Potential Business Models for EID Medical Countermeasures

Joe Larsen, PhD
Acting Deputy Director
BARDA CBRN Division
March 2015
The BARDA Model

• BARDA’s incentives to date have focused on:
  — Push incentives for advanced research and development
  — Pull incentives in the form of procurements
    • Stockpiling
    • Vendor Managed Inventory

• The future may require consideration of:
  — Alternative Pull Incentives
    • Prizes to award innovation and de-link profit from unit sales
    • Outright purchase of IP by USG
    • Fee for service agreements
• Established 5 year $200M public:private partnership in May 2013

• Supports the development of multiple antibiotic candidates

• Allows for activities and resources to be adjusted fluidly to adapt to technical risk and programmatic priorities

• Governance is through a BARDA:GSK Joint Oversight Committee

• Allows for external partnerships through co-development or in-licensing agreements
Pull Incentives focusing on Procurement

- Two models: Conventional Stockpiling and Vendor Managed Inventory
  - Conventional Stockpiling:
    - Example: Raxibacumab
    - USG places order, contractor fills
    - Advanced and milestone payments were used in the initial development
  - Vendor Managed Inventory
    - Examples: Neupogen, Leukine
    - USG states inventory requirement, industry guarantees that quantity in their inventory at all times and USG rights to use it
Partial De-linkage Model

• Development occurs up to End of Phase 2 (EOP2)
• Industry partner enters into contract/agreement
• FDA approval triggers $300-500M payment to reward innovation
• Level of payment determined by novelty of technology, differentiation in market place, addressing unmet medical need, etc.
• Need for support of Phase III and Phase IV post-market commitments also factor into level of payment
• Industry still able to sell product commercially
• For antibiotics, stewardship plan and implementation is a condition of payment
• Product is developed to EOP2 (Antibiotics), or in the case of EID products EOP1

• USG or other entity buys IP from industry, assumes control

• USG or other entity manages further development
  — For EID products, would support manufacturing optimization for commercial scale and then pause development until disease emergence
  — Requires accurate and actionable risk assessment tools

• If disease emerges, terms could be negotiated to return or sell license back to industry
Fee for Service

• Establish a partnership with industry partner(s) that ensures readiness to rapidly develop EID countermeasures

• Use OTA to form consortium to rapidly screen mAbs, drug libraries, establish in vitro and in vivo models, conduct manufacturing, etc.

• When not actively responding, pay consortium a fee to have them on retainer to be in a “ready” position

• Staged approach to response: go to EOP1 initially, then ramp up if risk indicates threat is substantial enough

• Unclear if industry would have any interest in this model
Prize Model

- USG creates list of priority pathogens (20-40), with the ability to be modified (added to) at any time

- Establishes a prize that a company would win upon getting the product to an EOPI state (safety, CMC, non-clinical data)

- Prize value would be at least 11% plus cost of capital

- Generates a known business model that rewards successful research

- Would still require follow on infrastructure to respond to an EID event
Summary

• Alternative business models will likely be required to incentivize development and ensure market sustainability of infectious disease products

• A mix of push and pull mechanisms will be needed

• For EID products, partial or full de-linkage models will likely be necessary to reward innovation in the face of market uncertainty

• For EID products, conventional stockpiling/VMI likely do not represent viable, sustainable models

• There may be a role for international consortiums in establishing programs to incentivize development of these products