GAO

Comptroller General
of the United States

United States General Accounting Office
Washington, DC 20548

Decision

Matter of: SmithKline Beecham Corporation

File: B-283939

Date: January 27, 2000

John E. Daniel, Esq., Morgan, Lewis & Bockius, for the protester.
Thomas L. McGovern III, Esq., and Joy E. Sturm, Esq., Hogan & Hartson, for Glaxo Wellcome Inc.; and David C. Hammond, Esq., Powell, Goldstein, Frazer & Murphy, for Hoechst Marion Roussel, the intervenors.
Barbara J. Stuetzer, Esq., and Phillipa L. Anderson, Esq., Department of Veterans Affairs, for the agency.
Ralph O. White, Esq., and Christine S. Melody, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

DIGEST

Protester's challenge to the price evaluation scheme included in a solicitation for prescription drugs that anticipates evaluation of a per-dose price based on the only use for which all three of the competing drugs are approved by the Food and Drug Administration is denied, even though the evaluation does not consider certain uses of the solicited drugs that will have a different cost profile, where the per-dose price requested provides a common basis for evaluating prices, the agency has no basis for providing estimates for the other uses of these drugs, and the protester has not established that the solicitation's approach will produce a materially misleading result.

DECISION

SmithKline Beecham Corporation (SKB) protests the terms of request for proposals (RFP) No. RFP-797-NC-99-0020, issued by the Department of Veterans Affairs (VA) for 5-Hydroxtryptamine (5HT3) receptor antagonists, used for the treatment of nausea and vomiting (emesis) resulting from chemotherapy. SKB argues that the RFP's price evaluation methodology will not identify the proposal that will provide the actual lowest price to the government.

We deny the protest.

This procurement is part of the VA's program to standardize the availability of pharmaceuticals and medical/surgical items, through the use of its national formulary. A formulary is a list of prescription drugs, grouped by therapeutic class, that a health care organization prefers that its physicians prescribe. Drugs are chosen for a formulary on the basis of their medical value and price. Defense Health Care: Fully Integrated Pharmacy System Would Improve Service and Cost-Effectiveness, (GAO/HEHS-98-176, June 12, 1998) at 2 n.1. In addition to standardizing drug availability, the VA is using its national formulary to increase the continuity of VA care, standardize the processes for evaluating the safety and efficacy of drugs, and manage cost growth. VA Health Care: VA's Management of Drugs on its National Formulary, (GAO/HEHS-00-34, Dec. 14, 1999) at 4.

Prior to issuing this solicitation, the VA's Pharmacy Benefits Management (PBM) section, together with its Medical Advisory Panel (MAP), conducted a drug class review of the three known 5HT3 receptor antagonists,[1] which are: Dolasetron, manufactured by Hoechst Marion Roussel, Inc., and marketed under the name Anzemet®; Granisetron, manufactured by SKB, and marketed under the name Kytril®; and Ondansetron, manufactured by Glaxo Wellcome, Inc., and marketed under the name of Zofron®. The review concluded that the three drugs were equally efficacious in managing CINV and PONV; that they presented similar, and acceptable, levels of side effects; and that a single 5HT3 drug should be selected for the national formulary based on cost. Agency Report (AR), Tab 7, Drug Class Review, Oct. 1999, at 13.

The RFP, issued on July 21, 1999, sought fixed-price proposals to provide an indefinite quantity of the three 5HT3 receptor antagonists, and advised that award would be made to the offeror whose proposal was deemed most advantageous to the government considering price and past performance. RFP amend. 0003, at 2, 5. Of these two factors, offerors were advised that price would be more important than past performance, and that the agency's objective was to award to the offeror with the lowest per-dose price (PDP). Id. at 5.

To perform its PDP comparison of the three drugs, the RFP established an oral dosing level for each drug, as set forth below:

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[1] The VA's drug class review for the 5HT3 drugs analyzed efficacy of the drugs in the prevention and treatment of postoperative nausea and vomiting (PONV), the prevention of radiotherapy-induced nausea and vomiting (RINV), and the prevention of highly and moderately emetogenic chemotherapy-induced nausea and vomiting (CINV). AR, Tab 7, Drug Class Review, Oct. 1999, at 2. The protester's arguments focus on differences in the drugs in combating highly and moderately emetogenic CINV.

PRODUCT	STRENGTH	PATIENT DOSAGE	NO. OF TABLETS
Dolasetron	100 mg	100 mg	1
Granisetron	1 mg	2 mg	2
Ondansetron	8 mg	16 mg	2

RFP amend. 0003, at 2. The VA explains that it selected these dosing levels for its price evaluation because they are the FDA-approved dosing levels for these three drugs when treating patients with moderate CINV, and because the treatment of moderate CINV is the only condition for which there are FDA-approved dosing levels for the oral version of all three drugs.[2] AR, Legal Memorandum, Nov. 18, 1999, at 5; see also AR, Tab 7, Drug Class Review, Oct. 1999, at 2. Thus, put simply, the PDP will be based on the price for 1 tablet of Dolasetron, and 2 tablets each of Granisetron and Ondansetron.

SKB protests that the solicitation's price evaluation scheme is defective because it does not give reasonable assurances that an award to the offeror with the lowest evaluated price will result in the lowest cost to the government during actual performance. This argument is based on the premise that some portion of the VA population will need treatment for high CINV, rather than moderate CINV, and that the treatment of patients with high CINV using these drugs will have a relative cost different from the relative cost of the dosages used to treat moderate CINV.

The key to SKB's argument is the fact that the same dosage level (2 mg) of SKB's product, Granisetron, is approved by the FDA for the treatment of high and moderate CINV. In contrast, Ondansetron has been approved for the treatment of high CINV at a 24 mg dose; and there is no FDA-approved oral dose of Dolasetron for the treatment of high CINV. AR, Tab 7, Drug Class Review, Oct. 1999, at 11-12. To illustrate the potential difference in pricing, the table below includes: (1) the currently published Federal Supply Schedule (FSS) prices for each of the three 5HT3 drugs; (2) the dosage levels (and resulting FSS prices) for treating moderate CINV; and (3) the dosage levels (and prices) for treating high CINV.

[2] As discussed further below, only two of the drugs, Granisetron and Ondansetron, have FDA-approved dosing levels for treating patients with high CINV.

PRODUCT	FSS PRICE	MOD. CINV DOSE/PRICE	HIGH CINV DOSE/PRICE
Dolasetron	$33.83 per 100 mg tablet	1 tablet/$33.83	--[3]
Granisetron	$21.80 per 1 mg tablet	2 tablets/$43.60	2 tablets/$43.60
Ondansetron	$17.00 per 8 mg tablet	2 tablets/$34.00	3 tablets/$51.00

Id.; SKB's Comments, Dec. 3, 1999, at 5 n.5. Thus, as shown above, SKB's Granisetron is the most expensive of the 5HT3 drugs (using current FSS prices) for treating moderate CINV, and the least expensive for treating high CINV. This is the basis for SKB's argument that considering only the dosing levels for moderate CINV will not provide the lowest cost to the government in actuality.

The VA defends its price evaluation scheme as a reasonable attempt to objectively compare the price of these three drugs. As explained above, the VA notes that the treatment of moderate CINV is the only situation where there are FDA-approved oral dosage levels for all three drugs. It argues that if it attempted to calculate a PDP for treatment of high CINV, it would need to extrapolate an oral dosage level for Dolasetron, which would lead to further disputes. The VA also explains that while it can provide the offerors with the number of tablets of each drug used in prior years, it does not have historical data on, or a prospective estimate of, the portion of its patient population receiving chemotherapy who present high CINV versus moderate CINV. Finally, the VA explains that the protester's approach to focusing only on the distinction between high and moderate CINV is overly simplistic because the treatment of high CINV often involves combining a moderate dose of one of the 5HTC drugs together with other antiemetic agents.[4]

The Competition in Contracting Act requires that agencies consider the cost to the government in evaluating competitive proposals. 41 U.S.C. § 253a(b)(1)(A), (c)(1)(B) (1994); Health Servs. Int'l, Inc.; Apex Envtl., Inc., B-247433, B-247433.2, June 5, 1992, 92-1 CPD ¶ 493 at 3-4. While it is up to the agency to decide upon an appropriate and reasonable method for proposal evaluation, it may not use an

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[3] While there is not yet an FDA-approved dosage of oral Dolasetron for the treatment of high CINV, the protester points out that the American Society of Health-System Pharmacists Therapeutic Guidelines (included in the agency's report) state that "a dose of 200 mg [of Dolasetron] may be required in patients receiving highly emetogenic chemotherapy." AR, Tab 21, at 742. Using this guidance, the price for using Dolasetron to treat high CINV would be $67.66 per dose.

[4] Moving beyond the protester's focus on differences in the dosage levels of these drugs to treat moderate and high levels of CINV, we note that there are other uses of these drugs--such as the prevention of PONV and RINV--that are also not captured by the PDP comparison set forth in the solicitation.

evaluation method that produces a misleading result. Id. at 4. Such method must include some reasonable basis for evaluating or comparing the relative costs of proposals, so as to establish whether one offeror's proposal would be more or less costly than another's. See Health Servs. Int'l, Inc.; Apex Envtl., Inc., supra; Penn, Ferrara, Adler & Eichel, B-224224, Feb. 9, 1987, 87-1 CPD ¶ 134 at 3-4.

As a preliminary matter, we note that SKB's premise that some portion of the VA patient population will need treatment for high CINV, rather than moderate CINV, is unassailable. We also note that the VA's price evaluation, by definition, does not consider the dosing levels required to treat high CINV. In addition, we agree that the current FSS prices for these three drugs suggest that award to the offeror whose PDP presents the lowest cost for the treatment of moderate CINV may not, in every instance, result in the lowest cost to the government during actual performance, depending on how many VA patients require treatment for high CINV. The question for our Office is not, however, whether the VA's approach to evaluating prices is perfect, but whether, despite any limitations, it is reasonable under the circumstances here. For the reasons set forth below, we conclude that it is.

SKB argues that, as a legal matter, the VA's approach to evaluating prices here is analogous to the solicitation we reviewed in Globe Air, Inc., B-188611, June 6, 1977, 77-1 CPD ¶ 395, wherein we sustained a protester's challenge to an agency's approach to evaluating bids for helicopter services on the basis that the solicitation violated the statutory mandate to consider the cost of performance in making a contract award. In sustaining that protest, we noted that the price evaluation considered only one function (and the associated costs) of the helicopter services that, upon review, represented only 25 percent of the helicopter time required by the agency. Globe Air, Inc., supra, at 4. The record showed that for the remaining 75 percent of the helicopter time required by the agency, a different set of costs would apply, and also showed that a different offeror would likely prevail if those costs were considered. Id. at 5.

In our view, Globe Air is distinguishable from the facts presented here. In Globe Air, the agency had data showing that its price evaluation methodology accounted for only 25 percent of the helicopter time required. Thus, the methodology failed to consider the costs for the remaining 75 percent of the time, and did not provide an accurate determination of the lowest overall cost to the government. Here, the VA explains that while it has data on the quantity of 5HT3 drugs it has used in the past, it has no data on the portion of its patient population that will need treatment for high CINV versus moderate CINV. In this situation, the VA contends that its solicitation provides a reasonable and objective basis for comparing the costs of these drugs, while also providing information about the amount of drugs that will be needed.

We agree. Under the circumstances here, we think the more appropriate analogy is to our decision in Aalco Forwarding, Inc., et al., B-277241.15, Mar. 11, 1998, 98-1 CPD ¶ 87. There, in a procurement for moving services where the agency had no historical data regarding the need for different accessorial services associated with

international moves, the solicitation set forth a notional shipment, similar to a sample task, for which each offeror was asked to submit a price. The decision there held that where estimates for various types of required services are not reasonably available, an agency may establish a reasonable hypothetical, consistent with the RFP requirements, to provide a common basis for comparing the relative costs of the proposals.[5] Aalco Forwarding, Inc., et al., supra, at 11.

In addition to our view that the agency's approach appears reasonable given the limited information available to it, we also note that the protester has offered little evidence that it will be harmed by the solicitation's approach to evaluating prices. First, while we have no way of knowing what percentage of the VA patient population will need treatment for high CINV, the only evidence in the record suggests that it is a relatively small percentage of the VA patients receiving chemotherapy. Specifically, one of the intervenors, Glaxo Wellcome, submitted evidence with its comments which suggests that only 10 percent or less of the VA patient population receiving chemotherapy will need treatment for high CINV. Glaxo Wellcome Comments, Dec. 3, 1999, exh. 4. In contrast, SKB's comments included a table showing the cost per 100 VA patients (using FSS prices) with different percentages of patients needing treatment for moderate and high CINV. SKB Comments, Dec. 3, 1999, at 5. This table shows that even if the patient mix is 50-50 moderate/high CINV, SKB's drug would not be the lowest-priced option for treating the VA patient population. Instead, SKB's own materials do not show SKB to be the offeror with the lowest price until 75 percent of the patient population needs treatment for high CINV.[6]

Finally, we note that the national formulary is a listing of drugs, not a set of guidelines for their use. The drug that prevails in this competition will be listed on the formulary for VA physicians and pharmacies dispensing a 5HT3 receptor

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[5] An issue in Aalco that is not present here was a contention that the composition of the agency's so-called "notional shipment" was unreasonable. Here, the protester does not dispute the solicitation's dosage levels for the treatment of moderate CINV. SKB's Comments, Dec. 3, 1999, at 3 n.1.

[6] To be fair to SKB, we note that it offered these figures to demonstrate its point that the VA's price evaluation methodology could result, under some circumstances, in award to an offeror whose approach might actually yield a higher overall cost to the government. SKB points out, and we agree, that there is no reason to conclude that the prices received in response to this solicitation will be the same as the currently available FSS prices. On the other hand, these materials suggest that without a dramatic shift in the relative prices of these drugs, SKB will not be harmed by the VA's price evaluation scheme unless a sizable percentage of the VA patients receiving chemotherapy--probably more than a majority--need treatment for high CINV.

antagonist. How the drug is prescribed, how it is dosed, and which drug is prescribed for which indication, remains within the medical judgment of the VA's treating physician. This is not a requirements contract; the two other 5HT3 drugs will remain on the FSS, and will continue to be available to VA physicians if the contracted item is not the appropriate drug treatment therapy. Further, the record here shows that simply increasing the dosage of a 5HT3 drug--which is the foundation of SKB's argument that the solicitation's PDP evaluation method may not yield the lowest price in practice--may not be the most desirable medical approach to treating high CINV. These facts, unrebutted during this protest, further dilute the possibility that the VA's price evaluation method will fail to reflect the most likely actual cost to the government of using these drugs.

Accordingly, without some reason to conclude that the agency's approach will lead to an unreasonable evaluation of the likely cost to the government, and given the fact that the VA lacks data on the percentage of its patients that will need treatment for high, versus moderate, CINV, we have no basis to conclude that the solicitation's intended approach to evaluating prices is improper.

The protest is denied.

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of the United States