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

November 28, 2007

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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

(Editor-in-Chief, *Science*; President Emeritus, Stanford; Former FDA Commissioner)

Source: *Science*, March 19, 2004

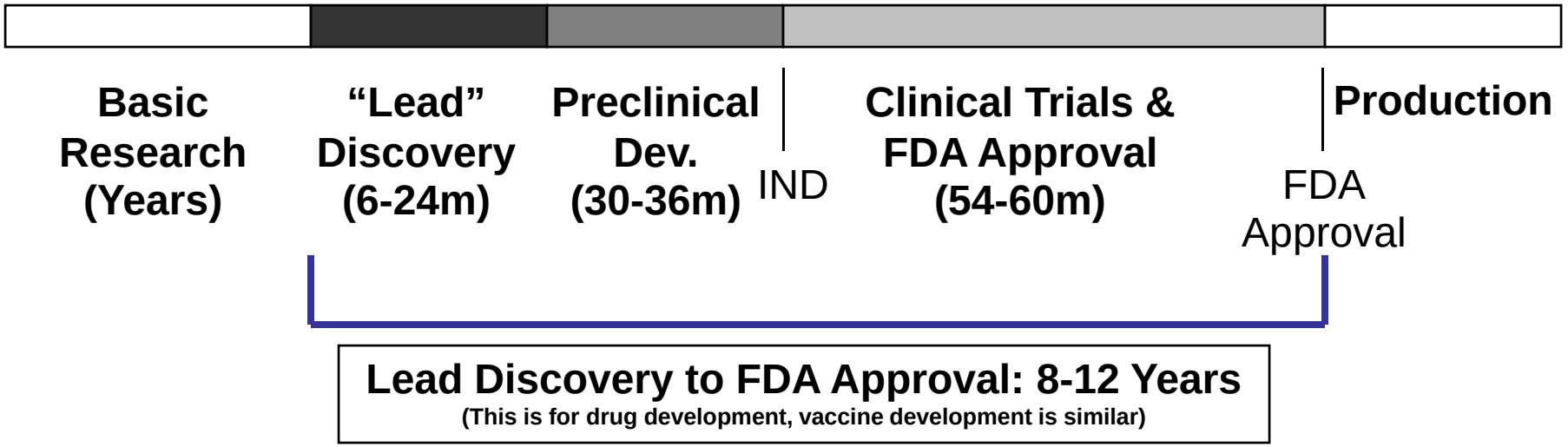
# Pipeline is Limited

| Number of Medicines in Development (as of 2004) | |
|---|---|
| Total | 506 |
| Anti-Virals not targeting HIV | 5 |
| Anti-Bacterials (*i.e.* antibiotics) | 6 |
| Anti-Bacterials with novel mechanisms | 0 |

Note: Survey of small-molecule drugs publicly disclosed to be in development by the 22 largest pharmaceutical & biotech firms as of early 2004. Spellberg, B. *et al.*, *Clinical Infectious Diseases*, vol. 38, p 1279–86, 2004.

# Countermeasure Development: Slow & $$$

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



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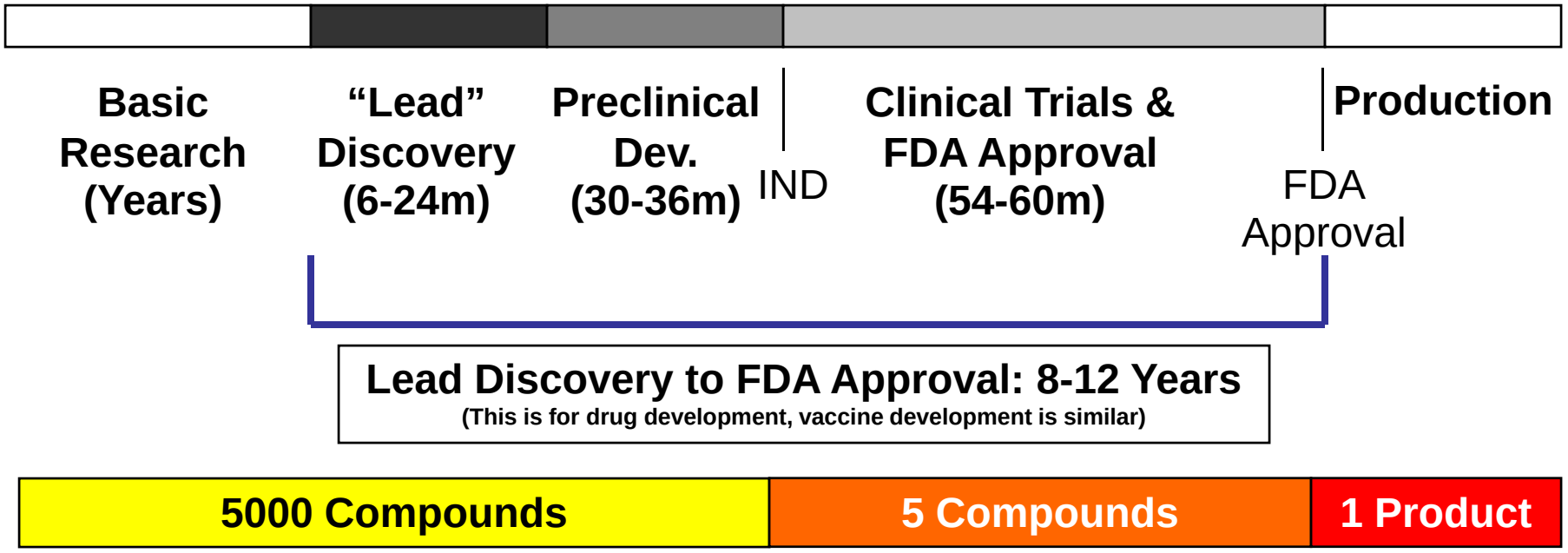


**A High Risk Endeavor**

# 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

| Agent | Vaccine | Therapy | Rapid/POC Diagnostic |
|---|---|---|---|
| Anthrax | Limited | Yes* | Limited |
| Smallpox | Yes | No | No |
| Plague | No | Yes* | No |
| Botulism | No | Limited | No |
| Tularemia | No | Yes* | No |
| VHF | No | No | No |

* 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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