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Comptroller General
of the United States

United States General Accounting Office
Washington, DC 20548

Decision

Matter of: Novavax Inc.

File: B-286167; B-286167.2

Date: December 4, 2000

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Michael J. Lacek, Esq., and Anne Robbins, Esq., Palmer & Dodge, for OraVax, Inc., an intervenor.
Elise Harris, Esq., and Scott C. Briles, Esq., Centers for Disease Control and Prevention, for the agency.
Tania Calhoun, Esq., and Christine S. Melody, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

DIGEST

Protests that contracting agency improperly interpreted and applied the solicitation's indemnification/insurance requirement as to the protester's and awardee's proposals, and improperly eliminated the protester's proposal from the competitive range, are denied where the record shows that the agency's interpretation of the requirement was reasonable and that its evaluation of both proposals and its competitive range determination were reasonable and consistent with the solicitation's requirements.

DECISION

Novavax Inc. protests its proposal's exclusion from the competitive range and the award of a contract to OraVax, Inc., under request for proposals (RFP) No. 2000-N-00001, issued by the Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), for the development and stockpiling of a smallpox vaccine. Novavax contends that the CDC improperly interpreted and applied the solicitation's indemnification/insurance requirement as to both proposals and improperly eliminated its proposal from the competitive range.

We deny the protests.

BACKGROUND

Over the centuries, smallpox has been feared as one of the most serious of all pestilential diseases. The practice of vaccination was invented to fight smallpox more than two hundred years ago. After an aggressive global vaccination program, smallpox was officially declared eradicated in 1980. In recent years, however, concern has grown that large-scale biological weapons research and production involving smallpox might still exist in many countries.[1]

The civilian population of the United States would be extremely vulnerable to a bioterrorist attack using smallpox virus. There is no effective treatment for the disease, which has a fatality rate of 30 percent or more. Routine immunization against smallpox ended in 1972 and it is estimated that no more than 20 percent of the population has any immunity from prior vaccinations.[2] The vaccine is no longer manufactured anywhere in the world and only 15.4 million doses of the 20-year-old vaccine are available for use in an emergency. Agency Finding and Determination at 2-3. Through HHS's anti-bioterrorism initiative, the CDC is coordinating and leading overall planning efforts to upgrade national public health capabilities to respond to biological and chemical terrorism. Smallpox virus is consistently ranked highest of the bioterrorism threat agents because of its potentially catastrophic public health effects, and replenishing diminished smallpox vaccine stocks is the top priority for HHS and CDC. Id.

This solicitation was issued on February 11, 2000. Its objective is to obtain a stockpile of 40 million doses of a smallpox (vaccinia) vaccine in the shortest time possible to be used in case of a public health emergency. The RFP required the successful contractor to develop a candidate smallpox vaccine; provide at least two pilot lot vaccines for use in conducting clinical trials; conduct clinical trials; obtain final licensure; produce at least 40 million doses of the vaccine; store a portion of the stockpile; and produce stockpile replacement vaccines or new vaccine lots. These tasks were divided into four line items subject to varying payment terms.

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[1] See generally Richard Preston, "The Demon in the Freezer," New Yorker, July 12, 1999, at 44-61, at <http://www.elastic.org/~fche/mirrors/cryptome.org/smallpox-wmd.htm>.

[2] Mark G. Kortepeter and Gerald W. Parker, "Potential Biological Weapons Threats," Emerging Infectious Diseases, Vol. 5, No. 4, July-Aug. 1999, at 524-26; see also "Smallpox Fact Sheet," Johns Hopkins University Center for Civilian Biodefense Studies, at <http://www.hopkins-biodefense.org/pages/agents/agentsmallpox.html>.

Award was to be made to the offeror whose integrated proposal (technical, business, and past performance) offered the highest technical merit at the best overall value to the government. Technical merit was to be considered significantly more important than cost or price. In addition to including technical and past performance evaluation criteria, the solicitation included a pass/fail requirement, referred to as an "absolute criterion," that each proposal demonstrate that the offeror "has the capability to provide indemnification/liability" in accordance with section H.14 of the solicitation. RFP § M.2. Section H.14 stated that "[t]he contractor shall indemnify or shall obtain insurance to indemnify, defend and hold harmless the government from any claims and cost resulting from acts, omissions, and mishandling of the vaccine."

Four firms submitted offers by the April 19 closing date and made oral presentations the following week. The agency's technical evaluation panel (TEP) evaluated the offers and found the proposals of both Novavax and OraVax technically acceptable.[3] Of the 100 technical points available, Novavax's proposal received 83.50 points and OraVax's proposal received 76.50 points. The TEP also found that both proposals appeared to have met the indemnity/insurance requirement, but the TEP had concerns about the adequacy and specificity of both proposals. In this regard, during the evaluation process the TEP realized that the language of section H.14 was insufficiently specific to put offerors on notice of the agency's requirements. Amendment No. 5 was drafted, in part, to address this problem.

Amendment No. 5 revised section H.14 to add the following specific requirements to the existing language:

> The indemnification/insurance coverage obtained shall include 1) clinical trials – adults; 2) clinical trials – pediatrics; 3) use in at risk laboratorians; 4) use in [immuno]-compromised individuals and [pregnant] women; and 5) use in emergency [situations]. A non-cancellable policy for the 20-year life of the contract shall be obtained by the Contractor prior to initiation of the clinical trials.

Amendment No. 5 also added section B.5 to the solicitation. This section added a required line item which was to "[reflect] the non-cancellable policy payment terms reached with the insurance providers for insurance which meets the requirements of [section] H.14." RFP § B.5(1). Section B.5 also stated that:

> (2) Backup documentation shall include a written justification as to how the amount of coverage was determined.

[3] The third offeror's proposal was evaluated as technically unacceptable and the fourth offeror withdrew its proposal after making its oral presentation.

(3) Proof of a guaranteed 20-year non-cancellable insurance policy from the insurance provider(s) shall be provided. This documentation shall clearly state the estimated cost of the coverage, the amount of the coverage, exactly what the coverage includes, and payment terms.

Amendment No. 5 also revised section F of the solicitation by stating that proof of insurance associated with section H.14 was to be delivered prior to conducting the clinical trials.

On June 19, the contracting officer established a competitive range comprised of the Novavax and OraVax offers. Oral discussions were conducted and final proposal revisions (FPR) were requested on June 22. Both FPR requests attached copies of Amendment No. 5 and asked the offerors to provide evidence of indemnification/insurance in accordance with that amendment.

During discussions, Novavax informed the agency that the major insurers of coverage for a large-scale, high-risk pharmaceutical project such as this were unavailable to Novavax because the market had been "locked up" by a competitor. Affidavit of Novavax's Vice President of Project Development at ¶ 10. Novavax asserted that insurers generally form a consortium to provide the coverage capacity required for such projects and the consortium insurers will provide only one quotation on the project. That quotation is specific to the project and not dependent upon the pharmaceutical company that will perform the work, assuming that each relevant company is an established entity of sufficient reputation. Once one of the insurers issues a quotation to one company, none of the insurers will provide any information to any other company--the market "locks up." When the contract for the project is awarded, the insurers open the market to the firm that wins the competition and make the quotation available to that firm. Id. at ¶ 6.

On July 19, the CDC issued Amendment No. 6 to again revise section H.14. The sole revision made by the amendment is highlighted in bold below:

> The Contractor shall indemnify or shall obtain insurance to indemnify, defend and hold harmless the Government from any claims and cost resulting from acts, omissions, and mishandling of the vaccine. The [indemnification]/insurance coverage obtained shall include 1) clinical trials – adults; 2) clinical [trials] – pediatrics; 3) use in at risk laboratorians; 4) use in immuno-compromised individuals and pregnant women; and 5) use in emergency situations. **The [indemnification]/insurance shall be obtained prior to initiation of the clinical trials. A non-cancellable policy for the 20-year life of the contract is preferred.**

Both offerors submitted FPRs by the July 24 closing date. The TEP evaluated the FPRs and concluded that OraVax's proposal met the absolute criterion regarding indemnification/insurance. The TEP evaluated the technical revisions proposed by OraVax, raised its technical score to 96 points, and ranked its proposal as technically superior. In contrast, the TEP concluded that Novavax's proposal failed to meet the absolute criterion and ranked its proposal as technically unacceptable. Since Novavax's proposal was found to be technically unacceptable on this basis, the TEP did not evaluate the firm's proposed technical revisions.

On August 8, the contracting officer eliminated Novavax's proposal from the competitive range for a second round of discussions based on its failure to meet the absolute criterion. As discussed below, the contracting officer agreed with the TEP's conclusion that Novavax's proposal failed to provide adequate indemnification/insurance coverage and failed to provide a liability risk assessment to include the total amount of liability coverage/cost required to indemnify the government over the life of the contract. The contracting officer acknowledged that Novavax's FPR stated that the industry standard was to release quotations to only one broker/insured party at a time and that the capacity of the market would be available to Novavax if it were awarded the contract. The contracting officer stated that, assuming this to be the case, if Novavax had included the risk assessment requested, the government could have concluded that the firm had a basic understanding of the amount of coverage and the associated costs required to indemnify the government for the life of the contract. This information was not submitted. Second Competitive Range Determination at 2-3.

Novavax filed its initial protest in our Office after its debriefing. The agency subsequently determined that urgent and compelling circumstances that significantly affect interests of the United States would not permit waiting for the decision of this Office concerning the protest and executed an "urgent and compelling circumstances" override of the statutory stay of OraVax's performance of this contract. See 31 U.S.C. § 3553(d)(3)(C)(i)(II) (1994). On September 20, OraVax was awarded the contract for an estimated $343,326,120. Novavax supplemented its protest after receiving the agency report. Novavax primarily alleges that the CDC improperly interpreted and applied the RFP's indemnification/insurance requirement as to both proposals and improperly eliminated its proposal from the competitive range.

DISCUSSION

The CDC explains that the immunological and epidemiological principles of smallpox protection and eradication are based on historical experience with the disease and its vaccines and are still in use today. What is different is the fact that tort liability and litigation concerns have altered the way medicine can be practiced, even in public health endeavors under emergency situations such as those contemplated here. Supplemental Report at 3. The indemnification/insurance

requirement was included to ensure that the government would be held harmless in case the new smallpox vaccine created liability due to an adverse event either during clinical trials or in case of a bioterrorist incident. The CDC characterizes the requirement as the most important hurdle in obtaining this contract; it was the sole pass/fail, or "absolute," criterion in this solicitation. Id. As the language of sections M.2 and H.14 of the RFP make clear, the CDC planned to evaluate the offerors' insurance proposals to assess their capability to provide a critical component of this project.

Evaluation of the Novavax Proposal

The CDC's request for Novavax's FPR asked the firm to "provide evidence of indemnification/insurance in accordance with Amendment No. 00005." In response, Novavax's technical FPR stated that the firm had secured a 20-year non-cancelable insurance policy of up to $[DELETED] million to indemnify, defend, and hold harmless the government from any claims and cost resulting from acts, omissions, and mishandling of the vaccine. Novavax stated that this coverage applied to each of the five categories set forth in section H.14. As it had stated during discussions, Novavax said that other insurers with the capacity to provide additional limits of coverage were unavailable to the firm due to the standard insurance industry practice of releasing quotations to only one broker/insured party, but that it would have the availability of these other markets after award. Novavax did not provide any information regarding how much additional coverage it would seek, nor did it explain how it would go about obtaining this additional coverage.

Novavax's evidence in support of these representations came in the form of two letters. The first letter, from an insurer, confirmed coverage of up to $[DELETED] million for the clinical trials and post-technology transfer phases. The letter listed various conditions to be satisfied prior to binding of coverage as well as several stipulations. The second letter, from an insurance broker, stated that the only coverage available to Novavax was the $[DELETED] million referenced above and repeated the firm's claims regarding the unavailability of quotations due to industry practice.[4]

The TEP concluded that Novavax's proposal was technically unacceptable because it failed to provide adequate coverage and failed to assess the total amount of coverage required to indemnify the government. The TEP stated that the firm's FPR only provided proof of a 20-year non-cancelable insurance policy in the amount of

[4] Novavax's business FPR provided pricing for the coverage it did obtain and included these same two letters as its sole backup documentation pursuant to section B.5(2) of the RFP.

$[DELETED] million to be in place prior to conducting clinical trials, which was an inadequate amount.[5] The TEP acknowledged Novavax's statement that other insurers that could provide additional limits of coverage were unavailable to it until and unless it were awarded the contract. The TEP stated, however, that Novavax's FPR failed to include a risk assessment estimating how much more coverage would be required and at what cost. According to the TEP, if Novavax had included such an assessment along with the information about the insurance industry practice of releasing quotations to only one broker/insured party at a time, the TEP could have concluded that the firm could provide the required coverage.

Novavax contends that it met the requirement to demonstrate its capability to provide indemnification/insurance in accordance with section H.14 by providing a firm quote for a 20-year non-cancelable insurance policy for $[DELETED] million covering all of the relevant categories, with assurances from its broker that more would become available when the market opened up to the winning offer. Novavax asserts that the CDC ignored the unrebutted facts concerning the unavailability of quotations and, instead, relied on the absence of unavailable data to conclude that Novavax's proposal was inadequate. Novavax charges that the CDC miscontrued its own requirements, failing to focus on exactly what section H.14 required.

It is not the function of our Office to evaluate proposals de novo. Rather, we will examine an agency's evaluation only to ensure that it was reasonable and consistent with the stated evaluation criteria and applicable statutes and regulations. Battelle Mem'l Inst., B-278673, Feb. 27, 1998, 98-1 CPD ¶ 107 at 14-15. A protester's mere disagreement with the agency's judgment does not establish that the evaluation was reasonable. Id. Where a dispute exists as to the actual meaning of a solicitation requirement, we will resolve the dispute by reading the solicitation as a whole and in a manner that gives effect to all provisions of the solicitation. Quality Elevator Co., Inc., B-276780, July 23, 1997, 97-2 CPD ¶ 28 at 5. Our review of the solicitation's provisions regarding the indemnification/insurance requirement shows that it is Novavax, not the CDC, that improperly construed what the RFP required.

Novavax asserts that the RFP did not require a "risk assessment" and characterizes the TEP's requirement of such an assessment as an unstated evaluation criterion. We do not agree.

Agencies are required to evaluate proposals based on the factors and significant subfactors specified in the solicitation. Federal Acquisition Regulation (FAR) § 15.305(a). However, in performing the evaluation, the agency may take into account specific, albeit not expressly identified, matters that are logically encompassed by the stated evaluation criteria. See Cobra Techs., Inc., B-272041,

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[5] The CDC's estimate of the coverage required was approximately $650 million. Declaration of the Project Officer at 3.

B-272041.2, Aug. 20, 1996, 96-2 CPD ¶ 73 at 3. Here, sections M.2 and H.14 of the RFP required offerors to demonstrate their "capability" to indemnify or obtain insurance to indemnify the government from "any claims and cost resulting from acts, omissions, and mishandling of the vaccine." In our view, an offeror cannot show that it is capable of obtaining insurance coverage to indemnify the government from the entire range of claims and costs that might arise from this vaccine project without demonstrating that it understands how much insurance coverage to obtain. A reasonably supported estimate of the government's exposure under this project is logically encompassed by the expansive language of this requirement. Section B.5(2) of the RFP makes this explicit by requiring that pricing for this insurance be accompanied by backup documentation which includes a "written justification as to how the amount of coverage was determined."

OraVax met this requirement by submitting a detailed risk assessment to estimate how much insurance coverage would be necessary in order to indemnify the government from the entire range of costs and claims that might arise under this vaccine project; the CDC states that there may have been other ways to meet the requirement. We do not agree with the protester that the TEP's references to a "required" risk assessment means that its proposal was evaluated against the detailed risk assessment submitted by OraVax. The TEP's use of this term to describe the information it was evaluating is explained by the fact that OraVax was the only offeror that submitted the information, which happened to be in the form of a risk assessment. While we agree that OraVax may have submitted more information than the RFP required, there is no question but that Novavax submitted less information than the RFP required. The TEP acted reasonably in evaluating its proposal accordingly.

Novavax also incorrectly asserts that the CDC improperly evaluated its proposal as offering only $[DELETED] million in coverage when it actually offered $[DELETED] million plus whatever else the market would have available. The record shows that the CDC knew very well what Novavax was offering but believed it was insufficient. There is no dispute that $[DELETED] million in coverage is a fraction of the amount of coverage that would be required to indemnify the government for the range of costs and claims that might arise over the course of this contract. Notwithstanding this undisputed fact, Novavax's proposal contained no information whatsoever that would allow the agency to ascertain that the firm knew how much additional coverage to seek and why. The firm's mere promise to obtain additional limits of coverage does not demonstrate its capability to obtain the appropriate amount of coverage.

Novavax's complaint that it could not obtain detailed information about the insurance available for this project because the market was "locked up"--and thus

that the RFP in effect was defective because it required submission of information only one offeror could obtain--is untimely.[6]

The solicitation clearly required offerors to demonstrate their capability to obtain insurance to indemnify the government from not just $[DELETED] million in costs and claims, but from the entire range of costs and claims that might arise under this vaccine project.[7] The record shows that, prior to the closing date for submission of FPRs, Novavax believed that the insurance market was "locked up." If Novavax believed that the nature of the insurance market precluded it from providing the information required by the solicitation, it was required to protest this issue prior to the closing date for receipt of FPRs. 4 C.F.R. § 21.2(a)(1) (2000); see Southern Research, B-266360, Feb. 12, 1996, 96-1 CPD ¶ 65 at 3. The firm's failure to protest prior to that date precluded the possibility that corrective action could be taken, if warranted, before the expenditure of time and effort. An offeror cannot learn of what it views as a requirement that cannot be met and continue to compete on that basis without objection, and then complain when it is not selected for award. See Southern Research, supra; see also Datron Sys., Inc., B-220423, B-220423.2, Mar. 18, 1986, 86-1 CPD ¶ 264 at 7.[8]

In any event, we do not believe that the standard industry practice referred to by Novavax should have been an impediment to providing the information that was both required by the RFP and the critical reason for the TEP's finding that Novavax's proposal was technically unacceptable--a reasonably based assessment of how much coverage would be necessary to fully indemnify the government.

Prior to the issuance of the solicitation, the CDC estimated the amount of coverage that would be required based on publicly available information regarding claims and awards data from the National Vaccine Injury Compensation Program (VICP).[9] Independently, OraVax reviewed publicly available reference material on previously

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[6] The intervenor vigorously disputes Novavax's assertion that the insurance market was "locked up."

[7] Novavax's allegation that a latent ambiguity in the indemnification/insurance requirement led it to reasonably interpret the solicitation as permitting its submission of such scant information is unsupported.

[8] For this same reason, Novavax's allegations that the CDC conducted inadequate market research and a de facto sole-source procurement are also untimely.

[9] The VICP was established by the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 et seq. (1994), as a no-fault alternative to the tort system for resolving claims resulting from adverse reactions to mandated childhood vaccines. VICP Home Page at <http://bhpr.hrsa.gov/vicp/abdvic.htm>.

used smallpox vaccines and their associated complications to assess the frequency of significant adverse reactions based on historical or projected incidents and made certain stated assumptions regarding the costs of such adverse reactions. This information, which was included in the firm's FPR, was provided to its insurers to obtain coverage information. This same publicly available information was available to Novavax, which could have made its own assumptions regarding the government's exposure and the level of insurance coverage that should be sought. The firm failed to avail itself of these resources and is responsible for the consequences.

Finally, Novavax contends that the CDC obtained enough information regarding the insurance market from the OraVax proposal to determine that Novavax could meet the requirements. The protester cites in particular the decision in Integrated Sys. Group, Inc., GSBCA No. 11156-P, Apr. 29, 1991, 91-2 BCA ¶ 23,961, for the proposition that the government must make use of information available to it in one proposal that is relevant to the evaluation of another proposal.

As an initial matter, the CDC was apparently willing to accept the firm's representations that it could not obtain this information but found Novavax's proposal technically unacceptable because it failed to provide for a sufficient amount of coverage or to submit any kind of assessment as to how much insurance coverage it would seek in order to fully indemnify the government. In this regard, the fact that OraVax demonstrated that it was capable of sifting the available data to ascertain the government's exposure in order to seek the appropriate level of coverage from its insurers sheds no light at all on the capability of Novavax to do the same thing. The case of Integrated Systems Group is inapposite here. In that case, the agency eliminated an offer for computer processors from the competitive range because it failed to include information showing that the processor met the solicitation's requirements. The Board held that the agency could rely upon the information submitted by another offeror, who had proposed the identical computer processor, in evaluating both proposals since to do otherwise would turn a procurement designed to supply the agency with compliant computer hardware into a test of which offerors have the most able computer analysts. Integrated Sys. Group at 122,541. Here, the agency is not procuring a fungible commodity such as computer processors, but is assessing the capability of the offerors to provide a critical component of this project. The two are not interchangeable.

Evaluation of the OraVax Proposal

Novavax contends that OraVax's proposal also does not meet the solicitation's requirements. It is not entirely clear to which requirements Novavax refers but, as noted above, the RFP requires the offeror to show that it is "capable" of "obtaining" insurance to indemnify the government for the entire range of costs and claims that might arise under this vaccine project. There are no more specific requirements beyond the five non-exclusive categories set forth in amendment No. 6, and offerors are not required to submit proof of insurance until prior to initiating clinical trials,

which can only occur after the new vaccine is developed and licensed. The general nature of this requirement affords the agency substantial latitude in determining whether or not a proposal is technically acceptable. Our review of the record shows that the agency reasonably determined that OraVax's proposal was technically acceptable.

In its FPR, OraVax estimated the level of the government's exposure and proposed a "tower" of insurance coverage to meet that level. For the first $100 million of coverage, OraVax stated that it had obtained firm commitments from three underwriters for an aggregate of $100 million of 20-year non-cancelable insurance for the required indemnification and included these quotations. For liability in excess of the first $100 million, OraVax said that its brokers were actively negotiating an additional $150 million of insurance on a 3-year rolling basis, and the terms for the first $100 million had been negotiated with a lead underwriter and were awaiting final approval. OraVax's FPR described several conditions set forth in these proposed policies. OraVax also included alternative proposals it had received from other insurers to address liability in amounts that exceeded the first and second tiers of insurance coverage in case informed consent was not used to limit liability.

The TEP concluded that OraVax's FPR met the RFP's requirements. The TEP stated that the firm provided proof of insurance for a non-cancelable 20-year policy for $100 million of coverage to be in place prior to conducting clinical trials, and provided commitment letters from three underwriters to provide an additional $550 million of coverage to be obtained prior to trials. This additional coverage was comprised of two 3-year rolling policies that automatically renewed unless certain conditions occurred, and a 20-year non-cancelable policy for $400 million. The TEP stated that this brought the obtainable insurance to $650 million and noted that OraVax had also provided an alternative proposal using informed consent which would require coverage of only $225 million.

Novavax contends that OraVax's proposal did not cover use in immuno-compromised individuals and pregnant women or use in emergency situations as required by amendment No. 6. However, OraVax's FPR states that the lead underwriter for its $100 million of coverage had accepted the language of amendment No. 6. That language includes the requirement that the coverage obtained shall include use in immuno-compromised individuals and pregnant women and use in emergency situations. OraVax's representation is supported by a letter from its insurance broker, who goes on to say that he is arranging for the other two underwriters for the first $100 million of coverage to see the new clause and obtain their agreement to it. The FPR indicates that OraVax's insurance broker was actively negotiating the excess liability coverage, and there is no indication that this coverage would exclude any required category. In our view, the information contained in OraVax's FPR is sufficient to show its capability to obtain insurance in accordance with the RFP's requirement.

Novavax next contends that the OraVax proposal contains conditions that were not faulted while the CDC criticized its proposal for its conditions. The solicitation did not prohibit conditions on the insurance coverage to be obtained. The general nature of the requirement gave the TEP substantial latitude to review such conditions and to consider whether they affected the proposal's technical acceptability. Both FPRs included conditions to their insurance coverage and neither set is comparable to the other. Our review of the record shows that the protester has mischaracterized some of the conditions in the OraVax proposal and we are not persuaded that any of the conditions required a finding of technical unacceptability. In contrast, the CDC has stated without rebuttal that one condition in the Novavax proposal--[DELETED]--was in and of itself so unacceptable that the proposal could have been rejected on that basis alone. Agency Supplemental Report at 17.

Novavax also asserts that the CDC mistakenly determined that OraVax was offering an additional $150 million of insurance from two brokers and an additional $400 million of insurance from another insurer when there were no firm commitments from these sources. The TEP's mistaken use of the term "commitment letters" in this context is of no moment because the RFP did not require offerors to submit evidence of firm commitments from insurers at the time of FPR submission. Offerors were only required to show that they were capable of obtaining the appropriate insurance coverage. Here, the record shows that OraVax was in active negotiations with specifically identified insurers to obtain this excess coverage and, given the general nature of the requirement, we cannot conclude that more was required.

Finally, Novavax asserts that the CDC incorrectly determined that OraVax provided the necessary liability risk assessment. Novavax faults the assessment for using data associated with the [DELETED] vaccine, which is not the vaccine to be used here, and for using data from the [DELETED], because the [DELETED] does not apply to this project. Novavax contends that neither source of data provides any particular guidance here and the assessment is speculative. Novavax's position is unsupported by the record.

Section C.4.1.d. of the RFP requires the contractor to establish vaccine equivalency to the currently approved vaccinia vaccine in accordance with existing FDA requirements. The agency's supplemental report included an affidavit from OraVax's Executive Vice-President, who states that [DELETED]. Affidavit ¶ 21; see also RFP § C.4.1.a.(3). The [DELETED] vaccine was commonly used during the time smallpox vaccination was routine. Agency Supplemental Report at 16. Novavax has not provided us any basis to disagree with the agency's conclusion that it is reasonable to infer that data concerning adverse events associated with the [DELETED] vaccine is a valid indicator of the expected risks to be encountered here. Similarly, while the [DELETED] does not directly apply to this vaccine project, its data includes information regarding monetary awards for vaccine-related bodily injury. Novavax

has provided us with no basis to disagree with the agency that this would be useful data to indicate likely amounts of recovery from vaccine-related injuries.

Competitive Range Determination

Novavax contends that the CDC violated Health and Human Services Acquisition Regulation (HHSAR) § 315.609 in eliminating its proposal from the competitive range because it failed to consider whether there was "no real possibility" that Novavax could improve its proposal to become the most acceptable proposal.

The FAR language that currently governs the establishment of a competitive range can be found in section 15.306(c)(1), which states, "Based on the ratings of each proposal against all evaluation criteria, the contracting officer shall establish a competitive range comprised of all of the most highly rated proposals, unless the range is further reduced for purposes of efficiency pursuant to paragraph (c)(2) of this section." The intent of this language was to permit a competitive range more limited than under the prior "reasonable chance of being selected for award" standard.[10] The explanatory preamble published at the time the current version of FAR Part 15 was issued states that the drafters had elected to require contracting officers to retain in the competitive range "only" the most highly rated offers rather than include in that range the potentially broader range of proposals that could be viewed as having a reasonable chance of award. 62 Fed. Reg. 51,224, 51,226 (1997); see SDS Petroleum Prods., Inc., B-280430, Sept. 1, 1998, 98-2 CPD ¶ 59 at 5.

In contrast with FAR § 15.306(c), HHSAR § 315.609(a) provides that "a proposal must be included in the competitive range unless there is no real possibility that it can be improved to the point where it becomes the most acceptable." Read literally, this language seems inconsistent with the entire concept of a competitive range--which contemplates a selection by the contracting officer of the proposals which, as they stand at the time, have a reasonable chance of award--since in almost every case there could be a "reasonable possibility" for a proposal to be so improved if the offeror is given enough opportunities and assistance. In our view, it would be unreasonable to interpret the HHSAR provision to effectively deprive HHS contracting officers--in any and all cases--of the authority to establish a more limited competitive range. Rather than such a literal interpretation, we think the HHSAR provision is more reasonably read to allow exclusion of proposals that are not among the most highly rated because, for example, they would require a substantial rewrite. This interpretation both gives effect to the language in the HHSAR provision

[10] The earlier language, FAR § 15.609(a) (June 1997), stated that the competitive range "shall include all proposals that have a reasonable chance of being selected for award" and that "[w]hen there is doubt as to whether a proposal is in the competitive range, the proposal should be included."

and is consistent with the fundamental concept of the competitive range in the FAR.[11]

The evaluation of proposals and the resulting determination as to whether a particular offer is in the competitive range are matters within the discretion of the contracting agency, since it is responsible for defining its needs and determining the best method of accommodating them. Laboratory Sys. Servs., Inc., B-256323, June 10, 1994, 94-1 CPD ¶ 359 at 2. Where a proposal is technically unacceptable as submitted and would require major revisions to become acceptable, the agency is not required to include it in the competitive range. Chant Eng'g Co., Inc., B-281521, Feb. 22, 1999, 99-1 CPD ¶ 45 at 3-4; Laboratory Sys. Servs., Inc., supra.

Here, we have already concluded that the TEP reasonably evaluated Novavax's proposal as technically unacceptable and hence not among the most highly rated proposals. While the contracting officer did not use the language referenced in the HHSAR provision, our review of the record shows that her determination was consistent with our understanding of its provisions. We agree with the agency's explanation in its supplemental report that the informational deficiency in Novavax's proposal was so material that it could not be adequately addressed without a substantial rewrite of the indemnification/insurance portion of its proposal, and that the proposal was reasonably eliminated from the competitive range.[12] Such a finding is expressly permitted by HHSAR § 315.609(h)(4) ("the contracting officer shall conduct a thorough review of the technical evaluation report to be assured that unacceptable proposals contain 'information' deficiencies which are so material as to preclude any possibility of upgrading the proposal to a competitive level except through major revisions and additions which would be tantamount to the submission of another proposal").

Novavax asserts that it was eliminated from the competitive range based on this "narrow aspect" of the solicitation, and that the main focus of the RFP was the effective manufacture, development, and stockpiling of a smallpox vaccine. The firm

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[11] By separate letter dated today we have advised the HHS Secretary of our view regarding the language contained in the agency's regulation.

[12] While Novavax contends that the agency's explanation is an improper post hoc rationale for excluding its proposal from the competitive range, citing Boeing Sikorsky Aircraft Support, B-277263.2, B-277623.3, Sept. 29, 1997, 97-2 CPD ¶ 91 at 15, post-protest explanations that provide a detailed rationale for contemporaneous conclusions, as is the case here, will generally be considered in our review of the rationality of selection decisions so long as those explanations are credible and consistent with the contemporaneous record. See Jason Assocs. Corp., B-278689 et al., Mar. 2, 1998, 98-1 CPD ¶ 67 at 6-7.

essentially contends that it need only provide additional supporting documentation to render its proposal technically acceptable. We do not agree.

First, Novavax's attempt to downplay the importance of this requirement is not supported by the record. As noted earlier, the CDC characterizes this requirement as the most important hurdle in obtaining the contract and it was the sole pass/fail, or "absolute," criterion in the solicitation. Indeed, during pre-solicitation industry exchanges, both Novavax and OraVax were informed that the liability requirement was the "biggest issue."

Second, as discussed above, the indemnification/insurance requirement required offerors to submit both a reasonably supported estimate of the government's exposure and an actual plan for obtaining the requisite coverage. The record shows that meeting this requirement involved substantial effort and action on the part of the offeror. There is no indication in the Novavax proposal that the firm performed any analysis of the government's exposure. We are not persuaded that it is possible to meet the requirement by simply submitting some unspecified documentation; work, analysis, and time are necessarily involved. Moreover, the record suggests that having such an assessment in hand is just the first step on the way to obtaining an adequate insurance plan to meet the solicitation's requirements. Obtaining this plan, even at the minimal level required by the solicitation, also takes work, analysis, and time. Novavax's insurance proposal addresses a fraction of the required level of coverage and would have to be completely rewritten in order to adequately address the solicitation's requirements. As a result, we cannot conclude that the contracting officer unreasonably excluded Novavax's proposal from the competitive range. See Chant Eng'g Co., Inc., supra.

The protests are denied.

Anthony H. Gamboa
Acting General Counsel