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Comptroller General
of the United States

United States Government Accountability Office
Washington, DC 20548

Decision

Matter of: Merck & Company, Inc.

File: B-295888

Date: May 13, 2005

Deneen J. Melander, Esq., and Steven A. Alerding, Esq., Fried, Frank, Harris, Shriver & Jacobson LLP, for the protester.
Lynn T. Burleson, Esq., TRICARE Management Activity, Department of Defense, 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

1. Government Accountability Office has jurisdiction to review a protest challenging the terms of a quotation request for a possible blanket purchase agreement which is being used by the Department of Defense's TRICARE Management Activity (pursuant to its statutory authority to establish a pharmacy benefits program, including a uniform formulary) to inform, and then implement, a TRICARE formulary determination.

2. Decision by the TRICARE Management Activity to consider the cost of pharmaceutical agents obtained by TRICARE beneficiaries at retail pharmacies participating in TRICARE's retail pharmacy network as part of its review of cost effectiveness undertaken to determine whether to add a pharmaceutical agent to the uniform formulary is reasonable where the statutory authorization for the pharmacy benefit program requires the agency to consider the cost effectiveness of pharmaceutical agents as part of any such determination, and where the record shows that more than half of TRICARE's expenditures for pharmaceutical agents are incurred for prescriptions filled by beneficiaries at such retail pharmacies.

3. Protester's assertion that the agency is unreasonably obtaining quotations applicable to only two of the venues where TRICARE beneficiaries can have their prescriptions filled (military treatment facilities and the mail order pharmacy), and is using what is, in essence, a plug number unique to each company (i.e., the Federal Ceiling Price applicable to certain types of purchases from the Federal Supply Schedule) for its assessment of the costs that will be incurred in purchasing each agent from participating retail pharmacies (the third venue where prescriptions can

be filled) is denied where the agency reasonably decided that it should consider the costs of pharmaceutical agents obtained by beneficiaries at such pharmacies; where the Secretary of the Department of Veterans Affairs has determined that the Federal Ceiling Price applies to TRICARE retail pharmacy purchases; and where the Federal Ceiling Price will be the actual price paid by TRICARE if the Secretarial determination, which is being challenged by certain pharmaceutical manufacturers, remains in place.

4. Protester's argument that a request for blanket purchase agreement price quotations improperly fails to identify the relative importance of clinical and cost effectiveness that will be used by the TRICARE Pharmacy & Therapeutics Committee to select pharmaceutical agents for inclusion on the uniform and basic core formularies is denied where the request is consistent with the statutory scheme, which does not identify the relative importance of these two considerations, and which reserves for the discretion of health care professionals the decision about which agents will be included on the formulary, and where, even though this request is limited to vendors submitting quotations for pharmaceutical agents included on their Federal Supply Schedule contracts, there is no requirement in the request that vendors select a particular configuration of their offered products.

DECISION

Merck & Company, Inc. protests the actions of the Department of Defense's (DOD) TRICARE Management Activity in announcing its first review of pharmaceutical agents[1] for inclusion in the newly-implemented, statutorily-based TRICARE uniform formulary.[2] To announce its review--which will include the angiotensin II receptor blocker (ARB) drug class, within which Merck manufactures an agent known as Losartan--TRICARE posted on its website an open letter to pharmaceutical manufacturers (dated December 22, 2004) explaining how it would assess the cost effectiveness of individual pharmaceutical agents in making formulary determinations.

In its December 22 letter, the agency simultaneously advised manufacturers of "an opportunity to provide cost information in the form of a Uniform Formulary Blanket Purchase Agreement price quotation," and advised how the DOD Pharmacy & Therapeutics (P&T) Committee would determine costs for any manufacturer that elected not to provide a price quotation. Agency Report (AR), Tab C.3, at 1. Merck

[1] The statute and regulations at issue here refer to individual drugs within a drug class as pharmaceutical agents. We will use this nomenclature within this decision.

[2] Bristol-Myers Squibb Co., a manufacturer of one of the pharmaceutical agents at issue in this matter, intervened in this protest on a limited basis in support of Merck. We permitted this limited intervention pursuant to our discretionary authority at 4 C.F.R. § 21.3(j) (2005).

raises five distinct challenges to the request for price quotations, and to the process TRICARE has chosen to gather prices for, and implement, its formulary decisions.

We deny the protest.

BACKGROUND

Section 701 of the Fiscal Year 2000 National Defense Authorization Act required that DOD "establish an effective, efficient, integrated pharmacy benefits program" within its managed healthcare program, which DOD refers to as TRICARE. Pub. L. No. 105-65, Div. A, Title VII, § 701(a)(1), Oct. 5, 1999, 113 Stat. 677 (now codified at 10 U.S.C. § 1074g(a)(1)). One part of the program authorized by this recently-enacted statute is the TRICARE uniform formulary. As discussed in greater detail below, TRICARE's uniform formulary is based on concepts and presumptions quite different from those reviewed in our previous decisions regarding so-called "formulary procurements"[3]--such as those conducted by the Department of Veterans Affairs (VA), or even other DOD entities. See, e.g., Bristol-Myers Squibb Co., B-294944.2, Jan. 18, 2005, 2005 CPD ¶ 16 (VA formulary); SmithKline Beecham Corp., B-283939, Jan. 27, 2000, 2000 CPD ¶ 19 (VA formulary); Bristol-Myers Squibb Co., B-281681.12, B-281681.13, Dec. 16, 1999, 2000 CPD ¶ 23 (DOD formulary).

As an overview, we note that TRICARE's authorizing statute and regulations presume the clinical efficacy of pharmaceutical agents for inclusion on the uniform formulary unless and until the agency reaches a different decision. In addition, a TRICARE formulary decision generally does not limit a beneficiary's access to a pharmaceutical agent. Instead, a decision to include a given agent on the formulary establishes a lower level of co-payment for beneficiaries; these co-payments also fluctuate depending upon the venue in which the prescription is filled--i.e., at a military treatment facility, via the mail order pharmacy, or at a retail pharmacy. Further, under TRICARE's formulary scheme, a committee of health care professionals makes the decision about both the clinical and cost effectiveness of pharmaceutical agents under consideration, and the committee may elect to make that decision without using any dedicated procurement vehicle whatsoever--meaning that the committee can simply import pricing information from existing Federal Supply Schedule contracts, and other relevant pricing information, to inform its formulary decisions.

[3] In addition, TRICARE advises, and our review confirms, that its actions implementing its statutory authorization to create a uniform formulary have not been previously challenged in any forum on any basis. AR at 5.

Statutory and Regulatory Framework for TRICARE's Uniform Formulary

The TRICARE program provides services to approximately 9.1 million beneficiaries, including active duty service members, their families, military retirees, and their eligible family members and survivors. Contracting Officer's (CO) Statement, Mar. 7, 2005, at 2. A central element of the newly-authorized TRICARE pharmacy benefit is establishment of a uniform formulary of pharmaceutical agents. 10 U.S.C. § 1074g(a)(2). Under this program, TRICARE expects to dispense almost $5 billion in pharmaceutical agents annually. AR, Tab C.40, at 6. Expenditures for the ARB drug class at issue here have become one of the 10 largest drug class expenditures in the military healthcare system. P&T Committee Minutes, Feb. 16, 2005, at 18.

TRICARE's uniform formulary process anticipates that individual pharmaceutical agents will be selected for inclusion on the formulary based on their relative clinical and cost effectiveness within their drug class. 10 U.S.C. § 1074g(a)(2)(A). Nonetheless, under the TRICARE system, all appropriate pharmaceutical agents must be presumed clinically effective unless DOD's P&T Committee finds that an agent "does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome over other drugs included on the uniform formulary." 10 U.S.C. § 1074g(a)(2)(B).

The P&T Committee also evaluates the costs of agents within a given drug class in relation to their safety, effectiveness, and clinical outcomes. 10 U.S.C. § 1074g(a)(2)(C). Both the evaluation of cost and clinical effectiveness are to be made pursuant to procedures developed by the Secretary, which are now set forth at 32 C.F.R. § 199.21 (2004). 10 U.S.C. § 1074g(a)(2)(D).

In considering the clinical effectiveness of a pharmaceutical agent, TRICARE's regulations advise that the P&T Committee has discretion based on its collective professional judgment about what sources should be reviewed, or relied upon, to make its determinations. 32 C.F.R. § 199.21(e)(1). The regulations identify in detail the types of sources and types of information that may be included in such a review, but do not limit the review to the sources and information identified. Id.

In considering the cost effectiveness of a pharmaceutical agent, TRICARE's regulations advise that the P&T Committee's review may include, but is not limited to, nine types of information. 32 C.F.R. § 199.21(e)(2)(ii). These are: (1) cost of the agent to the government; (2) impact on resource utilization and costs; (3) cost-efficacy studies; (4) cost-effectiveness studies; (5) cross-sectional or retrospective economic evaluations; (6) pharmacoeconomic models; (7) patent expiration dates; (8) clinical practice guideline recommendations; and (9) "existence of existing or proposed blanket purchase agreements, incentive price agreements, or contracts." Id.

In addition to the above-described decisions about whether to include a pharmaceutical agent on the formulary, there is another component of the TRICARE pharmacy benefit program that must be reflected here--i.e., the three venues where a TRICARE beneficiary can have prescriptions filled. A beneficiary's choice of prescribing venue has an effect on the cost of the prescription to the beneficiary. (There are also requirements for stocking one of these venues with pharmaceutical agents that are relevant here.) Finally, a beneficiary's choice of a prescribing venue also has an effect on the cost of the prescription to TRICARE, which we will address below.

The first, and least expensive, of the three venues available to TRICARE beneficiaries seeking to obtain prescription drugs is the military treatment facility (MTF). An MTF is a direct care facility where a beneficiary receives his or her prescription without any cost share. CO's Statement at 2. DOD explains that there are more than 536 dispensing facilities in 121 MTFs. AR, Tab C.40, at 6. Although MTFs dispense drugs directly to beneficiaries, the stock of drugs available at an MTF is likely more limited than the stock at other venues; this is because MTFs are only required to stock drugs consistent with the scope of health care services offered by an MTF. 10 U.S.C. § 1074g(a)(2)(E)(i). In recognition of this characteristic of an MTF, TRICARE has developed the concept of the basic core formulary, which is a subset of the uniform formulary, and constitutes the mandatory minimum set of pharmaceutical agents that must be stocked at each MTF pharmacy.[4] 32 C.F.R. § 199.21(h)(2)(ii).

The second of the three venues available for filling prescriptions is TRICARE's national mail-order pharmacy (TMOP), which, DOD explains, is one of the largest mail-order prescription operations in the nation. AR, Tab C.40, at 6. Using this option, beneficiaries can receive up to a 90-day supply of a pharmaceutical agent with a $3 co-payment per prescription for generic agents, a $9 co-payment per prescription for brand-name formulary agents, or a $22 co-payment for brand-name non-formulary agents. 32 C.F.R. § 199.21(i)(2)(v).

The third of the three venues available are retail pharmacies, and in particular, retail pharmacies that participate in the TRICARE retail pharmacy network (the "retail network pharmacies"). The agency advises that there are now over 54,000 retail network pharmacies. AR, Tab C.40, at 6. At retail network pharmacies, pharmaceutical agents are available to beneficiaries at the same co-payment as at the

[4] There is another subset of the uniform formulary, called the extended core formulary, which also applies only to MTFs. Merck advises that the extended core formulary is not relevant to its challenges here. Initial Protest, Feb. 4, 2005, at 9 n.7. Accordingly, we need not discuss it further.

TMOP, although each prescription is limited to no more than a 30-day supply.[5] 32 C.F.R. § 199.21(i)(2)(ii). (In the event a beneficiary has a medical need for a non-formulary agent, both the TMOP and retail network pharmacies must provide the agent at the $9 co-payment applicable to formulary agents. 32 C.F.R. § 199.21(i)(3)(i).)

As indicated above, a beneficiary's selection of one of the three prescribing venues also has cost implications for TRICARE. Specifically, MTFs and the TMOP are able to purchase pharmaceutical agents using the "Big Four" Federal Supply Schedule (FSS), operated by the General Services Administration (GSA).[6] AR, Tab C.3, at 1. As a result, TRICARE pays a standard government price, established in advance, for pharmaceutical agents purchased by MTFs and the TMOP.

Retail network pharmacies, however, because of their nature as private-sector entities, are not able to purchase pharmaceutical agents from the FSS, and thus are not able to obtain government discounts. Id. The practical implication of this situation for TRICARE is that it will not know how many drugs have been purchased from retail network pharmacies (or the price at which those drugs were purchased by the beneficiary), until it receives a request for payment from the retail network pharmacy for the difference between the purchase price and the applicable co-payment. These underlying and basic differences in the relationships between TRICARE and the prescribing venues are significantly related to Merck's protest issues.

TRICARE's Actions Related to its Request for Price Quotations for Agents in the ARB Drug Class

By letter dated December 22, 2004, and posted to the TRICARE website, the agency advised pharmaceutical manufacturers of the process by which the cost of pharmaceutical agents would be determined for purposes of deciding whether to include those agents on TRICARE's uniform formulary. AR, Tab C.3, at 1. The letter directed manufacturers to the website of the DOD's Pharmacoeconomic Center

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[5] TRICARE beneficiaries may also get their prescriptions filled at non-network retail pharmacies, but if they do, their co-payment for generic and formulary agents is $9, or 20 percent of the cost (whichever is greater), and their co-payment for non-formulary agents is $22, or 20 percent of the cost (whichever is greater). 32 C.F.R. § 199.21(i)(2)(iii)-(iv).

[6] In certain circumstances, manufacturers of pharmaceutical agents are required by statute to make their products available under the FSS, and to provide price discounts to the DOD, the Department of Veterans Affairs (VA), the Public Health Service (PHS), and the Coast Guard (collectively, the "Big Four"). 38 U.S.C. § 8126.

(http://www.pec.ha.osd.mil/PT_Committee.htm) for specific information about the drug classes to be reviewed in a February 2005 meeting of the P&T Committee.

The December 22 letter advised that the cost of a pharmaceutical agent for the formulary review would be determined "based on consideration of the cost of the agent under each of the three DOD venues for dispensing agents to TRICARE beneficiaries, i.e., [MTFs]; the [TMOP]; and the TRICARE Retail Pharmacy Program." Id. The letter also directed manufacturers to additional information, posted elsewhere on the website, titled "Uniform Formulary Blanket Purchase Agreement Information" (hereinafter, "Uniform Formulary BPA Information"). AR, Tab C.8. This posting sets forth general instructions for pharmaceutical manufacturers considering submitting price quotations for use in formulary determinations. In addition, the Uniform Formulary BPA Information reiterates that formulary reviews will consider the cost of a pharmaceutical agent under all three dispensing venues, and advises that the cost of those agents dispensed by non-network pharmacies will not be considered in making formulary determinations. AR, Tab C.8, at 1.

With respect to the cost of pharmaceutical agents dispensed by retail network pharmacies, both the December 22 letter (AR, Tab C.3, at 1) and the Uniform Formulary BPA Information (AR, Tab C.8, at 2) advise that TRICARE will look to the "Federal Ceiling Price" applicable to drugs purchased by DOD under depot contracting systems, again pursuant to 38 U.S.C. § 8126.[7] Both also explain that the Federal Ceiling Price was recently extended to the TRICARE retail pharmacy program by determination of the Secretary of the VA, which was distributed to pharmaceutical manufacturers via letter dated October 14, 2004. In its protest, Merck explains that the VA decision to consider the TRICARE retail pharmacy program a virtual depot contracting system is disputed by pharmaceutical manufacturers.[8]

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[7] The Federal Ceiling Price is the term used to describe certain discounts anticipated by 38 U.S.C. § 8126(a)(2) (a price that "may not exceed 76 percent of the non-Federal average manufacturer price. . . ."). This price may (but may not always) result in a deeper price discount for the government than the price of pharmaceutical agents found on the "Big Four" FSS, and is available to the government for purchases made via a "depot contracting system," as defined at 38 U.S.C. § 8126(h).

[8] In support of its assertion, Merck appended to its initial protest, at attachment L, a January 12, 2005, letter from the American Bar Association's Section of Public Contract Law to the Director of the Office of Federal Procurement Policy arguing that the VA decision requires the use of "notice and comment" rulemaking procedures before it can be implemented. Merck also submitted other documents related to this ongoing dispute during the course of the protest.

With respect to the cost of agents dispensed by the MTFs and the TMOP, both the December 22 letter and the Uniform Formulary BPA Information advise that manufacturers can elect to offer a reduction from their FSS prices, which will then be reflected in a BPA. Absent such a quotation, the letter advises that TRICARE will use the "Big Four" FSS price to determine the cost of dispensing an individual agent at the MTFs and the TMOP. AR, Tab C.3, at 1. The Uniform Formulary BPA Information further explains that the cost of brand name pharmaceutical agents for formulary determinations will be based on the lowest of the following: (1) the Federal Ceiling Price; (2) the "Big Four" FSS price; (3) the BPA price quotation, if any; and (4) the price specified in any existing price agreement applicable to the MTF and TMOP dispensing venues. AR, Tab C.8, at 1-2. In addition, it advises that price quotations for upcoming drug class reviews must be submitted via an attached template, and that the "P&T Committee will not accept multiple, conditional or marketshare based [quotations] at this time." Id. at 2.

The template for price quotations (also available at the website) collects limited information from manufacturers, who must represent that they hold existing FSS contracts for their drug, and agree that they will hold the quotation open for 180 days. AR, Tab C.9, at 2-3. The template permits manufacturers to submit separate quotations by dosage form and strength, with separate prices depending on whether the agent is dispensed by an MTF or the TMOP if the agent is included on the uniform formulary, and a separate MTF price if the agent is also selected for inclusion on the basic core formulary (the mandatory minimum list of pharmaceutical agents that all MTFs must stock). Id. at 3.

In addition to the general documents described above, TRICARE also posted specific information related to the P&T Committee's intended review of the ARB drug class. AR, Tab C.7. This document identified each of the seven agents within the class (including Merck's Losartan) and their respective dosing strengths, and advised that price quotations could be submitted until February 7, 2005. Id. at 1. Further, this document advised that the agents selected for the uniform formulary would form the pool of agents to be considered for the basic core formulary, for which, at least one, but not more than three, agents would be selected. Id. at 2.

Shortly before the February 7 due date for submission of price quotations, Merck filed a protest with our Office challenging what it terms "improprieties and other defects in a Request for Blanket Purchase Agreement Price Quotes (RFQ) issued by [DOD/TRICARE]." Initial Protest, Feb. 4, 2005, at 1. Despite the filing of Merck's protest, the P&T Committee went forward with its planned review of the pharmaceutical agents within the ARB drug class for inclusion on the uniform formulary.

In the minutes of the P&T Committee review, which were subsequently posted on the website of the DOD's Pharmacoeconomic Center, the Committee explained that it would identify its conclusions, present them to the Director of the TRICARE

Management Activity for approval, but not proceed with the award of a BPA until our Office ruled on the protest. P&T Committee Minutes, supra, at 21. During its review, the Committee selected six of the seven pharmaceutical agents in the ARB drug class, including Merck's Losartan, for inclusion on the uniform formulary; the Committee selected one of those six agents, not Merck's Losartan, for the basic core formulary. Id. at 20, 22.

DISCUSSION

Merck raises five distinct challenges to the above-described TRICARE actions, all of which are based on a theory of standard procurement policies and instruments. In our view, Merck's challenges ignore unique and basic underlying differences between the actions at issue here, and those at issue in the procurements Merck cites. Rather than paraphrase Merck's arguments--which, necessarily, begins the process of answering them--we set forth below each of Merck's contentions in its own words:

> 1. The RFQ improperly provides that the cost of pharmaceutical agents in the TRICARE Retail Pharmacy Network will be included in the DOD's evaluation of the cost effectiveness of agents for inclusion on the Uniform Formulary;
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> 2. The RFQ improperly provides that the cost of pharmaceutical agents in the TRICARE Retail Pharmacy Network will be considered to be the Federal Ceiling Price for purposes of the DOD's evaluation of the cost effectiveness of agents for inclusion on the Uniform Formulary;
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> 3. The DOD's methodology under the RFQ for calculating the weighted average cost per day of therapy is flawed because it is based upon historical usage data that is unreliable due to the limited usage of newer pharmaceutical agents;
>
> 4. The RFQ fails to adequately explain the relative importance of clinical effectiveness and cost effectiveness, and the relative importance of the various clinical factors, in the evaluation; and
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> 5. The DOD's refusal to accept alternative price quotes under the RFQ is unreasonable and inconsistent with the [Federal Acquisition Regulation's] "best value" mandate.

Initial Protest, Feb. 4, 2005, at 2.

Jurisdiction

Shortly after Merck's protest was filed, TRICARE requested partial dismissal of three of the bases of this protest, specifically the arguments numbered 1, 2, and 3 above, on the ground that our Office lacks jurisdiction to review its actions related to the selection of pharmaceutical agents for TRICARE's uniform formulary. TRICARE contends that the statute which governs its uniform formulary is not a procurement statute, and points out that even if it canceled its request for BPA price quotations, it could continue with its planned decision about which agents to include on the formulary.

As an initial matter, our review of government actions is limited to procurements of goods or services by a federal agency. 31 U.S.C. § 3551(1) (2000). In our view, the agency's actions here clearly constitute a procurement. Specifically, TRICARE has requested quotations leading to the establishment of one or more BPAs for purchasing selected pharmaceutical agents.[9] The selection of these agents will be done by TRICARE under its pharmacy benefits statute. That selection decision, in turn, will trigger significant procurements of the pharmaceutical agents selected.[10]

As relevant to this case, our Office is authorized to decide bid protests "concerning an alleged violation of a procurement statute or regulation." 31 U.S.C. § 3552(a) (2000), amended by the Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005, Pub. L. No. 108-375, § 326, 118 Stat. 1811 (2004). Although protests usually involve alleged violations of statutes that are indisputably procurement statutes, such as CICA, we will hear protests alleging violations of other statutes or regulations when those statutes or regulations bear directly on federal agency procurements. Sam Gonzales, Inc.--Recon., B-225542.2, Mar. 18, 1987, 87-1 CPD ¶ 306 at 2 (provision of the Bankruptcy Act prohibiting discrimination against debtors did not bear directly on a federal agency procurement for purposes of determining jurisdiction, although GAO issued a decision on the merits at the request of the agency and the Bankruptcy Court); Solano Garbage Co., B-225397, B-225398, Feb. 5, 1987, 87-1 CPD ¶ 125 at 3, recon. denied, B-225397.2, B-2253978.2, June 5, 1987, 87-1 CPD ¶ 571 (jurisdiction exists over protest alleging violation of 42 U.S.C. § 6961, part of the Resource Conservation and Recovery Act of 1976, because interpreting the statute at issue "does not change the fundamental nature of the

[9] In essence, these orders will be "teed up" by the BPA that results from this selection decision, so that the agency will be able to place multiple repetitive orders for the pharmaceutical agents, as anticipated by FAR § 8.404(b)(4).

[10] In fact, the requirement that all MTFs stock, and provide with no co-payment, all pharmaceutical agents placed on the basic core formulary, see 10 U.S.C. § 1074g(a)(2)(E)(i); 32 C.F.R. § 199.21(h)(2)(ii), will translate almost immediately to FSS purchases by MTFs.

dispute as one requiring us to decide, under CICA, whether a 'solicitation, proposed award, or award complies with statute and regulation'"). See also Peter N.G. Schwartz Cos. Judiciary Square Ltd. Partnership, B-239007.3, Oct. 31, 1990, 90-2 CPD ¶ 353 at 4 (jurisdiction exists over protest alleging violation of 40 U.S.C. § 490(h), a provision related to GSA's lease authority, because the statute will "directly bear upon federal agency procurements").

With respect to the statutory grant of authority to TRICARE to establish a uniform formulary, we agree with the agency that the central purpose of this statute is to task TRICARE with providing pharmacy benefits to its beneficiaries, and with establishing a process for making pharmaceutical agents available to beneficiaries at each of the possible prescription dispensing venues. See generally 10 U.S.C. § 1074g. For purposes of determining whether our Office has authority to review this protest, however, we believe that the TRICARE pharmacy benefits statute is appropriately viewed as a procurement statute as well. It is abundantly clear that formulary decisions made by TRICARE (at least for MTFs and the TMOP) will lead to the purchase of pharmaceutical agents using the FSS--that is, to procurements of goods by a federal agency. This is precisely the kind of statute which bears directly on a federal agency procurement, even though the statute exists primarily for other purposes. As a result, we have jurisdiction to consider whether the agency is reasonably complying with the TRICARE pharmacy benefits statute, and is conducting the procurement fairly.

The Substance of Merck's Challenges

We turn first to Merck's initial contention that the RFQ[11] here improperly provides that the cost of pharmaceutical agents in retail network pharmacies will be included in the evaluation of cost effectiveness that will be made to determine whether to include an agent on the uniform formulary.

In reviewing the reasonableness of TRICARE's solicitation for the purchase of pharmaceutical agents for its formulary, we note first the statutory directive that TRICARE's selection of agents for inclusion on its uniform formulary must consider the relative clinical and cost effectiveness of those agents. 10 U.S.C. § 1074g(a)(2)(B). In addition, the regulations that implement this statute provide that one of the elements that may be considered as part of a determination of cost

[11] Merck refers to all of the information posted at the DOD's Pharmacoeconomic Center website collectively as the "RFQ." In our view, Merck's use of the term RFQ does not capture the distinction between general process information disseminated by TRICARE about its approach to this and subsequent formulary reviews, information related to this particular review, and information related to the specific BPA anticipated here. In the discussion below we will refer to the source of each disputed provision by name, with a citation to its placement in the agency report.

effectiveness is the cost of the pharmaceutical agent to the government. 32 C.F.R. § 199.21(e)(2)(ii).

While Merck correctly points out that there is no requirement within the statute to consider the cost of pharmaceutical agents dispensed at each of the venues available to beneficiaries for filling prescriptions, we note, as does Merck, that the record shows that 31 percent of all TRICARE prescriptions are filled at retail network pharmacies, and that these prescriptions represent 52 percent of TRICARE's expenditures for prescription drugs. AR, Tab C.40, at 6. Given the significant proportion of TRICARE prescriptions filled at network retail pharmacies, together with the statutory and regulatory mandate to consider the cost effectiveness of these agents when considering whether to include them on the uniform formulary, we see nothing unreasonable in the agency's decision to consider their cost when they are obtained by beneficiaries at retail network pharmacies. In addition, and for the same reasons, we think this decision is well within the discretion given TRICARE authorities, and can, in no way, be termed a violation of the pharmacy benefit statute.

We also disagree with Merck's contention that the decision to evaluate the cost of agents dispensed via retail network pharmacies in making formulary decisions in some way renders invalid the request for price quotations, or the anticipated BPA. In Merck's view, considering the cost of agents dispensed at retail network pharmacies "creates a fundamental disconnect between the requirements covered by the RFQ and the costs to be included in the evaluation." Protester's Comments, Mar. 21, 2005, at 20.

The problem with Merck's characterization of this situation is that the agency's requirements here, as discussed below, are broader than the subset of purchases encompassed by this quotation request. Moreover, we think Merck's implicit suggestion that the "award decision" should be based only on information solicited by the quotation request ignores the limited purpose of both the quotations requested, and any BPA that results.

The agency here has a requirement to provide ARBs to TRICARE beneficiaries, and it meets this requirement through three distinct dispensing venues--only two of which (MTFs and the TMOP) can purchase pharmaceutical agents using the FSS. In addition, the agency seeks to quantify the costs associated with dispensing agents from all three of these venues as part of deciding which agents it will include on its formulary--a goal we view as reasonable, and consistent with the statute's mandate to consider costs. The quotation request used here simply imports pricing information (from manufacturers willing to provide it) to inform that formulary decision, and the BPA that results, if any, provides a mechanism to obtain for MTFs and the TMOP the prices that were used to make the formulary selection decision.

As Merck recognizes, nothing about this price quotation request, or any BPA that results from it, can provide private-sector retail network pharmacies the right to order pharmaceutical agents using the government's FSS contracts with manufacturers, including the government's FSS contract with Merck. For this reason, nothing about this quotation request is legally invalid or improper because it does not solicit a quotation from manufacturers for the cost of these agents when procured by beneficiaries via retail network pharmacies (in fact, if TRICARE had solicited such a quotation, it would, under current circumstances, essentially be meaningless). We also see nothing invalid about this request simply because the evaluation the P&T Committee undertakes to make a formulary determination will consider other costs (i.e., those paid at retail network pharmacies), and a host of other information not solicited here. In short, we see nothing improper about TRICARE's approach of soliciting quotations to inform its formulary decision about the costs that will be incurred in two of the three applicable dispensing venues, and not soliciting quotations for the retail network pharmacy portion of the cost equation.

Merck next argues that, in the event our Office agrees that TRICARE can consider the cost of pharmaceutical agents dispensed via retail network pharmacies in making formulary decisions--and we do--we should nonetheless determine that TRICARE's use of the Federal Ceiling Price of such agents for its determination is improper.

Given our view that TRICARE's decision to consider the cost of pharmaceutical agents dispensed via retail network pharmacies was within its discretion to implement its statutory mandate to establish a uniform formulary, we think the agency also enjoys reasonable discretion in its attempt to quantify what these costs might be. Again, as with the decision to consider such costs, Merck correctly points out that there is nothing in the statute or the implementing regulations that requires TRICARE to consider the Federal Ceiling Price in its review of cost effectiveness. Nonetheless, we begin by noting that the statute delegates to the agency the discretion to develop appropriate procedures in its implementing regulations. 10 U.S.C. § 1074g(a)(2)(D). These regulations identify the information that may be reviewed, but do not limit the information that can be considered to that identified. 32 C.F.R. § 199.21(e)(2)(ii). Within these regulations, the very first type of information identified as appropriate in a cost effectiveness review is the cost of the agent to the government. Id.

In this regard--and in a decision with far broader consequences than simply the determination of what pharmaceutical agents will be selected for the uniform formulary--the Secretary of the VA has issued a written finding that, in his view, certain provisions of the Veterans Health Care Act of 1992 (which are now codified at 38 U.S.C. § 8126(h)(3)) apply to the prescriptions filled under TRICARE's Retail Pharmacy Program. AR, Tab C.3, at 2, C.21. As explained by both TRICARE and Merck, DOD has begun using this authority to seek refunds from pharmaceutical manufacturers for the costs paid by TRICARE for beneficiaries' prescriptions that

exceed the amount of the Federal Ceiling Price. The VA decision is under challenge elsewhere by Merck and other pharmaceutical manufacturers.

That said, our bid protest forum is not the venue to litigate decisions of the VA Secretary extending the applicability of the Veterans Health Care Act to the TRICARE Retail Pharmacy Program. For our review is the far more limited issue of whether TRICARE acted unreasonably in deciding to use the Federal Ceiling Price as an estimate of the cost it will pay for prescriptions filled by beneficiaries at network retail pharmacies in making its formulary determination. While the VA Secretary's decision may be the subject of litigation elsewhere, unless and until the decision is overturned, we are not sure TRICARE reasonably could have acted in a manner inconsistent with this decision. In addition, since the decision, if upheld, will result in the Federal Ceiling Price being the actual price that TRICARE will pay for these prescriptions, we cannot see how the decision to use this figure as an estimate of future costs for the limited purpose of selecting agents for the uniform formulary was unreasonable.

With respect to Merck's third basis of protest--i.e., that the agency is planning to rely on flawed historical dosing data in assessing cost for purposes of determining whether to include an agent on the formulary--we agree with TRICARE's response that Merck is blurring the distinction between evaluations made in a standard procurement, and the deliberations of the P&T Committee here. As indicated earlier, TRICARE posted specific information related to the P&T Committee's review of the ARB drug class. AR, Tab C.7. This document advised that the committee would rely on historical utilization data to compute an overall weighted average cost per day of therapy with each agent. Id. at 2. Merck complains that the use of historical data here could result in misleading results because newer pharmaceutical agents may not have acquired usage in all relevant patient profiles, and thus may have more limited dosing ranges.

While we are aware that there are newer agents within the ARB drug class, as well as recent developments in the use of certain agents in this class for the treatment of conditions other than high blood pressure,[12] we are not prepared to conclude that the P&T Committee's reliance on historical usage data is unreasonable. In addition, while we recognize that the VA, in a recent ARB procurement which was restricted to only two of the agents in the ARB drug class, decided not to rely on its historical usage data, see Bristol-Myers Squibb Co., supra, at 5, we do not think the VA's

[12] See Boehringer Ingelheim Pharm., Inc., B-294944.3, B-295430, Feb. 2, 2005, 2005 CPD ¶ 32 at 2-3 (two of the seven agents within the ARB drug class, including Merck's Losartan, have been shown to also be effective in the treatment of diabetic nephropathy, and two others have been shown to be effective in the treatment of heart failure); Bristol-Myers Squibb Co., B-294944.2, Jan. 18, 2005, 2005 CPD ¶ 16 at 3 (same).

approach there mandates a conclusion that the DOD approach here is unreasonable. In this regard, we note that the VA was procuring two ARBs for the purpose of treating diabetic nephropathy, and was concerned that the historical usage data would reflect the use of these agents to treat simple hypertension. Id. Here, there is no suggestion that the future use of these drugs will be limited in the same way VA limited it, so that it is less clear that past usage might differ from usage in the future. In any event, it is not appropriate for us to substitute our judgment for that of the P&T Committee about what the future usage of these drugs might be.

We are also struck, at this juncture, by the difference between the formulary decisions at issue here, and those reviewed in our prior cases, including the two cases cited above. In those cases and others, an agency used the procurement process to have a price competition between pharmaceutical agents after making a determination that the agents could be compared head-to-head, resulting in the selection of only one. See, e.g., Bristol-Myers Squibb Co., supra, at 5-7.

Here, TRICARE has selected six of the seven agents in the ARB drug class, including Merck's Losartan, for the uniform formulary. P&T Committee Minutes, Feb. 16, 2005, at 20. Given the inclusion of Merck's agent on the uniform formulary, Merck's apparent concern about losing out on a price competition appears to relate only to the decision about which of these agents should be listed on the basic core formulary. In recognition of the fact that the basic core formulary exists to address the expected scope of treatment to be provided in MTFs, the P&T Committee concluded that the majority of ARB usage would be for the treatment of simple hypertension. Id. at 21. As a result, the Committee selected a single ARB based on its efficacy and cost effectiveness in treating hypertension--not heart failure, and not diabetic nephropathy. Id. at 22. Based on this record we see nothing to suggest that Merck's drug would have fared differently against the one selected for the basic core formulary even if the historical usage data had been scrapped in some effort to estimate future usage of newer and more refined agents. In short, the results of the P&T Committee review suggest that Merck was not prejudiced by the agency's reliance on historical usage data to make its formulary selection decision.

Merck's fourth basis of protest is that the agency failed to explain the relative importance of clinical effectiveness and cost in the P&T Committee's evaluation, and that the relative importance of these two considerations had to be identified in the request for price quotations. We disagree. The statute authorizing TRICARE's pharmacy benefits program requires that the agency make decisions about the inclusion of pharmaceutical agents on its formulary based on a consideration of the relative clinical and cost effectiveness of the agents. 10 U.S.C. § 1074g(a)(2)(A). There is nothing in the statutory scheme (or in the regulations that implement it) that identifies the relative importance of clinical and cost effectiveness; the statute mandates only that both be considered.

Similarly, there is no requirement under the statutory scheme here that manufacturers of pharmaceutical agents be advised of the relative importance of these two considerations. In this regard, we disagree with Merck's contention that our decision in COMARK Federal Sys., B-278343, B-278343.2, Jan. 20, 1998, 98-1 CPD ¶ 34, requires the inclusion of an evaluation scheme in the request for price quotations used here. As we explained in COMARK, when an agency reviews competing vendors' schedule offerings, but does not shift to vendors the burden of selecting items to propose, there is no requirement that vendors be given notice of the agency's needs or the selection criteria; a requirement to identify selection criteria arises when vendors are called upon to select a particular configuration among multiple possibilities with no guidance about how to do so intelligently. Id. at 4-5.

Here, Merck sells its ARB under its FSS contract; admittedly, it sells this ARB in 25, 50, and 100 mg. tablets. TRICARE has asked for a price quotation that could result in additional price reductions (which will be reflected in a BPA) because the agency assumes that selecting a manufacturer's ARB for inclusion on the uniform formulary will generate repetitive purchases. Merck need consider no configuration of different products, nor any particular configuration of its tablet sizes; it simply needs to consider whether a higher volume of sales might provide a basis to offer a reduction from its existing FSS prices. We know of no evaluation criterion it needs to make this assessment.

Merck's final basis of protest is that the agency has unreasonably concluded that it will not consider alternative price quotations for its formulary deliberations. Again, we disagree.

In the December 22 letter to pharmaceutical manufacturers, and in the generic Uniform Formulary BPA Information (AR, Tabs C.3 and C.8, respectively) posted on the website, TRICARE advised manufacturers that the P&T Committee would not accept multiple, conditional, or market share-based price quotations at this time. The record here reflects that TRICARE received requests from Merck, and other manufacturers, that it reconsider this restriction, and that the agency decided not to do so.

As indicated above, the template for submission of price quotations used here, AR, Tab C.9 at 3, allowed manufacturers to provide both an MTF and a TMOP price for their agents if included on the uniform formulary; manufacturers were also allowed to submit a second MTF price if included on the basic core formulary. In Merck's view, TRICARE abused its discretion by not also allowing submission of quotations contingent upon being the only agent selected for the formulary.

In response to Merck's contention, TRICARE submitted an affidavit from one of its analysts working in support of the P&T Committee. In the affidavit, the analyst explains that there was concern within the agency that the acceptance of multiple

price quotations from a single manufacturer would significantly increase the complexity of the analysis of the relative cost effectiveness of the agents within this class, and that doing so would unduly complicate the committee's deliberations. Affidavit of Pharmacoeconomic Center Analyst, Mar. 8, 2005, at 4. There was also a concern that granting requests for multiple contingent quotations[13] could require extending the deadline for submission of price quotations in order to allow the companies additional time, and that doing so could result in postponing the long-scheduled meeting of the P&T Committee with a ripple effect on patient appointments with physician members of the committee. Id. To emphasize the importance of this ripple effect, the affiant explained that more than 700 patient appointments were not scheduled in order to permit the P&T Committee's physician members to attend the meeting. Id. Finally, the affiant expressed his opinion that manufacturers faced with only a single price quotation option, in the midst of substantial competition, might be more inclined to give a better price than they would if faced with multiple nuanced options. Id. at 4-5.

Merck correctly points out that there is evidence in this record that certain officials in the agency believe it might be appropriate to adjust the format of the template for future formulary deliberations to permit submission of multiple contingent quotations. On the other hand, even the e-mails in the agency record which Merck highlights as evidence of agency agreement with its position show careful weighing of numerous competing considerations. See, e.g., AR, Tab C.31 (earlier e-mail from the affiant discussed above indicated that TRICARE's decision not to make this change would likely "leave money on the table"). Our review of these documents shows a thoughtful consideration of the implications of permitting multiple contingent quotations, followed by a decision to knowingly opt for a somewhat conservative approach in this first attempt to complete a formulary review under the new statute. We see nothing in these documents to support a conclusion that the agency was acting arbitrarily, or in any way unreasonably, by not accepting, at this juncture, multiple, conditional, or market share-based price quotations.

The protest is denied.

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General Counsel

[13] For example, one ARB manufacturer, not Merck, asked to be allowed to submit one price if its agent was the sole ARB on the basic core formulary (BCF), a slightly higher price if its ARB was one of two selected for the BCF, and a slightly higher price again if its ARB was one of three selected for the BCF. Id. at 3.