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COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510-6250

November 13, 2013

The Honorable Nicole Lurie, M.D., M.S.P.H.
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
200 Independence Ave, S.W.
Washington, D.C. 20201

Dear Dr. Lurie:

The Project BioShield Act of 2004 was enacted to promote and expedite the creation of medical countermeasures for use against chemical, biological, radiological and nuclear (CBRN) agents.¹ The Act authorized the Secretary of the Department of Health and Human Services (HHS) to spend \$5.6 billion to procure countermeasures for the Strategic National Stockpile through limited competition and sole source contracts from 2004 through 2013. In 2013, Congress authorized an additional \$2.8 billion for countermeasures from 2014 through 2018.²

As part of the Subcommittee's ongoing oversight of contract management, I request that you provide information and documents regarding the management and oversight of contracts for countermeasures. Specifically, I request that you provide a list of all CBRN-related countermeasures procured between fiscal years 2004 and 2013. Please submit your response using the spreadsheet provided with the following information for each procurement:

- (1) Contract number;
- (2) Brand and generic name of countermeasure procured;
- (3) Type of countermeasure (e.g., vaccine, antitoxin, etc.) and purpose, including intended target population;
- (4) Contract dates;
- (5) Contractor or company name and DUNS number;
- (6) Total contract value;

¹ Pub. L. No. 108-276 (2004).

² Pub L. No 115-5 (2013).

- (7) Whether the contract award was limited competition or sole-source;
- (8) Number of doses procured;
- (9) Cost per dose;
- (10) Expiration date of countermeasure or approximate shelf-life;
- (11) Whether the countermeasure is approved by the Food and Drug Administration;
- (12) Whether the countermeasure is intended for the Strategic National Stockpile;
- (13) Whether the countermeasure is associated with an Emergency Use Authorization;
- (14) Whether the countermeasure has uses for multiple agents and/or any commercial application; and
- (15) The date of the Material Threat Determination that authorized the procurement.

For each procurement listed above, I request that you also provide information sufficient to show the justification for using a limited competition or sole-source contract award. I also request that you provide information about any advisory or consulting contracts for the Office of the Assistant Secretary for Preparedness and Response, the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) or the Biomedical Advanced Research and Development Authority (BARDA) regarding CBRN countermeasure procurement or material threat assessments, including the company name, DUNS number, names of advisors or subject matters experts that were used, contract dates, contract value and contract number.

To assist the Subcommittee in understanding the role of BARDA's research and development contracts in countermeasure procurement, I request that you provide the following information:

- (16) For each procurement associated with Project BioShield funds, information sufficient to show whether the contractor ever received BARDA funding to develop any aspect of the countermeasure which was procured;
- (17) The dates BARDA funding was received;
- (18) Funding amounts provided; and
- (19) BARDA's policy for ownership of patents and intellectual property that are a direct result of government funding.

To assist the Subcommittee in understanding BARDA's future funding requirements for continued countermeasure research and development, I request the following information:

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- (20) A comparison of funding over the last five years between Project Bioshield expenditures for research and development of countermeasures for CBRN agents and funding for non-Project Bioshield research and development, including countermeasures for pandemic flu and other infectious diseases;
- (21) The current funding requirements for maintaining and stockpiling countermeasures currently funded through Project Bioshield;
- (22) The anticipated fiscal years 2014 and 2015 funding reduction for research and development of countermeasures;
- (23) Whether there is a plan in place to determine which countermeasures will no longer be funded for research, development or stockpiling purposes given any budget shortfalls; and
- (24) For countermeasures that would no longer be maintained or stockpiled, the anticipated financial impact through lost development dollars, committed resources, etc.

I request that you provide this information as soon as possible, but in no case later than **December 6, 2013**. If you determine that you will be unable to make a complete production by this date, please contact Subcommittee staff to discuss possible modifications to this schedule.

The jurisdiction of the Subcommittee on Contracting Oversight is set forth in Senate Rule XXV clause 1(k); Senate Resolution 445 section 101 (108th Congress); and Senate Resolution 64 (113th Congress). An attachment to this letter provides additional information on how to respond to the Subcommittee's request.

Please have your staff contact Sarah Garcia with the Subcommittee staff at (202) 224-5602 with any questions. Please send any official correspondence relating to this request to Kelsey_Stroud@hsgac.senate.gov.

Sincerely,



Claire McCaskill
Chairman
Subcommittee on Financial and Contracting
Oversight

cc: Ron Johnson
Ranking Member
Subcommittee on Financial and Contracting Oversight

Enclosure