United States Department of Health & Human Services
Office of the Secretary
Office of Public Health Emergency Preparedness (OPHEP)

Acquisition Process, Programs, and Policy Under Project BioShield

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Project BioShield

The "Project BioShield Act of 2004"
became Public Law 108-276 on 21 July 2004

PURPOSE:

To accelerate the research, development, purchase, and availability of priority medical countermeasures to protect the US population from the effects of chemical, biological, radiological, and nuclear (CBRN) threat agents.

A Bipartisan Effort

- The House version of the bill (H.R. 2122) was passed by a vote of 421-2 on 16 July 2003.
- The Senate version of the bill (S. 15) was passed by a vote of 99-0 on 19 May 2004.

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Project BioShield

Three-features of the program:

- **Accelerated** R&D by providing NIH/NIAID with new authorities
- **Acquisition:** establishes a secure funding source from FY04-FY13 for purchase of security countermeasures
  - Authorizes utilization of the **$5.6B Special Reserve Fund** established in the FY04 DHS Appropriations Bill (P.L. 108-90)
- **Availability:** establishes an Emergency Use Authorization for medical products

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Project BioShield Acquisition Process

- Findings by Secretaries of **DHS** and **HHS** **
  - Determination of material threat
  - Determination that medical countermeasures are necessary to protect public health
  - Establishment of Requirements and Acquisition Strategies
  - Determination that acquisition of the countermeasure with the Special Reserve Fund (SRF) is appropriate
    - Evaluation of commercial market
    - Production & delivery is feasible within 8 years
    - Numbers of doses required
  - Joint recommendation that the SRF be made available for the procurement
- Approval by the President (Delegated to OMB)
- HHS Executes Acquisition Program

**** Statutory requirements as defined in *The Project BioShield Act of 2004 (P.L. 108-276)***

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Condition for BioShield Acquisition

- Product must be on an estimated timeline for approval, licensure or clearance by the FDA within 8 years of Secretary determination based on:
  - Expert judgment on the development status
  - Safety and efficacy data to support pathway to licensure

Therefore:

- Early- and mid-stage development must be funded by other government programs, venture capital, and industry.

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Terms for Project BioShield Contract

- No payment may be made until a portion of the total number of units contracted for has been delivered to the government.
  - Usable product
- Discounted payment for product that is not licensed, cleared, or approved at the time of delivery.
  - Delivery to the SNS is contingent on the availability of sufficient data to support emergency use
  - Additional payment upon licensure, clearance or approval
- Vendor must seek approval, clearance, or licensure of product.
- Contract duration usually 5-8 years.

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Usable Product

- The definition of a “Usable Product” is contained in each RFP published on the FedBizOpps website.
- The definition includes a statement that it is the sole responsibility of the responder to the RFP to contact the appropriate regulatory Center within the FDA
- The Food and Drug Administration is the ultimate arbiter and regulator.

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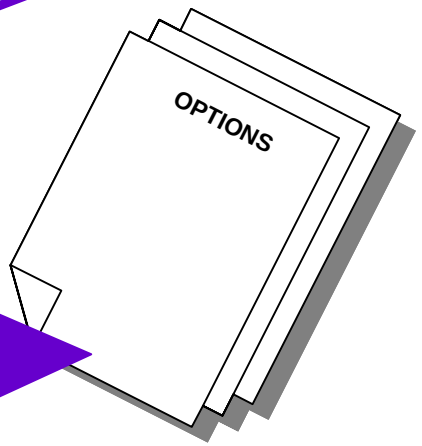
Factors Considered in Developing Acquisition Options

Product Specifications	Development Milestones & Cost Estimates	Funding Strategy	Acquisition Strategy and Timelines	Acquisition Options
✓ Composition	✓ Clinical	✓ BioShield-eligible?	✓ Near-term strategy	✓ Pros
✓ Formulation and Packaging	✓ Non-clinical	✓ BioShield-ready	✓ Long-term strategy	✓ Cons
✓ Storage requirements	✓ Manufacturing			
✓ Deployment logistics	✓ Regulatory Pathway for licensure / Confidence in licensability			
✓ Licensure requirement	✓ Development tools and infrastructure			
✓ Licensure indications				



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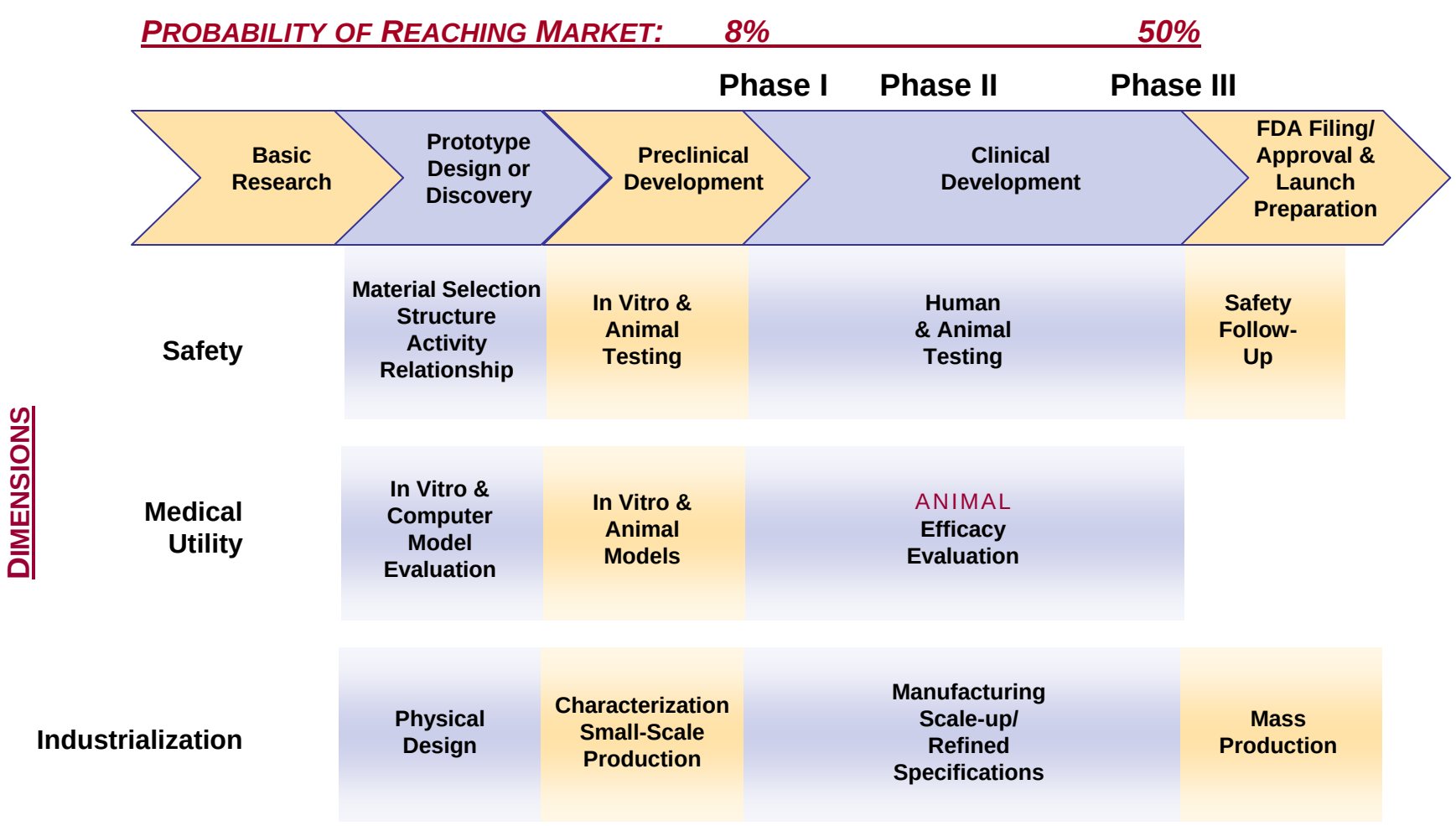
Medical Countermeasures: Challenges to Accelerated Development



Adapted from the FDA Critical Path Report (March 2004)

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Challenges to Development (cont'd)

- The pathway from medical product concept to a safe, effective, and reliably manufactured product suitable for regulatory approval can be a long and expensive one.
- Small and medium sized companies need substantial consultation and support from the acquisition agency and from the FDA to succeed in meeting regulatory requirements.
- The requirements of the "Animal Rule" are a special challenge for product development.
- Requires biocontainment infrastructure sufficient to support animal efficacy testing.

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HHS Approaches to Support Advanced Development

- HHS has proposed $160 million in advanced development funding in the FY07 budget to support promising candidates and decrease the risk in the Project BioShield acquisition programs.
- Legislative solutions have also been proposed.

HHS understands that the requirement of the Project BioShield Act of delaying payment until product delivery presents significant financial challenges for small companies.

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HHS Solutions for Improving the BioShield Acquisition Process

- Improving transparency
  - PHEMCE Strategy
  - Implementation Plan will establish priorities, requirements, timelines
  - Clear points of contact within government
  - Stakeholders Portal
  - Annual stakeholders' meeting
- Enhancing USG support
  - Provide OPHEP on-site technical oversight
  - Assist manufacturers through FDA technical working group teams
  - Provide advance payments as appropriate
  - Advanced development funding

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HHS Solutions for Improving Acquisition Process (cont)

- Government
  - Creating the Public Health Emergency Medical Countermeasures Enterprise (CDC, FDA, NIH, OPHEP) to guide the development of the PHEMCE Strategy and Implementation Plan, including research, development, acquisition, stockpiling, deployment, and utilization of medical countermeasures.
  - Streamlining the final decision-making authorities for procurement strategies.

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The Public Health Emergency Medical Countermeasures Enterprise Supports

Project BioShield