



**Comptroller General
of the United States**

Washington, D.C. 20548

Decision

Matter of: The Research Foundation of State University of New York

File: B-274269

Date: December 2, 1996

Benjamin J. Luft, M.D., James R. Dennehey, Esq., and Concetta Angilella, Esq., for the protester.

Theodore M. Hess-Mahan, Esq., Ropes & Gray, for New England Medical Center, an intervenor.

Richard Brown, Esq. and Michael Colvin, for the Department of Health and Human Services, for the agency.

Charles W. Morrow, Esq., and James A. Spangenberg, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

DIGEST

Agency reasonably accepted in its cost evaluation the proposed costs of proposals offering significantly different technical approaches to performing clinical studies where the solicitation contemplated proposals based upon the offerors' creativity in developing and designing their own protocols for the study and the agency reviewed the cost elements of each proposal and found each proposal's cost reasonable and realistic for the particular study proposed.

DECISION

The Research Foundation of State University of New York (SUNY) protests the award of a contract to New England Medical Center (NEMC), by the Department of Health and Human Services, National Institute of Allergy and Infectious Diseases (NIAID), under request for proposals (RFP) No. NIH-NIAID-DMID-96-09, for clinical studies of chronic lyme disease.

We deny the protest.¹

The RFP, issued June 15, 1995, contemplated a cost reimbursement, level-of-effort, contract for a 5-year term. The contractor is to develop the research infrastructure for NIAID to address two essential issues--the evaluation of therapeutic approaches to treat patients with chronic lyme disease and the pathological basis/bases of the

¹A hearing was conducted to obtain testimony regarding the protest issues.

condition.² The statement of work requires the contractor to conduct clinical studies in patients with documented and well-defined chronic lyme disease, and advises that the major focus of the studies will be on the therapeutic effects of antimicrobial agents; that assessments of the pharmacological properties of drugs used singly or in combination with other therapeutic medications shall be part of the studies when necessary and appropriate; and that pilot studies of treatments for other manifestations or infections associated with lyme disease may also be proposed.

The RFP required that each offeror, as part of its proposal, would develop and design protocol(s) for conducting clinical studies of lyme disease. The protocol is the offeror's technical approach to conducting the clinical study of the disease and includes such things as the drugs that the offeror proposed to utilize in studying treatment of the disease, the duration of the treatment, and the number of patients to be included in the study. The RFP required offerors to submit a detailed protocol for a controlled phase III study and also advised that they could submit up to two pilot studies as well if appropriate. The RFP advised offerors that "it is anticipated that a phase III study would require 150-300 patients, a phase II study would require 30-60 patients." The RFP contemplated that the offerors would rely upon their own creativity and expertise in developing and designing the offered protocol, and that the selected firm's protocol(s) likely would be modified after award based upon the recommendations of the project officer; to this effect, the RFP advised offerors that the award of the contract did not commit the government to approve any of the studies presented in the offeror's proposal--that the project officer would determine the actual studies to be undertaken.

The RFP advised that the technical evaluation would receive paramount consideration over cost, but that in the event of technically equal proposals, cost would become more important. The technical criteria were "Scientific and Technical Approach" worth 50 percent, "Personnel" worth 25 percent, and "Facilities/Resources" worth 25 percent.

NIAID received proposals from SUNY and NEMC by the October 15 initial closing date. Both proposals were included in the competitive range; NEMC's proposal received a score of 58 points and SUNY's proposal received a score of 55 points. Following technical and cost discussions, the offerors submitted best and final offers (BAFO) by May 1, 1996.

²Lyme disease is the most common tick-borne disease in the United States. The term "Post-Lyme Disease Syndrome" is a condition of chronic or intermittent symptoms related to lyme disease that may be caused by either active infection that has escaped control with the use of conventional antibiotic regimens; and/or permanent damage caused by the original infectious process.

The offerors' proposed protocols were significantly different from each other. Specifically, SUNY's proposed protocol involved studying a larger number of patients under a combination therapy, four-arm study, whereas NEMC's proposed protocol involved a monotherapy, two-arm study with fewer patients.³

NIAID rated the BAFOs with equal technical scores of 79. NEMC's BAFO cost was \$4,194,968 and SUNY's BAFO cost was \$5,323,058. NIAID evaluated the realism of the cost proposals and determined that each offeror's estimate was realistic based upon its technical approach. On May 28, NIAID made award to NEMC based upon its lower-cost, technically equal proposal.

The agency has indicated that the project officer is currently considering modifications to NEMC's protocol based upon recommendations received from an Advisory Review Panel. These modifications involve increasing the duration of treatment, the addition of more patients, and incorporating a second drug. VT at 11:38:11-11:39:10, 13:15:07-13:15:41. When the project officer decides what modifications should be made, the agency will require the protocol to be amended and will authorize the study to commence.

SUNY's primary basis for protest is that NIAID failed to conduct a proper cost evaluation and merely accepted, and compared as the basis for award selection, the offerors' bottom-line proposed costs without further analysis. SUNY notes in this regard that since each offeror's proposed protocol differed significantly in size and complexity, the proposed costs should be somehow normalized to properly evaluate cost. SUNY suggests in this regard that each proposal's per patient cost could be calculated (dividing the total offered costs by the number of patients studied) as a basis to compare the proposal costs, in which case SUNY's proposal would have been found to be a better buy because of its lower per patient costs resulting in more scientific information per dollar. SUNY also contends that the agency should have evaluated the offerors' costs based upon the clinical study currently being considered by the project office rather than their proposed bottom-line costs, inasmuch as this study significantly modifies NEMC's proposed protocol from a monotherapy study to a combination therapy study that SUNY alleges more closely resembles SUNY's proposed protocol.

Where an agency evaluates proposals for the award of a cost reimbursement contract, an offeror's proposed costs are not dispositive, because regardless of the costs proposed, the government is bound to pay the contractor its actual and allowable costs. Federal Acquisition Regulation § 15.605(c). Consequently, a cost

³A four-arm study compares four treatment groups to each other and a two-arm study compares two groups. Combination therapy employs several drugs and monotherapy employs a single drug. Video Transcript (VT) at 11:36:50

realism analysis must be performed by the agency to determine the extent to which an offeror's proposed costs represent what should be reasonably incurred, assuming reasonable economy and efficiency, if that offeror's proposal were accepted for award. CACI, Inc.-Fed., 64 Comp. Gen. 71 (1984), 84-2 CPD ¶ 542. Because the contracting agency is in the best position to make this cost realism determination, our review is limited to determining whether the agency's cost evaluation was reasonably based and not arbitrary. General Research Corp., 70 Comp. Gen. 279 (1991), 91-1 CPD ¶ 183, aff'd, American Management Sys., Inc.; Dept. of Army--Recon., 70 Comp. Gen. 510 (1991), 91-1 CPD ¶ 492; Grey Advertising, Inc., 55 Comp. Gen. 1111 (1976), 76-1 CPD ¶ 325.

As noted above, NIAID determined both NEMC's and SUNY's proposed estimated costs to be reasonable and realistic for the technical approaches that each had proposed. The contracting officer testified that this determination was made after a comprehensive evaluation of the various cost elements contained in each offeror's proposal. For example, the agency examined each offeror's labor rates, travel expenses, salaries, levels of effort, fringe benefits, overhead rates, subcontractor costs, and material costs, and conducted cost discussions addressing the agency's cost concerns.⁴ VT at 14:10:34-14:12:07.

The contracting officer testified that it was not feasible to normalize costs, as suggested by the protester, because the agency was totally dependent upon each offerors' unique protocol design as a basis for determining costs. He stated that the agency did not have a predetermined preferred protocol design--since the RFP sought offerors' proposals for this purpose--and that the RFP contemplated that the offeror would design a protocol and that after award the project officer would determine the ultimate design of the clinical study by revising, as necessary, the contractor's proposed protocol. VT at 14:58:38-15:03:44. Agency representatives further testified that the contents of the revised protocol currently under consideration were not known at the time of award, but were the result of the recommendations of the Advisory Review Panel, and is being developed based upon NEMC's two-arm study, and that, even though the study being contemplated will take a combination instead of a monotherapy approach, the fundamental distinguishing features of NEMC's protocol remain. VT at 11:32:45-11:32:55, 11:35:38-11:37:58, 13:13:10-13:13:49, 13:18:01-13:18:10, 14:27:39-14:27:43. Furthermore, the contracting officer testified that evaluating and comparing the offerors' costs on a cost per-patient basis, as suggested by the protester, would not have been valid or meaningful because the proposed protocols contained more variables than patient numbers, for example, duration and types of treatment; such an evaluation would have been unjustifiably biased in favor of studies involving higher numbers of

⁴The record contains documentation evidencing that such an analysis was performed.

patients regardless of the technical quality of the study; and the RFP did not advise offerors that such an evaluation would be considered. VT at 14:07:36-14:09:36.

Based on our review, we agree with the agency that it could not normalize the costs as suggested by the protester. Cost normalization involves the measurement of offerors against the same baseline where there is no logical basis for the differences in approach or where there is insufficient information provided with the proposals, leading to the establishment of common "should have bid" estimates by the agency. The purpose of such an analysis is to segregate cost factors which are "company unique"—dependent on variables resulting from dissimilar company policies—from those which are generally applicable to all offerors and therefore subject to normalization. Bendix Field Eng'g Corp., B-246236, Feb. 25, 1992, 92-1 CPD ¶ 227. Here, the agency properly did not normalize costs, since the record shows that it had no predetermined basis upon which to measure similar costs. Dynallectron Corp.; Lockheed Elecs. Co., Inc., 54 Comp. Gen. 562 (1975), 75-1 CPD ¶ 17, aff'd, 54 Comp. Gen. 1009 (1975), 75-1 CPD ¶ 341 (normalization improper where varying costs between competing proposals results from innovative technical approaches).

With regard to the revised protocol currently being considered for placement under NEMC's contract, the agency had no basis, much less obligation, to project from each offeror's proposal and compare the agency's assessment of what it believed would be each offeror's cost of performing under this revised protocol.⁵ In this regard, the agency did not, at the time of award, know what clinical studies would be authorized by the project officer because they were not to be developed until after the award based on the awardee's protocol. Nor does the record support SUNY's assertion that the two-arm study under consideration more closely resembles SUNY's proposed four-arm protocol than NEMC's two-arm protocol.

Finally, the record confirms that the proposed costs of both proposals were analyzed and the subject of discussions and proposal revisions. SUNY has not shown NEMC's proposed costs for its technical approach were understated or that SUNY's were overstated. In sum, given that the cost realism analysis considered the best cost information available, we cannot conclude that NIAID acted unreasonably in comparing the estimated costs of the two proposals as the basis for award. Hager Sharp, Inc., B-258812, Feb. 17, 1995, 95-1 CPD ¶ 93.

⁵The contracting officer testified that while no exact cost figures have been developed regarding the proposed modification to NEMC's protocol because the actual study to be ordered has not been finalized, it was reasonable to assume from the information contained in NEMC's BAFO that the cost increase would be approximately \$300,000. VT at 14:02:21-14:03:14, 14:17:47-14:18:12, 14:21:55-14:23:07, 15:05:14-15:08:09.

SUNY also argues that NEMC's phase III protocol failed to meet the RFP's "minimum" guideline for numbers of patients because NEMC proposed protocol was not within the 150- to 300-patient parameter that the RFP stated was "anticipated" for such a study. We disagree. As indicated, the RFP contemplated creativity on the part of offerors in designing a protocol, such that the "anticipation" announced in the RFP cannot reasonably be interpreted as precluding an offeror from designing a phase III protocol with patient numbers outside the anticipated parameters. Here, NIAID found that NEMC's protocol, which involved 110 patients in two studies and 50 patients in one study and 270 patients overall, was an acceptable phase III study, VT at 12:59:20-13:05:22, and we see no basis to question this determination.

SUNY finally argues that the technical evaluation improperly gave more weight to the personnel and facilities over scientific approach than was announced in the RFP evaluation scheme. In support of this contention, SUNY only points to the source selection document, which recognized that NEMC's proposal received a higher score than SUNY's under personnel and facilities (as compared to SUNY's higher score under scientific approach). This contention has no merit. The source selection document only points out the differences between the two equally scored technical proposals. As indicated, NIAID made award to NEMC solely because of its lower cost, not due to any technical advantage relating to personnel and facilities.

The protest is denied.

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