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Decision

Matter of: Emergent BioSolutions Inc.

File: B-402576

Date: June 8, 2010

Jason A. Carey, Esq., Dana B. Pashkoff, Esq., and Susan Cortis Hill, Esq., McKenna Long & Aldridge LLP, for the protester.

Philip J. Davis, Esq., John R. Prairie, Esq., and Brian G. Walsh, Esq., Wiley Rein LLP, for PharmAthene, Inc., an intervenor.

Christopher M. Johnson, Esq., and Jonathan A. Baker, Esq., Department of Health and Human Services, for the agency.

Louis A. Chiarella, Esq., and Christine S. Melody, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

DIGEST

Protest that modification of contract for advanced development, testing, and production of anthrax vaccine was outside the scope of the original contract is denied where modification did not substantially alter the scope of work anticipated by the underlying solicitation.

DECISION

Emergent BioSolutions Inc., of Rockville, Maryland, protests the issuance of modification 0018 to contract No. N01-AI-30052 by the Department of Health and Human Services (HHS), Biomedical Advanced Research and Development Authority (BARDA), to PharmAthene, Inc., of Annapolis, Maryland, regarding the development and manufacture of a recombinant protective antigen (rPA) anthrax vaccine.¹

¹ The term “recombinant” refers to a product created using a genetic engineering technology in which one or more pieces of DNA are combined together. A protective antigen is a biochemical that produces an immunologic response that then protects animals or humans against challenges from the infectious agent. PharmAthene Comments, Apr. 12, 2010, attach. 2, GAO, Project BioShield: Actions Needed to Avoid Repeating Past Problems with Procuring New Anthrax Vaccine and Managing the Stockpile of Licensed Vaccine, GAO-08-88 (Washington, D.C.: Oct. 23, 2007) (GAO Project BioShield Report), at 1 n.1; Agency Report (AR), Tab 2, Project Officer’s Declaration, Apr. 1, 2010, at 2.

Emergent contends that the modification in question is beyond the scope of the original contract, and thus amounted to an improper sole-source award to PharmAthene.

We deny the protest.

BACKGROUND

The anthrax attacks in September and October 2001 raised significant concerns regarding the United States' preparedness to respond to health emergencies that threaten national security. Hearing Transcript (Tr.) at 48.² In response to the anthrax attacks, HHS launched an effort to rapidly develop a second generation, rPA anthrax vaccine.³ The PharmAthene contract and modification subject to protest here represent a part of that HHS effort.

Vaccines are complex biological products given to a person or animal to stimulate an immune reaction the body can "remember" if it is exposed to the same antigen later.⁴ GAO Project BioShield Report, supra, at 12. In contrast to most drugs, vaccines have no simple chemical characterization. As a result, testing and evaluating vaccines involves measuring their effects on living organisms, and their quality can be guaranteed only through a combination of in-process tests, end-product tests, and strict controls over the entire vaccine manufacturing process. Id.

The development of medical countermeasures, such as vaccines, is comprised of various stages of scientific research: (1) basic discovery research and development; (2) advanced development; and (3) late stage development. In the basic discovery research and development stage, universities, biotechnology companies, and pharmaceutical companies do basic research that leads to candidates that could be considered for further evaluation. The first stage also involves pilot-scale manufacturing efforts. Once sufficient data have been gathered, the basic discovery research and development stage culminates with the product developer submitting

² Our Office conducted a hearing, during which testimony was presented regarding the issues raised in the protest.

³ The first generation licensed anthrax vaccine is anthrax vaccine adsorbed, or BioThrax. It is currently used by the United States military and is administered in five doses prophylactically. BioThrax is licensed and manufactured by Emergent. Id. at 50-53.

⁴ In contrast to drugs, which are generally small molecules of 20 to 100 atoms, vaccines are very large, complex molecules or mixtures of molecules; the rPA anthrax vaccine consists of approximately 83,000 atoms. Emergent Comments, Apr. 15, 2010, exh. 1, Declaration of Emergent Vice President, Apr. 15, 2010, at 2-3.

an investigational new drug (IND) application to the Food and Drug Administration (FDA) for acceptance. Tr. at 65.

The advanced development stage takes an IND-accepted candidate through Phase 1 and Phase 2 clinical testing. In Phase 1, clinical testing is performed on a relatively small number of healthy adults (20-50) with the primary purpose being to determine whether the candidate is safe. Id. By contrast, the primary purpose of Phase 2 clinical testing is to determine whether the candidate is also effective. At the hearing conducted by our Office, the Director of BARDA's Chemical, Biological, Radiological and Nuclear Medical Countermeasures Division summarized the Phase 2 clinical testing process as follows:

If you complete a successful Phase 1 clinical trial, you then enter into Phase 2 clinical testing. You also start developing a more robust manufacturing process. You start developing tests and assays that will enable you to eventually validate the manufacturing process.⁵ As you move down progressively through the development pipeline, you submit at a certain point in time a protocol to the FDA for entry into what's known as a Phase 2 dose finding study. A dose finding study is designed so that you can determine the optimal dose when given to a healthy adult that will elicit what we think is a protective immune response. That's typically called Phase 2A. Phase 2B is when you take a relatively larger population, hundreds of healthy adults, and you vaccinate them with that optimal dose determined in 2A.

Throughout that whole process of clinical testing, there is a concurrent process, as I alluded to, of process validation. And in essence, what – how the FDA defines that is the documented evidence that the manufacturing process that you're developing for Phase 3 clinical testing is well controlled, consistent and robust, and the material that is eventually manufactured through that process can be released according to predetermined specifications. So at the end of process validation, what one does is run what are known as three consistency lots. That is the ultimate test as to whether you've validated your process. These are done at scale, using the protocols, the standing operating procedures that will eventually be used to launch the product into the market. Those consistency lots are tested both in the laboratory, they are characterized, they are tested in animals, and they're tested eventually in the large Phase 3 trial.

Id. at 66-67.

⁵ An assay is a procedure for testing and/or measuring the activity of a drug or vaccine in an organism or organic sample. Tr. at 296.

The subsequent late stage development occurs after Phase 2 clinical testing has been completed, and includes large-scale manufacture, Phase 3 clinical trials (involving thousands to tens of thousands of individuals), and the submission of an application for licensure to the FDA. *Id.* at 42, 67-68.

The development of medical countermeasures such as vaccines is extensively regulated by the FDA. The FDA has developed guidelines that vaccine developers must follow in all stages of development in the areas of animal testing, human testing, and assay development. Further, with regard to manufacturing process development, the FDA has established current good manufacturing practices (cGMP). cGMP represent the manufacturing standards applicable to all drugs and vaccines. cGMP are not a static set of regulations; rather, as the FDA interacts with drug developers and learns what current good practices are, the FDA then imposes on other developers those same standards. AR, Tab 2, Project Officer's Declaration, Apr. 1, 2010, at 2; Tr. at 68-69.

In September 2002, HHS awarded a contract to PharmAthene for Phase 1 clinical testing related to the development of an rPA anthrax vaccine (the "Phase 1" contract). The Phase 1 contract, which was to be completed by September 2003, represented the first step in the advanced development stage of rPA anthrax vaccine. HHS also awarded a similar Phase 1 contract to Emergent.⁶

On May 23, 2003, HHS issued request for proposals (RFP) No. RFP-NIH-NIAID-DMID-03-29. The RFP contemplated the award of one or more cost-plus-fixed-fee contracts for the continued advanced development, testing, and production of rPA anthrax vaccine. The RFP included Federal Acquisition Regulation (FAR) clause 52.243-2, Changes–Cost Reimbursement (Alternate V), applicable to research and development contracts. The RFP also stated that the purpose of the procurement was to continue the advanced development and production of an rPA vaccine, suitable for licensure, to protect the general United States population against inhalation anthrax when administered in an immunization series of not more than three doses.⁷ AR, Tab 5, RFP at 3.

⁶ The rPA anthrax vaccine development contracts here were actually awarded to the predecessor companies of both PharmAthene and Emergent. Protest, Mar. 3, 2010, at 4. For ease of reference, however, this decision will refer only to the eventual successors-in-interest, PharmAthene and Emergent.

⁷ The solicitation also stated that "[a]lthough it was not the intent of this RFP to progress an rPA anthrax vaccine to [FDA] licensure, the clinical and animal studies proposed in response to this RFP were to be those required for a licensure path and consistent with intermediate-scale manufacturing" AR, Tab 5, RFP at 3.

In addition to its stated purpose, the RFP established six performance objectives that a successful offeror was to accomplish, as follows:

- a) Manufacture, formulate, fill, finish, release, and deliver to the government as single doses, up to [3–5 million] doses of rPA anthrax vaccine from at least three (3) current cGMP consistency lots. This cGMP manufacturing shall be preceded by transfer of assay and process technologies, process development and validation and engineering runs sufficient to ensure production of at least three cGMP consistency lots suitable for Phase 3 trials and acceptable to the FDA.
- b) Develop and validate product release and characterization criteria, serological assays and reagents that shall ultimately support [Biologics License Application (BLA)] submission and product licensure.
- c) Develop, implement and execute accelerated and long-term stability testing programs that shall ensure the safety, sterility, potency and integrity of the IND vaccine inventory.
- d) Store, maintain, and replenish the rPA vaccine inventory, as necessary, through the end of this contract.
- e) Conduct preclinical and clinical testing to assure the safety and efficacy of the initial and stored vaccine inventory, and to obtain data that shall contribute to submission of a . . . BLA to the . . . FDA. Preclinical testing shall include two well-characterized, appropriate animal models with *B. anthracis* spore aerosol challenge to enable correlation of efficacious immune response in animals to immune response in man. These models shall continue to be refined such that data provided from future pivotal studies [shall] be adequate to support vaccine licensure under the animal rule.
- f) Conduct initial Phase 2 clinical trials.

Id. at 3-4.

The RFP also established, consistent with the performance objectives, 17 specific milestones that an awardee was to accomplish. For example, Milestone 4 required the contractor to complete development and validation of all assays necessary for product characterization, release, and potency evaluation, while Milestone 16 required the contractor to complete the stability testing plan for drug substance and drug product. Id. at 6-8. While the objectives represented the higher level, broader contract requirements, the milestones detailed, at a lower level, the various steps the contractor would have to accomplish to meet the objectives. Tr. at 298. The RFP also stated that the milestones provided an awardee with the ability to refine its

processes and plans after award based on consultations with HHS and FDA. AR, Tab 5, RFP at 9.

The RFP included a 3-year period of performance beginning on or about September 24, 2003. AR, Tab 5, RFP at 1. The intent of the RFP was to have an “accelerated development effort” in which the contractor, contracting agency, and FDA worked as a team to shepherd the rPA anthrax vaccine program through the regulatory and development process. Tr. at 47, 77-78. The RFP’s 3-year schedule was, at best, very optimistic; in this regard, it was generally known in the biotech industry that the 3-year schedule was not realistic for the scope of work to be accomplished. See GAO Project BioShield Report, supra, at 15 n.24.

On September 29, 2003, HHS awarded PharmAthene a contract for the continued development of an rPA anthrax vaccine, as well as the production, testing, and release of 3 million doses made from at least three cGMP consistency lots (the “Phase 2” contract).⁸ The Phase 2 contract awarded to PharmAthene had a total estimated cost of \$71,292,000 and a 3-year period of performance—from September 30, 2003 to October 13, 2006.⁹ AR, Tab 8, PharmAthene Phase 2 Contract.

From 2003 to 2009, HHS modified PharmAthene’s Phase 2 contract on 17 occasions prior to the modification which Emergent now protests. Some of these modifications were administrative in nature (e.g., novation agreements). Other modifications involved no change in contract cost or performance period, but increased the amount of contract funding. Additionally, HHS executed several intervening modifications to account for PharmAthene’s increased costs and/or performance delays, including changes in FDA regulations and recommendations, various setbacks to the development effort (e.g., failure of validation of potency assay, bacteriophage contamination (viral infection) of large scale manufacture of

⁸ The scope of work (i.e., objectives and milestones) of PharmAthene’s Phase 2 contract was identical to that of the underlying solicitation with one exception: while the RFP required a range of 3–5 million vaccine doses be manufactured and delivered, PharmAthene’s contract required that 3 million doses be manufactured and delivered.

⁹ HHS also awarded Emergent a Phase 2 rPA anthrax vaccine development contract. Notwithstanding the terms of the RFP, the Phase 2 contract awarded to Emergent had a 4-year period of performance—from September 30, 2003 to September 29, 2007. Id., Tab 44, Emergent Phase 2 Contract, at 1. Additionally, in November 2004, HHS awarded Emergent an \$877.5 million contract for the development, manufacture, and delivery of 75 million doses of its rPA anthrax vaccine. By December 2006, however, HHS had terminated both Emergent’s Phase 2 development contract and its 2004 production contract because of vaccine stability problems. Tr. at 258-59; GAO Project BioShield Report, supra, at 3, 18.

bulk drug substance), increased need for the oversight of subcontractors, technology transfer requirements, manufacturing facility changes, and additional studies. Id., Tab 18, Mod. 0008; Tab 19, Contracting Officer Memorandum, Aug. 3, 2006; Tab 23, Mod. 0010; Tab 24, HHS Request for Change to Active Contract, May 8, 2007; Tab 34, Mod. 0016; Tab 32, HHS Funding Request, Apr. 21, 2009; Tr. at 286-91. By November 20, 2009, PharmAthene's Phase 2 rPA anthrax vaccine development contract had a total estimated cost of \$117,736,200 and a completion date of June 30, 2011 (compared to the original estimated cost of \$71,292,000 and completion date of October 13, 2006). AR, Tab 36, Mod. 0017.

On December 29, 2009, HHS posted a notice in FedBizOpps announcing the agency's intent to again modify the PharmAthene Phase 2 contract. The notice contained a brief description of the planned contract modification, stating that the scope of work included "manufacturing activities, such as process scale up and validation, assay validation, and non-clinical safety assessment and study plans." HHS Dismissal Request, Mar. 10, 2010, attach. 1, HHS Special Notice, Dec. 29, 2009. The notice did not include either the size or the duration of the planned modification.

On January 12, 2010, Emergent submitted a statement of interest in response to the HHS notice; Emergent also stated its concern that the planned modification may be beyond the scope of the original contract. Id., attach. 2, Emergent Response to Special Notice, Jan. 12, 2010. Emergent subsequently requested a copy of the statement of work for the planned contract modification, which the agency elected not to provide. Id., attach. 3, Contracting Officer Email, Jan. 22, 2010.

On February 22, HHS issued modification 0018 to PharmAthene's Phase 2 rPA anthrax vaccine development contract. The modification increased the estimated contract cost by \$61,041,425--from \$117,736,200 to \$178,777,625--and extended the period of performance by 18 months--from June 30, 2011 to December 31, 2012. Modification 0018 also included three options for additional work, totaling an additional \$17,432,220. AR, Tab 39, Mod. 0018, at 1-3.

The scope of work for modification 0018 was comprised of seven milestones and related subtasks regarding the continued development, testing, and production of PharmAthene's rPA anthrax vaccine candidate. For example, Milestone 1 was "Stability Studies: Continuing and New," with the first subtask being "Ongoing [Bulk Drug Substance] Stability." Id. at 5. At the hearing held by our Office, the HHS Project Officer performed a detailed comparison, or "crosswalk," between the work requirements in modification 0018 and the work requirements in the original PharmAthene Phase 2 contract, as follows:

Starting with [M]ilestone 1, Stability Studies: Continuing and New. If you go back to the original statement of work and you look at Milestone 16, Milestone 16 requires the completion of the stability testing plan for drug substance and drug product. The milestone 1 in

modification 18, the stability studies required underneath this milestone are part of the stability testing plan for a drug substance and drug product. Both milestone 1 in modification 18 and milestone 16 in the original contract are required to meet objective C of the contract, which is the execution of the long-term stability testing program.

* * * * *

Milestone 2, the potency assay development and validation relates to [contract] objective B, the development and validation of product release and characterization criteria, including serological assays and reagents that shall ultimately support BLA submission and product licensure. The potency assays are a type of serological assay. They are used in product release and characterization and are required – the FDA has required that a potency assay be used to test the product to support its eventual BLA submission. Milestone 2 [of modification 0018] also corresponds to milestone 4 of the original contract . . . , where the contractor must complete development and validation of all assays necessary for product characterization, release and potency evaluation. The potency assays called for under milestone 2 of mod 18 are the assays that are required to complete milestone 4 of the original contract.

Tr. at 311-12, 317-18. This comparison continued for the other milestones within the modification as well. In sum, the HHS project officer testified that all aspects of the modification 0018 scope of work, including options, were already required by the objectives and milestones of PharmAthene’s Phase 2 contract, *i.e.*, that no aspect of the scope of work for modification 0018 went beyond the scope of work of the original contract. *Id.* at 310-40, 386-91, 422-28.

PharmAthene issued a press release announcing the receipt of modification 0018 (including its size and duration) on February 23, and Emergent filed its protest with our Office on March 3.

DISCUSSION

Emergent protests that modification 0018 exceeds the scope of the original contract, and that it therefore constitutes an improper sole-source award under the Competition in Contracting Act of 1984 (CICA), 41 U.S.C. § 253(a)(1)(A) (2006).¹⁰

¹⁰ Emergent’s protest challenges only the changes to the PharmAthene Phase 2 contract resulting from modification 0018, and not also the prior, intervening modifications. This decision thus addresses only whether modification 0018 was within the scope of the original competition and contract.

Emergent argues, among other things, that modification 0018 increases the size, scope, and duration of PharmAthene's Phase 2 rPA anthrax vaccine development contract such that the contract as modified is materially different from the contract as originally awarded.

As a preliminary matter, the agency argues that Emergent's protest here is untimely. Specifically, HHS contends that Emergent was aware of the agency's intent to modify the PharmAthene Phase 2 contract based on the notice issued on December 29, 2009, but did not file its protest with our Office until March 3, 2010, more than 10 days after the basis of protest was known. We disagree.

Under our Bid Protest Regulations, 4 C.F.R. § 21.2(a)(2) (2010), a protest based on other than an apparent solicitation impropriety must be filed not later than 10 days after the basis of protest is known or should have been known. Here, HHS's notice regarding modification 0018 did not provide Emergent with sufficient information to formulate a basis of protest; it consisted of only a very brief description of the types of work to be performed under the contract modification, and did not state either its size or duration. The record also shows that Emergent was unaware of these details prior to PharmAthene's February 23, 2010, press release. Given that a primary basis of the original protest was the magnitude of the contract price increase, and that Emergent's protest was filed within 10 days after learning of the cost magnitude of the modification, the protest is timely. See Defense Sys. Group et al., B-240295 et al., Nov. 6, 1990, 1990 U.S. Comp. Gen. LEXIS 1182 at *11-13; National Data Corp., B-207340, Sept. 13, 1982, 82-2 CPD ¶ 222 at 4.

Once a contract is awarded, our Office generally will not consider protests against modifications to that contract, because such matters are related to contract administration and are beyond the scope of our bid protest function. 4 C.F.R. § 21.5(a); DOR Biodefense, Inc.; Emergent BioSolutions, B-296358.3, B-296358.4, Jan. 31, 2006, 2006 CPD ¶ 35 at 6; Engineering & Prof'l Servs., Inc., B-289331, Jan. 28, 2002, 2002 CPD ¶ 24 at 3. An exception to this general rule is where, as here, a protester alleges that a contract modification is beyond the scope of the original contract, because, absent a valid sole-source determination, the work covered by the modification would be subject to the statutory requirements for competition. Lasmer Indus., Inc., B-400866.2 et al., Mar. 30, 2009, 2009 CPD ¶ 77 at 6; DOR Biodefense, Inc.; Emergent BioSolutions, supra.

In determining whether a modification triggers the competition requirements under CICA, we look to whether there is a material difference between the modified contract and the contract that was originally awarded. Engineering & Prof'l Servs., supra, at 4; AT&T Commc'ns, Inc. v. Wiltel, Inc., 1 F.3d 1201, 1205 (Fed. Cir. 1993). Evidence of a material difference between the modification and the original contract is found by examining changes in the type of work, costs, and performance period between the contract as awarded and as modified. Overseas Lease Group, Inc., B-402111, Jan. 19, 2010, 2010 CPD ¶ 34 at 3; Atlantic Coast Contracting, Inc.,

B-288969.2, June 21, 2002, 2002 CPD ¶ 104 at 4. We also consider whether the solicitation for the original contract adequately advised offerors of the potential for the type of changes found in the modification, and thus whether the modification would have materially changed the field of competition. See DOR Biodefense, Inc.; Emergent BioSolutions, *supra*; Atlantic Coast Contracting, Inc., *supra*.

As detailed below, we conclude that the record demonstrates that the scope of the original contract was not substantially changed by modification 0018, and thus the changes to the contract would not have had a substantial impact on the field of competition for the original contract award.¹¹

The RFP and resulting Phase 2 contract called for a research and development (R&D) effort. Unlike contracts for supplies and services, most R&D contracts are directed toward objectives for which the work or methods cannot be precisely described in advance; it is difficult to judge the probabilities of success or required effort for technical approaches, some of which offer little or no early assurance of full success. FAR § 35.002. Our decisions have recognized that additional latitude for modifying a contract may exist where the contract is for R&D work, noting that the scope of such contracts is often flexible because of unanticipated changes due to the lack of definitiveness of the government's requirements. DOR Biodefense, Inc.; Emergent BioSolutions, *supra*, at 7; Everpure, Inc., B-226395.4, Oct. 10, 1990, 90-2 CPD ¶ 275 at 4-5.

Additionally, the scope of work of the RFP and original PharmAthene Phase 2 contract was a broadly-defined one: the continued advanced development, testing, and production of rPA anthrax vaccine suitable for FDA licensure, as well as specific objectives and milestones that were to be accomplished in support thereof. Given this broad scope of work, we think the RFP and original contract reasonably contemplated that there would be developmental changes and setbacks during performance, including, as here, those resulting from changes in FDA guidance, manufacturing facility changes, technology transfer requirements, and additional studies. See AT&T Comm'ns, Inc. v. Wiltel, *supra*, at 1205-06 (a broad original

¹¹ In its initial protest, Emergent argued that modification 0018 triggered the competition requirements under CICA because of the increase in costs between the contract as awarded and as modified. Protest, Mar. 3, 2010, at 6. HHS specifically addressed this aspect of the protest in its report to our Office, AR, Apr. 5, 2010, at 9-11, and Emergent's comments offered no rebuttal of the agency's position. Emergent's Comments, Apr. 15, 2010, at 2-4, 21-32. Where, as here, an agency provides a detailed response to a protester's assertion and the protester does not respond to the agency's position, we deem the issue to have been abandoned. Remington Arms Co., Inc., B-297374, B-297374.2, Jan. 12, 2006, 2006 CPD ¶ 32 at 4 n.4; L-3 Commc'ns Westwood Corp., B-295126, Jan. 19, 2005, 2005 CPD ¶ 30 at 4.

scope of work may validate a broader range of later modifications without further competition).

The record also reflects that the original objectives of PharmAthene's Phase 2 contract have not changed, and that modification 0018 continues rather than alters the original contract objectives. As stated by the HHS project officer, "[t]he steps in [the] process have changed over time, but the end result has remained the same." Tr. at 293. We agree. Where the type of work under a contract as modified remains substantially unchanged, we do not view modifications of the technical requirements of performance to be outside the scope. Atlantic Coast Contracting, Inc., supra. Furthermore, a technical change to a contract should be viewed in the context of the contractor's obligations "as a whole." AT&T Comm'ns, Inc. v. Wiltel, supra, at 1206. Quite simply, given the broadly-defined, developmental nature of the PharmAthene Phase 2 contract requirements, we conclude that modification 0018 does not represent a material difference in the type of work from the original contract.

Further, we think that the solicitation for the original contract adequately advised offerors of the potential for the type of changes that occurred during the course of contract performance (*i.e.*, changes in processes and activities but not objectives), and that in the context of the type of R&D work at issue here, modification 0018 encompasses changes which the field of competitors could reasonably have anticipated. DOR Biodefense, Inc.; Emergent BioSolutions, supra, at 7; Engineering & Prof'l Servs., supra, at 4.

Emergent argues that the work requirements of modification 0018 are beyond the scope of work of the original contract in one particular regard. Specifically, the protester contends that the RFP expressly provided that the original contract would not fund animal aerosol challenge studies, yet modification 0018 now funds such studies. Emergent argues that, as a result, this work is out-of-scope and needs to be competitively procured.¹²

The original solicitation stated, in relevant part,

¹² Emergent alleged that a second aspect of modification 0018 (*i.e.*, gap analysis studies) also represented work beyond the scope of the original contract. Emergent Comments, Apr. 15, 2010, at 30-32. HHS addressed this aspect of the protest at the hearing, tr. at 445-46, and Emergent's post-hearing comments offered no rebuttal of the agency's position. Emergent Post-Hearing Comments, May 13, 2010, at 27-29. Similarly, Emergent alleged that modification 0018 made PharmAthene's rPA anthrax vaccine candidate a "new product." HHS addressed this aspect of the protest at the hearing, tr. at 196-98, 451-53, and Emergent's post-hearing comments offered no rebuttal of the agency's position. Emergent Post-Hearing Comments, May 13, 2010, at 5-29. Accordingly, we deem these protest issues to be effectively abandoned.

A critical component of an rPA vaccine database and licensure of any rPA vaccine will be controlled animal efficacy data and aerosol challenge data in relevant animal models. However, there is a worldwide shortage of Biosafety Level 3 aerosol challenge capacity . . . so it is therefore essential that this capacity be used as efficiently as possible to generate these crucial data. . . . Accordingly, [HHS] intends to directly fund the conduct of the aerosol animal challenge studies associated with this advanced rPA vaccine development effort through a separate contract with a separate contractor. . . . This close government/contractor relationship will enable efficient implementation of a comprehensive core of well-designed aerosol challenge studies that should provide quality data to support product licensure using the animal rule.

AR, Tab 5, RFP at 4.

Thus, while the objectives and milestones in the RFP required a successful offeror to design, construct, and analyze the animal aerosol challenge studies necessary for FDA product licensure, the offeror did not have to perform the actual studies itself. As HHS essentially made itself a subcontractor to a successful offeror with regard to the performance of the animal aerosol challenge studies, tr. at 242-44, the RFP informed offerors that they did not need to budget for the performance of animal aerosol challenge studies. By contrast, as part of modification 0018, PharmAthene is to perform such animal aerosol challenge studies.

In our view PharmAthene's performance of animal aerosol challenge studies does not materially change the nature of the original rPA anthrax vaccine development contract. The RFP and original contract already required PharmAthene to design and construct animal aerosol challenge studies, receive and evaluate the resulting data, and submit the data to the FDA as part of product licensure. What modification 0018 changed was who--PharmAthene or HHS--was to perform such animal aerosol challenge studies. We see no basis to conclude that this change materially altered the type of work required under the original contract, or would have affected the original field of competition.

Emergent also argues that modification 0018 improperly funds development work that was supposed to be completed by PharmAthene prior to award of the Phase 2 contract. Specifically, Emergent contends that the changes to PharmAthene's product and process are such that the contractor now needs to repeat various studies that were a prerequisite to Phase 2 contract award. Because these studies have not yet been performed, Emergent argues, PharmAthene's product would have been ineligible for award, and conducting studies that were prerequisites to award of the original contract is outside the scope of the contract.

The RFP established various “prerequisites for participation” for the Phase 2 contract, as follows: “offerors must have manufactured a cGMP pilot lot of bulk rPA, have produced filled and finished vialled rPA, and have completed a Rabbit toxicology safety and immunogenicity study.” AR, Tab 5, RFP at 4. PharmAthene completed all prerequisites required of offerors for award of the original Phase 2 contract (which Emergent does not dispute). Tr. at 503-05. As part of its changes in manufacturing facilities and product formulation, however, PharmAthene now plans to conduct, if determined necessary by the FDA, additional non-clinical toxicity and immunogenicity studies in rabbits. AR, Tab 39, Mod. 0018, at 8.

At the hearing conducted by our Office, the HHS project officer acknowledged that modification 0018 may require PharmAthene to repeat various activities that were prerequisites for award of the Phase 2 contract. Tr. at 507. However, the project officer explained the relationship between the original and additional studies as follows:

They do not replace the data or the information that was gained from the initial prerequisites that were completed. They are not intended to replace them in their entirety. They are intended to build upon that body of data in order to supply a complete picture of the vaccine candidate at this point in time.

* * * * *

The agency has required, as the manufacturing process has gone through development and changes have been made, that the test material that results from that manufacturing process be tested in animals to evaluate its safety, its efficacy, its immunogenicity. This is an iterative process, and the FDA requires that manufacturers show that their vaccine will work for its intended indication in animals.

Id. at 506-07.

We find no merit in Emergent’s argument. The agency awarded PharmAthene a Phase 2 rPA anthrax vaccine development contract in 2003, and the fact that PharmAthene may have to re-perform certain studies that were prerequisites in no way invalidates that original award decision. More importantly, we conclude that the various non-clinical toxicity and immunogenicity studies that PharmAthene again may have to perform are not beyond the scope of the original contract. As detailed above, the record shows that all milestones and subtasks within modification 0018, including the studies here, are required to fulfill the objectives and milestones of PharmAthene’s Phase 2 contract; the fact that such studies were also prerequisites does not alter that determination. Further, we see no basis to conclude that performance of these non-clinical toxicity and immunogenicity studies materially

changes the type of work required under the original contract, or the original field of competition.

Lastly, Emergent argues that modification 0018 is beyond the scope of the original contract because it disregards the accelerated development schedule, which was a critical requirement of the RFP and resulting contract awarded to PharmAthene. As set forth above, the RFP anticipated a 3-year period of performance, and modification 0018 extends the existing schedule by 18 months.¹³ HHS's decision to relax the contract's 3-year accelerated development schedule, Emergent argues, affected other firms within the original field of competition. Emergent Comments, Apr. 15, 2010, at 25-28.

Although we look to the performance period to determine whether a modification exceeds the scope of the original contract, time does not have the same degree of importance in every type of contract. Where, as here, a contractor is provided additional time to perform a contractual obligation, that modification does not necessarily constitute an out-of-scope change, unlike the situation where time is used to define the extent of the obligation, such as under a requirements contract. DOR Biodefense, Inc.; Emergent BioSolutions, supra; Defense Sys. Group et al., supra. Additionally, as discussed above, our decisions have recognized that research and development contracts may warrant additional latitude for changes to their performance terms, including duration, because the type of work under these contracts involves greater uncertainty. DOR Biodefense, Inc.; Emergent BioSolutions, supra (5-year extension of vaccine development effort was not an out-of-scope change of the original 10-year contract).

In any event, Emergent fails to establish how it was prejudiced by the relaxation of the contract's 3-year schedule. Competitive prejudice is an essential element of a viable protest, and where the protester fails to demonstrate prejudice, our Office will not sustain a protest. McDonald-Bradley, B-270126, Feb. 8, 1996, 96-1 CPD ¶ 54 at 3; see Statistica, Inc. v. Christopher, 102 F.3d 1577 (Fed. Cir. 1996). Here, the alleged relaxation in schedule requirements had no impact on Emergent's ability to compete originally; Emergent was both part of the original field of competition and was awarded a Phase 2 contract. While Emergent argues that the alleged relaxation of schedule requirements would have affected other offerors in the field of competition, the protester has not demonstrated how this alleged relaxation caused it any harm. See Armed Forces Hospitality, LLC, B-298978.2, B-298978.3, Oct. 1, 2009, 2009 CPD ¶ 192 at 9-10; Blackwater Lodge & Training Ctr., Inc., B-311000.2 et al., Nov. 10, 2008, 2009 CPD ¶ 66 at 3-4. Accordingly, there is no basis for finding that any relaxation of

¹³ While Emergent argues that modification 0018 extends the performance of PharmAthene's Phase 2 contract to 9 years, Emergent Comments, Apr. 15, 2010, at 25, the time extensions associated with earlier modifications (totaling 4 years, 8 ½ months) are not the subject of Emergent's protest here.

the schedule requirements relating to the rPA anthrax vaccine Phase 2 development effort resulted in any prejudice to Emergent.

The protest is denied.

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Acting General Counsel