Potential Business Models for EID Medical Countermeasures

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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

Portfolio Partnership for Antibacterial Drug Development

- 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

Full De-linkage Model

- 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