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DECISION THE COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

FILE: B-218359.2 **DATE:** August 22, 1985

MATTER OF: Syva Company

DIGEST:

1. Agency's specification for a drug testing system does not unduly restrict competition where agency establishes prima facie case that the restriction is legitimately related to its minimum needs and protester, while disagreeing with the agency's technical judgment, fails to clearly show that the agency's decision to restrict competition is clearly unreasonable.

2. Agency is fulfilling duty to take steps to increase competition by expressing willingness to consider alternative methods, encouraging prospective offerors and reviewing impediments to competition.

Syva Company (Syva) protests as unduly restrictive of competition request for proposals (RFP) No. DLA120-84-R-0774 issued by the Defense Logistics Agency, Defense Personnel Support Center (DLA). The RFP seeks, on a brand name or equal basis, a drug test system employing a radioimmunoassay test method (R-method). Syva sells a drug test system based on the enzyme immunoassay test method (E-method) and contends that the solicitation precludes it from offering its functionally equivalent product.[1/]

[1/] Syva's protest of this procurement to our Office was initially dismissed as untimely by our decision in Syva Co., B-218359, Mar. 28, 1985, 85-1 C.P.D. ¶ 376. We found that Syva's protest against the requirement for a system employing the R-method was a protest against a specification requirement and, since it initially filed its protest with the contracting agency after the initial closing date, the protest was untimely. Syva requested reconsideration of our dismissal. By our decision in Syva Co.--Reconsideration, B-218359.2, May 6, 1985, 85-1 C.P.D ¶ 503, we reversed our previous decision. We held that, even though the original

We deny the protest.

The drug test kits being procured here are for the Department of Defense (DOD) drug testing program. These kits are used to detect the presence of certain drugs at specified concentrations in urine. Drug screening tests are performed by nine military urinalysis laboratories throughout the United States and West Germany on over 2.5 million urine specimens a year from members of the armed services. All of the drug testing laboratories currently use drug test systems employing the R-method as the initial procedure for drug screening. Prior to June 1, 1985, DOD policy was that either the E-method or the R-method could be used to screen urine specimens, DOD Directive 1010.1, encl. 3, para. "D" (Mar. 16, 1983), but DOD policy was revised to provide that

> "[t]he initial test [by drug testing laboratory] shall use a radioimmunoassay (RIA) process unless a different process has been approved by the [Assistant Secretary of Defense for Health Affairs] for the specific laboratory concerned upon recommendation of the Biochemical Testing Advisory Committee."

DOD Directive 1010.1, encl. 3, para. "E" (Dec. 28, 1984). Any specimen tested positive under the initial procedure is then subjected to additional confirmatory testing by a different methodology; all laboratory confirmatory testing of positive results is by gas chromatography/mass spectrometry (GC/MS). DOD Directive 1010.1, encl. 3, para. "F" (Dec. 28, 1984).

RFP contained a provision similar to that in the amended RFP which was the subject of protest, the amended RFP was for a subsequent year's needs and therefore tantamount to a new procurement. Since the protest was filed prior to the amended RFP's closing date, we concluded that it was timely filed. DLA now maintains that the amendment did not constitute a new procurement and requests that we reinstate our initial decision dismissing the protest. DLA, however, does not present any arguments which were not considered in reaching our decision on reconsideration and we will therefore address the protest on the merits.

The drug testing program primarily is intended to promote the health and fitness of members of the military, and it has been successful in reducing the drug problem in the military. The results of a member's urinalysis, however, may be used to support criminal or administrative actions against that individual. Maintaining the scientific integrity of the program by using reliable detection procedures is essential so as not to undermine the confidence in the program held by those in positions of responsibility who must decide whether they should initiate criminal or administrative actions based solely on test results or the confidence held by the individual military member in the fairness of the program. See S. Rep. No. 500, 98th Cong., 2d Sess. 233-234 (1984). We also note that GC/MS is a highly labor intensive and expensive method of drug testing and consequently reliability of initial testing is important in order to avoid unnecessary, costly confirmatory tests.

Syva contends that the restriction to drug test systems employing the R-method is not justified because its system utilizing the E-method performs as well or better than systems employing the R-method. Syva states that the reliability of its system has been proven in mass volume testing, having been used for drug testing in commercial laboratories throughout the world and by the United States Coast Guard. It also cites several clinical studies which demonstrate the reliability of the E-method in detecting the presence of drugs in urine.

Syva further contends that its drug test system is significantly less expensive than a system employing the R-method. It lists the following cost saving factors: (1) the E-method, in contrast to the R-method, does not use radioactive ingredients and therefore does not have radioactive waste disposal problems; (2) Syva reagents have a longer shelf life than that required in the solicitation and therefore make inventory control easier; (3) the Syva system does not require the use of disposal glass test tubes necessary for the R-method; and (4) due to a high level of automation, the E-method is less labor intensive than the R-method and thus fewer employees are necessary.

Syva also argues that, by restricting the procurement to drug test systems employing the R-method, DLA has created a sole-source procurement and it has not met its duty to foster competition. As evidence of DLA's resistance to the E-method, Syva cites the following items: (1) its equipment

was installed at Ft. Meade for testing, but the agency refused to test it; (2) DOD Directive 1010.1 was revised to restrict usage of the E-method; (3) an outside drug testing laboratory which used a system employing the E-method was required to use the R-method; and (4) DLA has not accepted the offered opportunity to observe the operations and results of commercial laboratories using the E-method. It asks that DLA be directed to study the feasibility of using the E-method system as an alternative process in order to increase competition.

DLA responds that this procurement was limited to drug testing systems employing the R-method because systems employing the E-method are not reliable. As evidence, it points to a quality control report prepared by the Armed Forces Institute of Pathology for the period of January through March 1985. This report showed that CompuChem Laboratory, an outside contractor which, during this period, performed the initial drug screening tests using the E-method, had only a 49.1 percent correct rate on positive blind samples, while during the same period the three military laboratories being reviewed, all of which used tests employing the R-method, had correct rates of 93.2, 99 and 99.2 percent. DLA further states that the Coast Guard procurement called for drug testing systems employing the E-method only because, prior to the procurement, the Coast Guard had purchased services from different laboratories, a great majority of which used this method, and it followed its previous experience. In actuality, DLA learned that the Coast Guard did not consider the E-method reliable because it had a 58.1 percent correct rate on positive samples in fiscal year 1984 and similarly poor results in fiscal year 1983 and the first half of fiscal year 1985, and it relied on its confirmatory testing for discharge procedures. DLA further asserts that Syva has failed to present any detailed evidence demonstrating that its drug test system can, in fact, meet the agency's need for reliability. Roche Diagnostic Systems (Roche), manufacturer of an R-method test system, has supplemented DLA's arguments against the reliability of the E-method introducing into the record several clinical studies and other documents indicating that the E-method does not accurately analyze urine for the presence of drugs.

DLA also disputes the alleged cost savings of the E-method. It states that: (1) the alleged labor savings of the E-method are questionable because the government may

choose not to use Syva's fully automated proposal; (2) Syva does not take into account the premium the firm proposes to charge to cover the cost of its computer assisted workflow management system; (3) Syva failed to take into account the cost of storing the existing equipment which is used toward the R-method; and (4) a change from the R-method to the E-method would require retraining personnel and revising operating procedures manuals.

Next, DLA argues that this is not a sole-source procurement and that it has sought and will continue to seek competition for procurements of this nature. It points out that two other firms responded to the original solicitation and submitted offers on some of the items. The offers were rejected because the RFP was an "all or none" solicitation requiring an offer on all items. However, DLA states that it has been encouraging these firms, as well as others, to enter the market and to develop a full line of products. In fact, the agency has targeted subsequent procurements of drug testing kits for review by the Medical Competition Advocacy Section in order to identify and remove impediments to competition. DLA also states that it is interested in Syva competing for this contract and it has talked to Syva representatives about the E-method and requested data to confirm the reliability of the study, but it has not received any. The agency explains that the proposed test of Syva's system at Ft. Meade was canceled because it was determined to be improper to conduct the test in light of Syva's competition for this contract and its pending protest, it had a personnel shortage at the time, and Syva did not submit a practical plan for conducting the test.

A protester contending that a solicitation requirement is unduly restrictive has a heavy burden of proof. The contracting agency has broad discretion in determining its minimum needs and the best methods of accommodating those needs. The Trane Co., B-216449, Mar. 13, 1985, 85-1 C.P.D. ¶ 306. Where, as here, a protester challenges a specification as unduly restrictive of competition, the initial burden is on the procuring agency to establish prima facie support for its contention that the restrictions it imposes are needed to meet its minimum needs. Once the agency establishes prima facie support, the burden is then on the protester to show that the requirements complained of are clearly unreasonable. Polymembrane Systems, Inc., B-213060, Mar. 27, 1984, 84-1 C.P.D. ¶ 354.

We find that the agency has established a prima facie case for restricting this procurement to drug test systems employing the R-method. The agency determined that a reliable test system was critical to its needs, and concluded that the E-method does not offer the necessary reliability. The agency's conclusion is supported by clinical studies, its experience at CompuChem and the Coast Guard's experience, all of which indicate that the systems employing the E-method are not accurate at detecting the presence of drugs.

The agency and the protester disagree regarding the reliability of the drug test systems employing the E-method. Syva bases its claim of reliability on the method's widespread use in commercial laboratories, the Coast Guard procurement and clinical studies. Syva's reliance on widespread use by commercial laboratories is not supported by details of the experience at these laboratories; it merely asserts that widespread use is an indication of reliability. Syva also merely relies on the fact that the Coast Guard was procuring systems using the E-method as evidence of reliability of that method. Reliance on the Coast Guard procurement as indicating reliability is misplaced, because the Coast Guard was only following its past practice in making the procurement and in fact it does not believe that the E-method is reliable. As to the clinical studies cited by Syva, these studies provide questionable support. For example, Syva cites a nationwide survey of drug testing laboratories conducted by the Center for Disease Control to show the E-method compares favorably with the R-method. The statistics presented by Syva from the survey, however, are for confirmatory testing of positive samples, while the test systems being procured here are for detection purposes, not confirmation. The survey showed that for the detection of positive samples the R-method had 100-percent accuracy for each drug while the accuracy of the E-method ranged from 92 to 99 percent. Moreover, an examination of the studies cited by Roche raise other questions about the reliability of the E-method. For example, an article, entitled "Problems of Mass Urine Screening for Misused Drugs," in the October-December 1984 issue of the Journal of Psychoactive Drugs discusses several field test situations in which the E-method tests have had a high percentage of incorrect results. Thus, the available studies do not clearly indicate that the E-method is reliable.

In our view, Syva has failed to meet its burden of showing that the agency's decision to restrict the procurement to the R-method was clearly unreasonable. DLA and Syva obviously disagree over the technical merits of the E-method; however, mere difference of opinion does not invalidate the agency's conclusions. RCA American Communications, Inc., B-213995, Apr. 19, 1984, 84-1 C.P.D ¶ 450. Since we conclude that DLA has sufficiently demonstrated that a system employing the E-method will not meet its legitimate needs, the question of cost savings which might be accrued from the use of the E-method is irrelevant. Id.

Finally, as noted above, there were two other sources for R-method test systems that were rejected because the RFP was an "all or none" solicitation and they were unable to submit offers on all R-method test systems. In the circumstances, the "all or none" award provision had the effect of reducing the RFP to a sole source solicitation. We agree with Syva that DLA has a duty to take whatever steps are practicable to increase competition for these procurements. The record, however, indicates that DLA is actively seeking competition for procurements of this nature. First, DLA indicates that it will review use of the "all or none" provision before using it in future procurements. Second, it has expressed willingness to use the Syva system if it is presented with test data indicating its reliability. (Although Syva contends it has presented such information, we have found otherwise; our Office will not require DLA to conduct its own tests of Syva's system where the agency has demonstrated a reasonable basis for determining that the system will not meet its needs. See Biomarine Industries; General Electric Co., B-180211, Aug. 5, 1974, 74-2 C.P.D. ¶ 78. Moreover, we find that DLA did not test Syva's system at Ft. Meade only because of the pending protest and logistical problems.) Further, although DOD Directive 1010.1 no longer specifies the E-method for use for drug screening, the revision still allows for use of the E-method upon approval. In our view, these steps show that the agency is fulfilling its duty to increase competition.

Harry R. Van Cleve
General Counsel