dietary problems for some Jewish and Islamic veterans, a matter which is not addressed by the MAP or the RFQ. To the extent this presents a problem, it can be resolved by the ability of VA physicians to order drugs which are not on the national formulary.

this BPA was apparent on the face of the RFQ, making any challenge to it a matter concerning an alleged solicitation impropriety. Thus, Pfizer was required to file its protest on this ground prior to the closing time for receipt of proposals. Bid Protest Regulations, 4 C.F.R. § 21.2(a)(1) (1997). Here the initial closing date was March 3 and the revised closing date was April 4. Since Pfizer did not raise this issue until it filed its April 10 comments, the issue is untimely and not for consideration. Moreover, as with the single-award issue discussed above, this issue is a matter within the VA's exercise of its medical policies and judgments which we will not consider. Bristol-Myers Squibb Co., supra.

The protest is denied.

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