Medical Countermeasures for Biosecurity Threats: Opportunities for the Congress

“Our greatest concern is that terrorists might acquire biological agents, or less likely, a nuclear device, either of which could cause mass casualties.”


Bioterrorism is a Strategic Threat to the United States

• Biological weapons have the potential to be highly lethal
• There are no technical barriers to a non-state actor developing a biological weapon
  – All knowledge and technologies are accessible, inexpensive, dual-use, easily hidden
• Biological weapons have strong appeal as asymmetric weapons
  – No need for a “super-power” grade weapon
  – Al Qaeda and other non-state groups have clearly expressed interest in them
  – Unlike nuclear weapons, pathogens have no “return address,” so little to hold at risk
• The power of biological weapons is linked to the upwards trajectory of global bioscience in 21st century – biological research must proceed, but also must be aware of risks
• The United States does not currently have sufficient medical countermeasures to respond to the majority of biosecurity threats – robust effort & investment required

Developing Medical Countermeasures
Opportunities for the Congress

1. Fund BARDA advanced development activities appropriately
   • $1.07B authorized for FY06-08 in PAHPA (PL 109-417)
   • Only $99M appropriated to date
   • FY08 L-HHS conference report has $149M – Large gap in funding

2. Enable and support risk tolerance at HHS/BARDA
   • There will be future contract and product failures – the nature of drug development
   • HHS needs freedom to operate – excess caution has unintended negative consequences

3. Education of HHS, Congress, Private Sector
   • Each stakeholder needs a better understanding of the others to enable success

4. FDA Priority Review Vouchers to Reward Development of Medical Countermeasures
   • Vouchers would have limited social/indirect costs – potential for high value to developer
   • PRV for tropical diseases in 2007 FDA Act (PL 110-85) – expand to biosecurity threats