Preparing for Bioterrorism:
Project BioShield, BARDA and the Medical Countermeasure Enterprise

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Three Questions:

1. What trends are driving the need to develop new medical countermeasures? (aka: Why worry?)
2. What is the status of developing and procuring these new medicines & vaccines?
3. What actions can the Congress take to improve the situation?
Question #1

1. What trends are driving the need to develop new medical countermeasures? (aka: Why worry?)
“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; January 2005
Infectious Diseases: Neglected Threat – Systems Fragile

SARS 2003

H5N1 Flu 2005 – ??
Nature is NOT the “Ultimate Bioterrorist”
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Thinking Enemy
Offense has the Advantage over Defense
• Possibility of Engineered Pathogens
• Devastating Tactics
Bioterrorism as Strategic Threat

• Highly lethal
• Accessible, inexpensive, easily hidden
  – Possibility of “Reload” attacks
• Appeal of asymmetric weapons
  – No need for super-power grade weapon
  – Al Qaeda, and other non-state groups, have clearly expressed interest in biological weapons
• Trajectory of global bioscience in 21st C
• Global vulnerability to infectious disease
Bioweapons – Asymmetric Threat

- There are *no technical barriers* to a non-state actor developing a biological weapon
- Knowledge widely dispersed, materials accessible, cheap
- Dual use – hard to track, easily hidden
- State and non-state actors possess or are seeking capabilities
- **No return address, little to hold at risk**
Challenges of Responding to Epidemics – Natural or Deliberate

- Different from “traditional” security threat
- Pervasive uncertainties: scope, location, who is at risk, timeline
- Bioscience, medicine, public health at core of response
  - Institutional capacities may be fragmented, inadequate
- Government leaders frequently unfamiliar with key issues
Epidemic Management: Preparation Matters

- Situational awareness
- Care of the sick
- Public involvement
- *Effective medical countermeasures*
Question #2

2. What is the status of developing and procuring these new medicines & vaccines?
Lack of Investment in Infectious Disease R&D

“Increasingly, the U.S. market is driving them [pharmaceutical and biotech companies] toward drugs aimed at the diseases of richer, older Americans and away from antimicrobials, vaccines, and the like.” – Donald Kennedy

(Former FDA Commissioner)

Source: Science, March 19, 2004
**Pipeline is Limited**

<table>
<thead>
<tr>
<th>Number of Medicines in Development (as of 2004)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>506</td>
</tr>
<tr>
<td>Anti-Virals not targeting HIV</td>
<td>5</td>
</tr>
<tr>
<td>Anti-Bacterials <em>(i.e. antibiotics)</em></td>
<td>6</td>
</tr>
<tr>
<td>Anti-Bacterials with novel mechanisms</td>
<td>0</td>
</tr>
</tbody>
</table>

Countermeasure Development: Slow & $$$. New Drug: est. $400-800M+, 8-12+ years

- **Basic Research (Years)**
- **“Lead” Discovery (6-24m)**
- **Preclinical Dev. (30-36m)**
- **Clinical Trials & FDA Approval (54-60m)**
- **Production**

**Lead Discovery to FDA Approval: 8-12 Years**
(This is for drug development, vaccine development is similar)
Countermeasure Development: Slow & $$$

New Drug: est. $400-800M+, 8-12+ years

Lead Discovery to FDA Approval: 8-12 Years
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5000 Compounds 5 Compounds 1 Product

A High Risk Endeavor

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5000 Compounds  5 Compounds  1 Product
Players in Drug Development

• Academic Research Labs
  – Basic science discoveries
  – Funded by the USG

• Biotechnology Firms
  – Take discoveries and show proof-of-concept
  – Limited economic resources & experience

• Big Pharma
  – Special expertise in late stages: clinical trials, FDA, and production
  – Significant economic resources

Must Engage All Players
## FDA Approved Countermeasures for Bioterror Agents of Concern

<table>
<thead>
<tr>
<th>Agent</th>
<th>Vaccine</th>
<th>Therapy</th>
<th>Rapid/POC Diagnostic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anthrax</td>
<td>Limited</td>
<td>Yes*</td>
<td>Limited</td>
</tr>
<tr>
<td>Smallpox</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Plague</td>
<td>No</td>
<td>Yes*</td>
<td>No</td>
</tr>
<tr>
<td>Botulism</td>
<td>No</td>
<td>Limited</td>
<td>No</td>
</tr>
<tr>
<td>Tularemia</td>
<td>No</td>
<td>Yes*</td>
<td>No</td>
</tr>
<tr>
<td>VHF</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

* Antibiotic therapies are only effective if bacterium is not resistant.
Implications for Biosecurity

• Limited products on the shelf → Limited options for national leaders
• Response time: Months to years
• “Fixed Defenses” necessary for top threats, but not sustainable in long-term
  – too expensive, limits scope of effective response
• Must rejuvenate medicine and vaccine development – faster, more agile, less $$
• USG beginning to adapt: “Flexible Defense”
  – HSPD-18
  – PHEMCE Strategy
Question #3

3. What actions can the Congress take to improve the situation?
Opportunities for the Congress

1. Fund BARDA advanced development activities appropriately
   - $1.07B authorized for FY06-08
   - Only $99M appropriated to date
   - FY08 L-HHS Conference Report has $149M
     - Significant funding gap

2. Enable/support risk tolerance at HHS/BARDA
   - There will be unavoidable contract/product failures
   - HHS needs freedom to operate
Opportunities for the Congress

3. Education of HHS, Congress, Private Sector
   – Each stakeholder needs a better understanding of the others
   – Alliance for Biosecurity

4. FDA Priority Review Vouchers for Biosecurity Threats
   – Reward for development of medical countermeasures
   – Limited social/indirect cost – potential for high value to developer
   – PRVs for tropical diseases created in 2007 FDA Act (PL 110-85)
   – Current program could be expanded to biosecurity threats
Vision of Victory: Global Health Security
Thank You

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