Texas A&M University Regional Blue Ribbon Biodefense Panel
"Human Animal Interface for Biodefense workshop"
24 February 2015

Observations and Policy Recommendations

Observation #1: Ongoing lack of strong, centralized leadership and authority for Biodefense and Emerging Infectious Disease Preparedness and Response

Recommendation #1: Re-establish a Special Assistant to the President for Biodefense and Emerging Infectious Diseases for Health Security to drive priority and focus. The Special Assistant will need authority to review and advise on agency budgets, and propose consolidation where appropriate, to achieve national goals at any point during the budget submission process.

Observation #2: The challenges for bridging the valley of death for medical countermeasures, surveillance and diagnostics are similar if not more difficult for animal health. Lack of adequate attention and funding is a long-standing problem. Importantly, effective solutions for active preparedness against emerging infectious disease and bioterror threats lie at the interface of human and animal health.

Recommendation #2: This is also a leadership issue and the Special Assistant to the President, once reestablished, must drive priority and focus across the human and animal nexus for government agencies that have authorities and appropriations for public health, animal health, security and the economy.

Observation #3: The BARDA model is a good model. BARDA has achieved significant accomplishments to date, particularly for medical countermeasure programs that started a decade or so ago. However, a systemic risk-averse culture has emerged amongst many USG contracting officials, and even program managers. If this is allowed to continue, it will curtail progress and will serve as a disincentive to biotechnology and pharmaceutical industry participation. This observation is consistent from many others regarding BARDA contracting that is becoming a barrier to industry; and that the BARDA model needs to be refreshed to meet national security and preparedness objectives.

Specifically, HHS is applying a DOD acquisition model designed for weapons systems to the life science enterprise, biotechnology sector, and pharmaceutical industry for biomedical countermeasures. This acquisition model has had mixed, to poor results for the DOD medical countermeasures advanced development program. For BARDA, it has resulted in rigid and risk-averse implementation of federal acquisition regulations, which is a disincentive to engagement of the very companies that are required to solve the problem.
**Recommendations #3:**
- Move AMCG (contracting) back under BARDA so contracting can regain the responsiveness to the program that it used to have, and benefit from BARDA technical expertise.
- BARDA should more readily utilize existing authorities to align with industry best practices wherever possible; one example is Other Transactional Authority (OTA).
- The Administration and Congress should explore novel incentives in addition to OTA such as government bonds.
- One option that should be considered is to graduate BARDA to an Operating Division in HHS as originally envisioned in Pandemic and All Hazard Preparedness Act 2006. This would include recasting BARDA with a flexible DARPA-like culture of risk tolerance and entrepreneurial awareness.

**Observation #5:** Limited implementation to date to protect human health by controlling infectious disease in animal host. This is a gap between USG department/agencies that either support human public health or animal health, but not both. Emerging infectious diseases such as Rift Valley Fever and MERS may offer this opportunity.

**Recommendation #5:** Task HHS and USDA as lead agencies to Identify critical animal disease threats that will transfer to humans, and take action to provide vaccinations and other controlled measures to control disease in animals to decrease likelihood of spread to humans. Development and deployment of a MERS vaccine for camels to mitigate human disease is an example that should be considered. An example where this strategy works is rabies. Rabies has long been controlled in domestic and wild animals as a prophylactic approach to protect human health.

**Observation #7:** Effective information sharing is a challenge at a centralized interagency level for biosurveillance

**Recommendation #8:** Optimize the NBIC early warning system and make this system work across the interagency.
- Build upon the successful model of trusted third parties to build trust and coordinate data sharing through an expanded network of university centers of excellence on surveillance.
- Fund and facilitate enhanced opportunities for data sharing and mining capacity within the National Animal Health Laboratory Network and state veterinary diagnostic laboratories.
- Improve information sharing opportunities through integration with the Laboratory Response Network (CDC’s LRN)
The last option was not discussed at the TAMU workshop, but the observation has been brought to my attention from others, and with a request for me to submit to the Panel for consideration.

**Observations #9:** We are limited to development, procurement and stockpiling medical countermeasures. The USG has limited ability to surge quickly in the face of new and emerging threats whether natural or intentional. Stock piling is expensive and not likely to be predictive of the next emerging infectious disease or bioterror attack. The USG needs to focus and aggressively invest in flexible and adaptable platform and manufacturing approaches as recommended in the medical countermeasures review and earlier. The USG has not vigorously pursued this strategy.

**Recommendations #4:**
- BARDA and DARPA: Identify 5 promising platform technologies in existence that could eventually be applied to vaccinations for major threats and develop them with sufficient FDA safety and efficacy data to make plug and play possible for any novel antigen payload with minimum efficacy testing
- Establish a bank of novel antigen payloads on ice for major and related threats to both animals and humans
- Lessen focus on stockpiling except for strategic threats like anthrax and smallpox.