BLUE RIBBON STUDY PANEL ON BIODEFENSE AND ITS ASSESSMENT OF PREPAREDNESS WITH DIAGNOSTICS FOR BIOLOGICAL THREATS

May 5, 2015

Purpose: Provide a brief assessment of strengths and weakness in preparedness with diagnostics for biological threats to the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Diagnostics Integrated Program Team (IPT).

STRENGTHS

- When we have them, they:
  - Help to ascertain full scope of an incident
  - Help to reliably distinguish infected from non-infected due to improved screening
  - Help to determine appropriate intervention strategies and decisions, including quarantine and isolation
  - Spare vaccines, treatments, and quarantine when they are not needed (saving valuable resources)

- The Panel can see that these areas are addressed by current diagnostic development and thinking from federal Departments and agencies

WEAKNESSES

- We don't have enough

- The need for diagnostics is an enormous capability gap

- Development of rapid point-of-care diagnostics largely ignored

- While drugs are certainly needed, we believe a more balanced portfolio is needed with diagnostics in general, and point-of-care diagnostics in particular

- We continue to rely on response – if we are going to keep doing that, and all indications are that we are continuing along the same path now – then we need to be better able to respond and diagnostics would help with that – *we need to foster effective response capabilities*

- Processes to develop diagnostics are too *ad hoc*

- 16 years after the 2001 anthrax incident the deployed diagnostics portfolio is largely unchanged.

- More laboratories are in the Laboratory Response Network (LRN), with a greater collective capacity for PCR testing. Environmental sampling now exists in the BioWatch program. Other than blood culture for patient management, antigen detection has not been enhanced.

- No plan is in place for operational use (e.g., whether the Strategic National Stockpile would send out kits; whether the LRN would have enough capacity, whether a surge manufacturing capability for reagents would suffice). These issues would need to be considered in framing anthrax diagnostics product-specific requirements (PSRs), which, in turn, would inform operational planning. PSRs are needed to support acquisition.

- Rapid point-of-care diagnostics significantly improve outbreak management
    - Some basic requirements
        - RAPID
        - Patient-side
        - Hundreds or thousands to distribute broadly
        - Able to be used by even those with limited training
        - Should better enable health care providers to identify diseases they have not seen before and that are in early presentation
        - Should inform other-than-clinical decisions, too (e.g., those based on attribution

- Recommendation 30 from the *Blueprint for Biodefense* (2015) – Incentivize development of rapid point-of-care diagnostics

    - Action Item a. Develop requirements for rapid point-of-care diagnostics for all material biological threats and emerging infectious diseases (medium term – 1-3 years, which means 2016-2018)

        - We talk about prioritizing diagnostics for material biological threats and emerging infectious diseases, but this presupposes that the material threat determinations are current and remain accurate.

        - Further, you can't prioritize an emerging infectious disease before it has actually emerged.

- We see that Biomedical Advanced Research and Development Authority (BARDA) has prioritized (to some extent, even as evidenced by this IPT) the development and acquisition of rapid point-of-care diagnostics, but the Panel thinks there should be even greater priority to produce a more balanced portfolio

- We know that BARDA has engaged in plans but we are still hearing that academia and industry are not fully engaged + operational planning is weak because it involves so many other parties

- We realize that simply saying that industry needs more incentives is not enough - lack of a conventional diagnostics market to drive development