

## Medical Countermeasures for Biosecurity Threats: Opportunities for the Congress

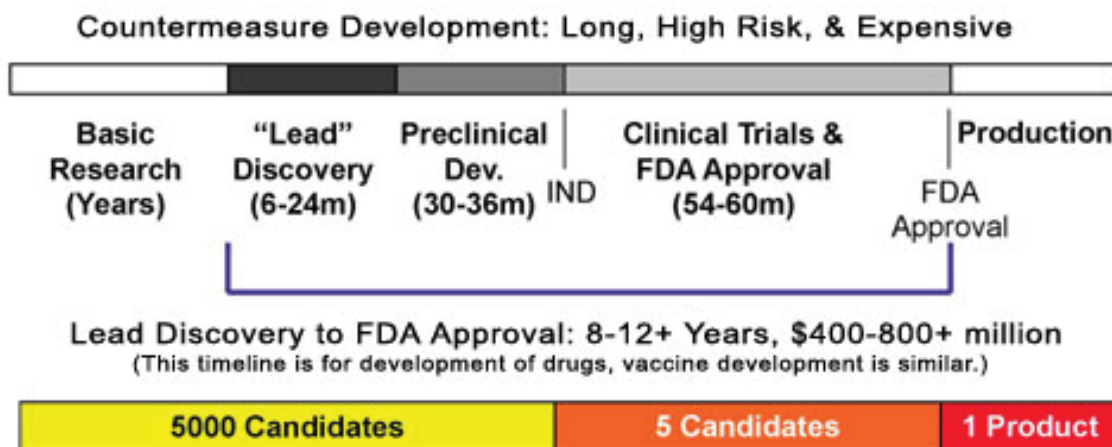
“Our greatest concern is that terrorists might acquire biological agents, or less likely, a nuclear device, either of which could cause mass casualties.”

*Mapping the Global Future* – Report of the National Intelligence Council’s 2020 Project, Jan. 2005

### 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
-