Medical Countermeasures
State of Affairs

BARDA Industry Day: Contracting for Countermeasures
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Rear Admiral, US Public Health Service
The PHEMCE transformed

“End-to-end” has taken on new meaning

<table>
<thead>
<tr>
<th>Requirements</th>
<th>R &amp; D</th>
<th>Advanced Development</th>
<th>Acquisition &amp; Stockpiling</th>
<th>Storage &amp; Maintenance</th>
<th>Deployment</th>
<th>Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASPR/OPP</td>
<td>NIH</td>
<td>ASPR/BARDA</td>
<td>ASPR/BARDA</td>
<td>CDC/SNS, ASPR/BARDA</td>
<td>CDC/SNS, ASPR/OPEO</td>
<td>CDC, ASPR</td>
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</tbody>
</table>

All partners work together on all components

Other federal partners:
- Department of Veteran Affairs
- Department of Homeland Security
- Department of Defense
- U.S. Department of Agriculture
One ASPR: Two Critical Roles

PHEMCE Executive

Governance
Assessment
Strategy
Coordination

PHEMCE Partner

Policy
Operations
Contracting
Development

All partners work together on all components
We’ve come a long way...

- Improved governance and coordinated decision making
- Better defined regulatory pathways and more informed science
- Innovation in development and procurement
- Smarter stockpiling and utilization
- Responsible stewardship
A clear and comprehensive strategic direction

• Improved governance and coordinated decision making
  • Good governance balanced with speed
  • Multi year budgeting
  • Coordination mechanisms are replicable across threats - portfolio reviews, in process reviews, integrated product teams

• Better defined regulatory pathways and more informed science

• Innovation in development and procurement

• Smarter stockpiling and utilization

• Responsible stewardship
Very good feedback from our In Process Reviews

<table>
<thead>
<tr>
<th>Category</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notification process</td>
<td>Excellent</td>
</tr>
<tr>
<td>Quality of information provided pre-IPR</td>
<td>Excellent</td>
</tr>
<tr>
<td>Time provided to present position</td>
<td>Excellent</td>
</tr>
<tr>
<td>Quality of guidance and questions posed during IPR</td>
<td>Excellent</td>
</tr>
<tr>
<td>Quality of post-IPR feedback</td>
<td>Excellent</td>
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</table>
Thinking about licensure from the start

• Improved governance and coordinated decision making

• Better defined regulatory pathways and more informed science
  • Clarity on regulatory framework
  • Early involvement helps FDA know what science will be needed down the road
  • Highest priority regulatory issues for resolution identified

• Innovation in development and procurement
• Smarter stockpiling and utilization
• Responsible stewardship
Changing the way we develop and buy products

- Improved governance and coordinated decision making
- Better defined regulatory pathways and more informed science
- Innovation in development and procurement
  - Decision to buy made with utilization in mind
  - Strategies for at-risk communities
  - Contracting improvements
  - New ways of partnering and stimulating development
- Smarter stockpiling and utilization
- Responsible stewardship
Over 110 product candidates in BARDA development pipeline by 2012
Nearing FDA approval

- H5N1 Vaccine with Adjuvant
- Recombinant-based Influenza Vaccine
- Anthrax Antitoxin
- Botulinum Antitoxin
- Next-Gen Portable Ventilators
Recent FDA approval

Cell-based Influenza Vaccine
Bold approaches to stimulating development

- Centers for Innovation in Advanced Development and Manufacturing
  - New model for partnership
  - Core services for smaller companies
  - Platform technologies
  - Increased domestic manufacturing capacity
  - Trained workforce

- Strategic Investor
  - A sustainable pipeline needs a strong business sector
End user needs inform all planning

- Improved governance and coordinated decision making
- Better defined regulatory pathways and more informed science
- Innovation in advanced development and procurement
- Smarter stockpiling and utilization
  - 2012 annual review of Strategic National Stockpile will align with PHEMCE prioritization framework
  - Utilization planning and guidance stemming from portfolio reviews
  - Cooperation in planning for potential threats (smallpox, anthrax), and responding when new threats emerge (H3N2v)
- Responsible stewardship
Stewards of taxpayer dollars and the public trust

• Improved governance and coordinated decision making
• Better defined regulatory pathways and more informed science
• Innovation in development and procurement
• Smarter stockpiling and utilization
• Responsible stewardship
  • Robust, trusted partnerships
  • Safe, effective countermeasures
Threats are real and evolving – to face them, we need:

• Strong partnerships

• Platform technologies, multi-use products

• Sustainable ways to maintain progress

• To tell our story
...it’s a marathon, not a sprint