

## BARDA FY10 ADVANCED DEVELOPMENT COST ESTIMATES FOR MEDICAL COUNTERMEASURES AGAINST BIOLOGICAL THREATS

(updated July 7, 2009)

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| FY09 BARDA advanced development funding .....  | <b>\$275M</b>    |
| FY10 funding required for BARDA to have a 90% chance of ultimately developing 1 successful medical countermeasure (MCM) for each requirement in the PHEMCE Implementation Plan ..... | <b>\$3,714M</b>  |
| FY10-FY16 advanced development funding needed to achieve 90% success rate .....  | <b>\$15,358M</b> |

- This analysis addresses only PHEMCE requirements for MCMs against biological threats. It does not include MCM requirements for radiological, nuclear, or chemical weapons, nor does it include diagnostics, biodosimetry tests, or CHEMPACKS. BARDA is responsible for all of these products.
- These estimates include ONLY advanced development costs, which do not include the costs of basic research, pre-clinical development, manufacturing, stockpiling, or maintaining these MCMs.
- Sustained funding (over many years) is necessary to successfully develop any MCMs, given the long timelines of biopharmaceutical development.

### **The number of MCMs currently in development yields a low probability of success:**

One option for the country would be to budget advanced development funding for only those candidate MCMs currently in development. Based on our survey, 1 year of BARDA advanced development funding for MCMs in development would cost \$1,053M in FY10.

However, biopharmaceutical development has very high failure rates. For every 5 small molecule drugs or 3 three biological therapeutics that enter advanced development, only 1 is ultimately granted FDA approval. Therefore, \$1,053M of funding for the candidate MCMs currently in development would produce the following probabilities of success:

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| • Anthrax vaccine: 80%                   | • Smallpox antiviral: 53%                |
| • Anthrax antitoxin: 77%                 | • Filovirus antiviral: 48%               |
| • Gram(+) broad-spectrum antibiotic: 69% | • Junin virus antiviral: 23%             |
| • Filovirus vaccine: 67%                 | • Gram(-) broad-spectrum antibiotic: 12% |

### **A substantial increase in BARDA funding is needed to increase the probability of success:**

If its current level of funding — \$275M — is continued annually, BARDA will be able to support only the 7 most mature MCM candidates in the pipeline. It will have no funding left for the 25 remaining candidates. Moreover, based on historical failure rates of drug development, it is likely that only 2 of those 7 candidates will ultimately receive FDA approval.

To have at least a 90% probability of developing 1 successful product for each PHEMCE biological threat requirement, the portfolio of candidate MCMs must be expanded. One year of BARDA advanced development funding for this larger MCM portfolio would be \$3,714M in FY10.

[Note: This updates the Center for Biosecurity's FY09 BARDA cost analysis with a new MCM candidate pipeline survey. Methodology is from: Matheny, J., M. Mair, and B. Smith, (2008) "Cost/Success Projections for US Biodefense Countermeasure Development," *Nature Biotechnology*, **26**:981-983.]