

Journal Brief

Incentives for Biodefense Countermeasure Development

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Bioterrorism is an urgent and growing threat, and medical countermeasures such as therapeutics and vaccines are available for only a fraction of potential biological weapons. The commercial biopharmaceutical industry is the principal source of the expertise that is needed to develop new countermeasures. Unfortunately, the existing U.S. policies that are designed to accelerate the commercial development of countermeasures have thus far not been able to stimulate sufficient investment by industry. The principal barriers to industry investment in biodefense countermeasures are:

- **The costs and risks inherent in all pharmaceutical R&D:** The transformation of a promising drug candidate into a marketable product typically takes 10 to 15 years from basic research to FDA approval. For every five products that enter clinical trials, only one receives FDA approval. The average cost to develop a single product, including the cost of capital and the cost of failures, has been estimated to be over \$800 million.
- **The costs and risks specific to biodefense countermeasure R&D:** Because the U.S. government is the primary purchaser of countermeasures, sales depend heavily on evolving threat assessments and government policies. There is also significant regulatory uncertainty for countermeasures, since many biodefense countermeasures must be approved using the FDA's new and relatively untested Animal Efficacy Rule.

The U.S. government has used financial incentives to spur commercial investment in countermeasure R&D. There are two basic types of financial incentives:

- **“Push” incentives that reduce industry’s cost for R&D:** These include
 - government-funded intramural and extramural research (for example, NIAID grants and contracts),
 - government-industry R&D collaborations (such as Cooperative Research and Development Agreements, or CRADAs),
 - liability protection for developers (SAFETY and PREP Acts), and
 - Orphan Drug R&D tax credits.
- **“Pull” incentives that increase industry’s revenues from R&D:** These include
 - FDA priority review,
 - Orphan Drug market exclusivity, and
 - BioShield procurement contracts.

To increase commercial investment in biodefense countermeasure development, a number of new incentives have been proposed, such as patent extensions and advance market commitments. The authors’ analysis of existing and proposed incentives suggests that the U.S. government should consider three steps to improve industry’s engagement in countermeasure development:

1. **Sufficient Funding:** Congress should fully fund the new BARDA Biodefense Medical Countermeasure Development Fund and expand BioShield Special Reserve funding beyond the current \$5.6 billion. This would allow HHS to support a broader portfolio of biodefense countermeasures, thus improving the chances of successful product development.
2. **Tradable Priority Review Vouchers:** Congress should establish tradable priority review vouchers to reward the development of new countermeasures. With a potential benefit to industry of \$300 million and a public cost of \$1 million or less, these vouchers would be highly cost-effective.
3. **Rigorous Evaluation:** A committee of the National Academy of Sciences or the National Biodefense Science Board should formally evaluate all current and proposed incentive programs as well as the potential for a “Virtual Pharma” model, in which HHS would actively manage and contract separate stages of countermeasure development and production to individual firms.