



United States Department of
Health & Human Services
Office of the Assistant Secretary for Preparedness and Response



Medical Countermeasures State of Affairs

BARDA Industry Day: Contracting for Countermeasures
December 10, 2012

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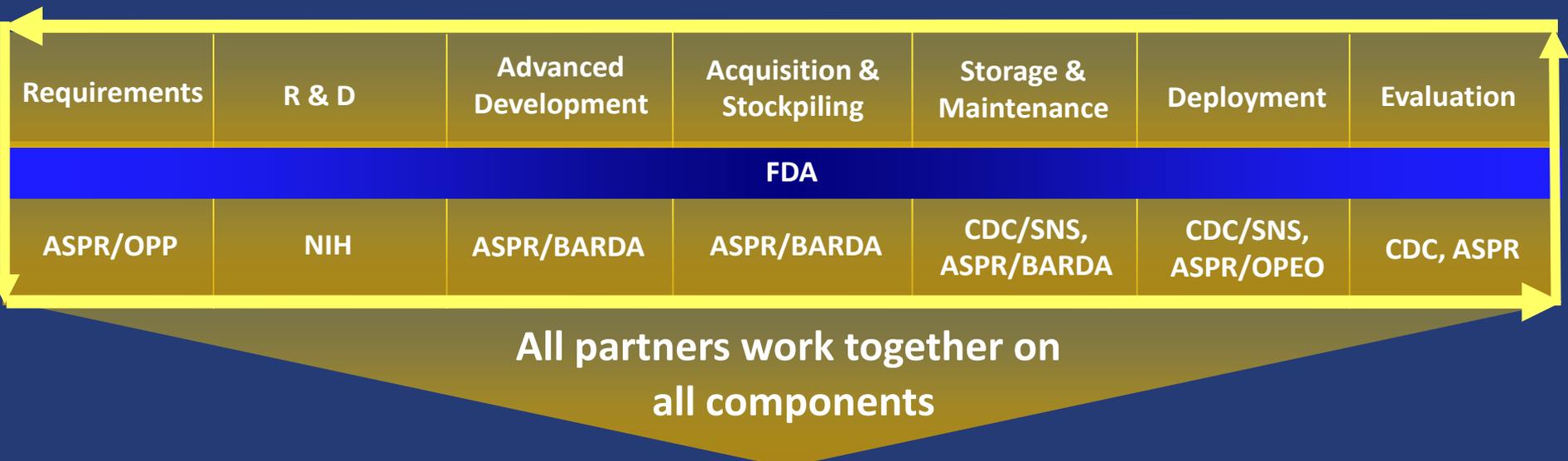
Rear Admiral, US Public Health Service



The PHEMCE transformed



“End-to-end” has taken on new meaning



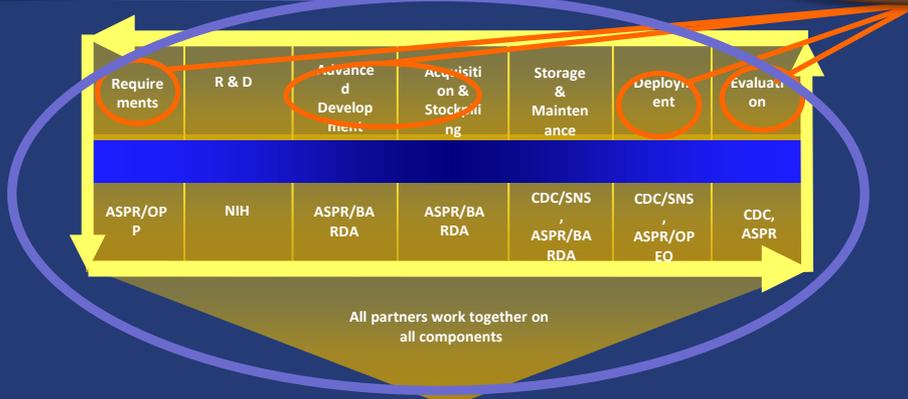
Other federal partners:

- Department of Veteran Affairs
- Department of Homeland Security
- Department of Defense
- U.S. Department of Agriculture

One ASPR: *Two Critical Roles*

PHEMCE Executive

PHEMCE Partner





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

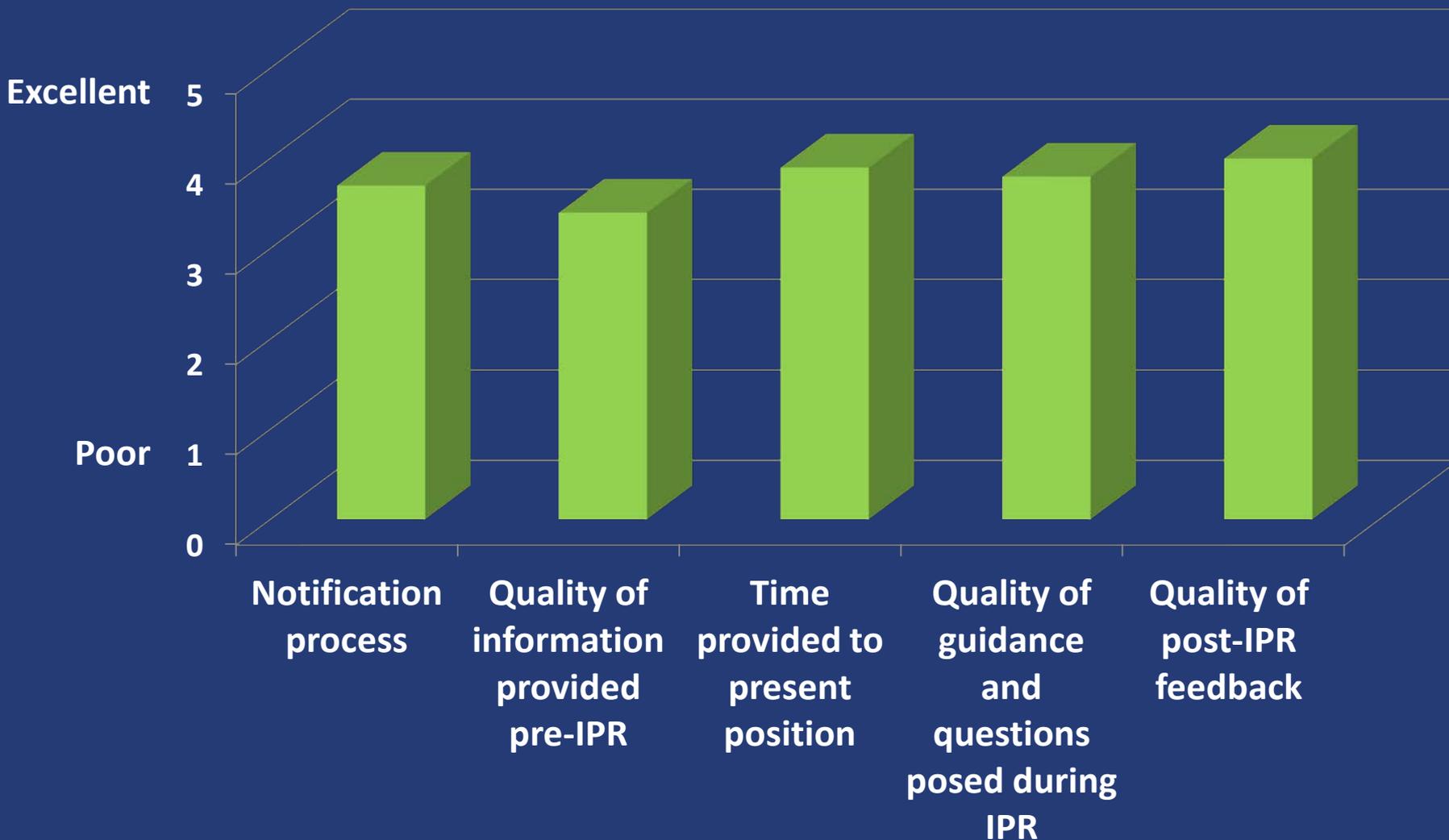


A clear and comprehensive strategic direction

- 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





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

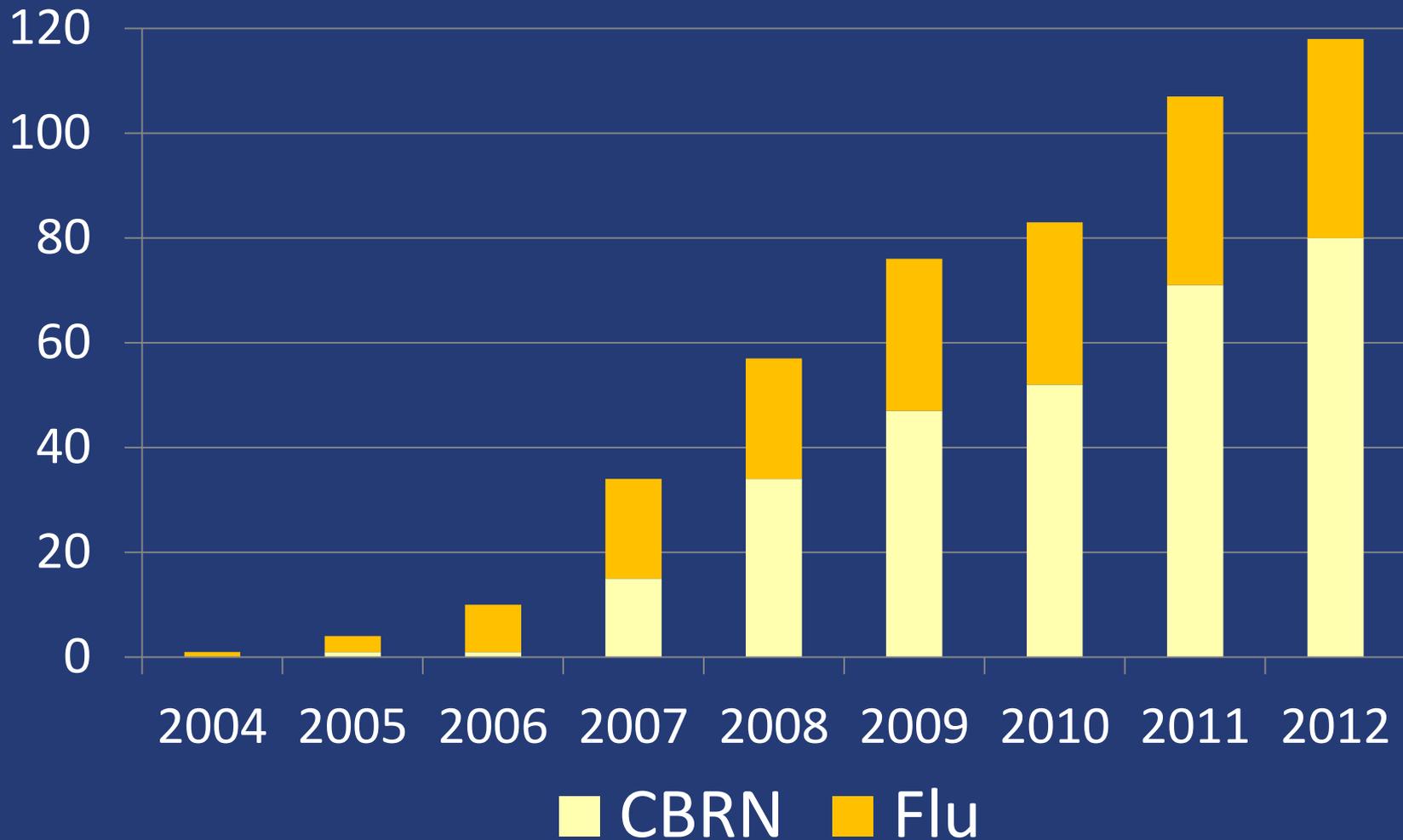


Changing the way we develop and buy products

- 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



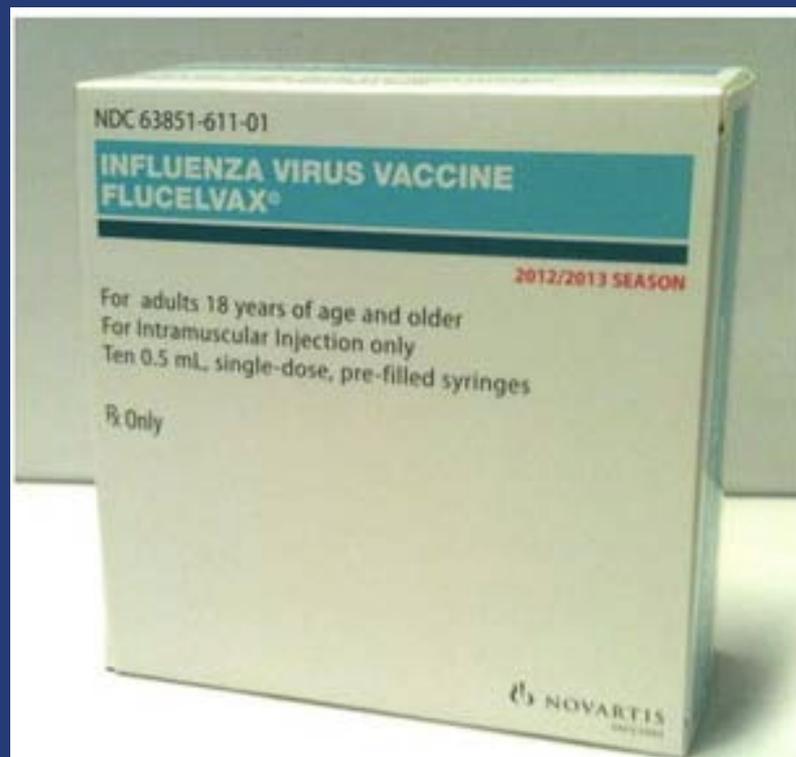
Next-Gen Portable Ventilators



Botulinum Antitoxin



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

ASPR
ASSISTANT SECRETARY FOR
PREPAREDNESS AND RESPONSE

