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HHS Looks To Existing Procurement Tool For Ebola Drugs

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As the U.S. government works to address the threat posed by the Ebola virus, one tool available to the U.S. Department of Health and Human Services in this effort is a broad agency announcement (BAA) originally issued in 2009 as a means of accelerating the development of vaccines, therapeutics, and diagnostics to prevent and treat the disease.

On Oct. 16, for instance, the agency highlighted that BAA in announcing the award of an $8.6 million contract for the development of an experimental Ebola vaccine. That announcement came on the heels of another HHS award in September 2014 — this one worth $42.3 million — for the development of a separate drug to treat Ebola infections, ZMapp.[1] And, HHS officials have signaled a readiness to look to the BAA in order to identify other qualified technologies for additional awards to combat Ebola.

In a recent press release announcing that HHS is "seeking additional proposals" for the advanced development of Ebola treatments, Robin Robinson, the director of HHS' Biomedical Advanced Research and Development Authority (BARDA), vowed that the agency would "push[] hard to advance the development of multiple products as quickly as possible for clinical evaluation and future use in preventing or treating this deadly disease." For companies with an interest in assisting the government in its Ebola prevention and treatment efforts, a strong working understanding of the above-referenced BAA and its requirements is vital.

BARDA initially issued a BAA for advanced research and development of chemical, biological, radiological and nuclear (CBRN) medical countermeasures in March 2009. The BAA was subsequently renewed several times, most recently in July 2013, though its central goal remained unchanged: to seek proposals for the advanced research and development of medical countermeasures to address CBRN agents that pose a threat to the U.S. population. Within this wide scope, the BAA specifically identifies the prevention and treatment of Ebola and other hemorrhagic diseases as one of its goals. In particular, three of the six research "areas of interest" (AOI) set forth in Part I of the BAA have particular relevance to the government's Ebola prevention and treatment efforts:

- Area of Interest 1 — Vaccines: This AOI concerns, among other things, "[a]dvanced development projects for vaccines against Ebola and Marburg viral hemorrhagic fevers." The BAA notes

that "proposed vaccine candidate[s] must have demonstrated protection from lethal challenge in non-clinical animal studies" (particularly in nonhuman primate studies), and that preference will be given to candidate products that have safety toxicity data, a preliminary formulation, or demonstrated small scale manufacturing processes.

- Area of Interest 2 — Antitoxins & Therapeutics: This AOI includes a focus on the "[d]evelopment of antibody treatments and other therapeutic agents for viral hemorrhagic fevers viruses," such as Ebola. Again, the BAA states that the proposed therapeutics candidate "must have demonstrated protection from lethal challenge in non-clinical animal studies" (particularly in nonhuman primate studies), and that preference will be given to candidate products that have safety toxicity data, a preliminary formulation, or demonstrated small-scale manufacturing processes

- Area of Interest 6 — Clinical Diagnostics: This AOI includes a focus on developing "in vitro diagnostic (IVD) devices that would provide rapid, accurate point-of-care (POC)/'field use' testing of the civilian population" in response to concerns about exposure to certain "bio-threat agents of interest," including Ebola. Also covered by this AOI are proposals for studies contributing to the development of knowledge concerning disease-specific markers (and the relationship of those markers to the diagnostic window of opportunity) of Ebola and other "agents of interest."

The BAA provides detailed information regarding research and technical objectives (Part II) and reporting requirements and deliverables (Part III). Additionally, Part IV of the BAA provides detailed instructions on the two-stage process for preparing and submitting proposals. Prospective offerors should note that the BAA specifies a series of quarterly deadlines for the submission of the first stage of proposals (consisting of a quad chart and white paper), with the next deadline set for Oct. 31, 2014.

Offerors who submit first-stage proposals that receive a favorable evaluation are then invited to submit a full proposal in accordance with a timeline set forth in a separate invitation letter. As specified in Part V of the BAA, final proposals are then evaluated on the basis of six different evaluation criteria: (1) program relevance; (2) overall scientific and technical merits; (3) offeror capabilities and experience; (4) cost realism and reasonableness; (5) past performance; and (6) other factors and considerations.

Although the BAA has existed, in various forms, since 2009, the events of recent weeks and months have refocused attention on the BAA as the government seeks to accelerate the pace of development for anti-Ebola drugs and vaccines by utilizing existing procurement vehicles.

Companies with the desire and capability to assist with this effort would be well advised to become acquainted with the BAA's framework and objectives, including its detailed proposal instructions and criteria.

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[1] Additionally, HHS recently issued a task order under its Centers for Innovation in Advanced Development and Manufacturing (CIADM) program inviting three qualified laboratories to submit proposals for the acceleration of production of experimental ZMapp doses.