Comptroller General
of the United States

Washington, D.C. 20548

Decision

Matter of: Pfizer, Inc.

File: B-277733

Date: October 27, 1997

Kenneth B. Weckstein, Esq., and Shlomo D. Katz, Esq., Epstein, Becker & Green, P.C., for the protester.
David C. Hammond, Esq., W. Bruce Shirk, Esq., and Mary Baroody Lowe, Esq., Powell, Goldstein, Frazer & Murphy LLP, for the Bayer Corporation, an intervenor.
Maura C. Brown, Esq., and Philip S. Kauffman, Esq., Department of Veterans Affairs, for the agency.
Mary G. Curcio, Esq., and John M. Melody, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

DIGEST

Agency properly may seek offers of two different formulations of a drug under a single solicitation, and make a single award based on low price, where agency determines that either formulation will meet its needs.

DECISION

Pfizer, Inc. protests solicitation No. M5-Q5-97, issued by the Department of Veterans Affairs (VA) for long-acting nifedipine. Pfizer principally argues that the solicitation improperly provides for a single award for long-acting nifedipine, ignoring the differences between two competing nifedipine products.

We deny the protest.

The solicitation was issued as part of a broader program underway at the VA to standardize pharmaceutical and medical/surgical items in order to achieve concentrated buying power by creating "national formularies" for various drugs.[1] The VA issued the solicitation here to establish a fixed-price contract for long-acting nifedipine tablets to be included on the national formulary. The solicitation provides for the award of a single contract based on low price.

[1]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 care for patients throughout the VA's national network of medical care facilities and to reduce costs.

Two manufacturers currently produce long-acting nifedipine--the Bayer Corporation, under the name Adalat CC, and Pfizer, under the name Procardia XL. Pfizer maintains that it is improper to compete these products against each other, and to make a single drug award, because they are not the same; they are neither generic equivalents nor bioequivelants as defined by the Food and Drug Administration (FDA). In this regard, Pfizer explains that the two have different dosing ranges, Procardia can be taken with or without food while Adalat must be taken on an empty stomach, and levels of Procardia stay constant in the bloodstream over 24 hours, while levels of Adalat vary. Pfizer also notes that the two products are not therapeutically equivalent because they have different effects on blood pressure, and that Procardia is FDA approved for treatment of both hypertension and angina, while Adalat is approved only for treatment of hypertension. Pfizer believes the two products should be procured separately.

The determination of an agency's minimum needs, and the best method of accommodating them, are matters primarily within the agency's discretion. Premiere Vending, 73 Comp. Gen. 201, 206 (1994), 94-1 CPD ¶ 380 at 7. The VA does not dispute that, because Procardia and Adalat are formulated differently, they are not generic equivalents or bioequivelants. Rather, the VA has determined that since the two drugs are pharmaceutically equivalent--they both contain the same amount of nifedipine--either formulation will meet its need for long-acting nifedipine. The VA states that, for its purposes, the differences which result from the different formulations--the absorption rate, the dosing range, and whether the drug can be taken with food--are not clinically significant, and will not produce significant side effects. Similarly, the VA does not consider significant for its purposes the fact that Procardia is approved for treatment of both hypertension and angina (while Adalat is approved only for treatment of hypertension), since there are angina drugs available on the national formulary. We conclude that, since the VA's requirement is for long-acting nifedipine, and the VA has determined it has no need for the additional qualities of Procardia, there is nothing improper in the agency's decision to make a single drug award.[2]

Alternatively, Pfizer argues that, if the drugs are competed against each other, the award decision should take into account the differences in the drugs, as well as the effect that switching drugs will have on patients, and not be based on price alone. However, an agency's discretion in determining its minimum needs extends to the

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[2]Pfizer argues that the drugs should not be competed against each other because, if Adalat is selected, patients currently taking Procardia will be switched to Adalat. According to Pfizer, this switch will have adverse effects on the patients. As we recently have held, however, the medical policies and judgments involved in an executive agency's decision to utilize a single drug award are not appropriate for consideration under our bid protest function. Pfizer, Inc., B-276362, June 6, 1997, 97-1 CPD ¶ 205 at 6.

evaluation criteria it will use. Pfizer, Inc., supra, at 3. As discussed, the VA has found that the differences in the two products are not material for its purposes, and that for the majority of patients who switch drugs there will be no adverse effects.[3] These are medical judgments that we will not question. Id. at 6. Accordingly, there is no basis for precluding award based on price.

Pfizer argues that if award is based on price alone, the VA must consider the cost impact that will result if Adalat wins the competition and patients with angina must take a second medication. Since the VA's requirement is for long-acting nifedipine for its national formulary--a need that either Procardia or Adalat will meet--the agency properly may base its price evaluation on the prices of the offered products; there is no basis for requiring the agency to consider cost savings that may result from differences in the two products that are unrelated to its requirement.

The protest is denied.

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[3]Pfizer asserts that the VA did not study the effects of switching patients from Procardia to Adalat. However, the record shows that the VA did conduct such a study. See Michael B. Ganz, M.D., and Brett Saska, Switching Long-Acting Nifedipine, Fed. Practitioner, May 1997. In any case, the need for and accuracy of the study are matters of medical judgment that we will not review.