

**National Biodefense Science Board**

**Markets & Sustainability Working Group Working Document**

***“Inventory of Issues Constraining or Enabling Industrial  
Involvement with Medical Countermeasure Development”***

**Request for Public Comment  
Published in Federal Register  
June 1, 2009**



## **Inventory of Issues Constraining or Enabling Industrial Involvement with Medical Countermeasure Development**

*Introduction:* The National Biodefense Science Board (NBSB) Medical Countermeasure Markets and Sustainability Working Group (M&S-WG) has posted a request for public comment in the Federal Register to solicit comment, feedback, and guidance from members of industry, other government agencies, and the public at large on their working document, “*Inventory of Issues Constraining or Enabling Industry Involvement in Medical Countermeasure Efforts.*” Posting of the working document in the Federal Register will serve to solicit and obtain public comment for consideration by the Working Group to strengthen and refine the document. The Working Group plans to present the document to the NBSB at the scheduled Fall 2009 public meeting of the Board.

*Background:* There exist a variety of limitations and barriers to biotechnology and pharmaceutical companies’ involvement in the biosecurity and biodefense efforts of the U.S. Government (USG), most notably medical countermeasure advanced research and development programs coordinated by the Department of Defense (DoD) and the Department of Health and Human Services (DHHS). Make-up of the medical countermeasure development efforts has been called fragmented, with confusing approaches used. To delineate and simplify the complexities of USG endeavors in medical countermeasure development, and the interactions between government agencies and private industry, the NBSB Markets & Sustainability Working Group (M&S-WG) assembled the enclosed inventory (or grid) of issues. This inventory includes factors that may discourage industry involvement or partnering with the USG in medical countermeasure development efforts, reported constraints to industry involvement, and potential solutions for relief from a particular constraint. The inventory has been catalogued by financial, legislative, scientific, human capital, regulatory, and societal elements.

The public is encouraged to consider submitting comments and/or recommendations on the content of this inventory. Requests for a copy of the inventory and accompanying Comment Revision Form should be sent to the NBSB's e-mail box at [NBSB@hhs.gov](mailto:NBSB@hhs.gov) with "M&S-WG Inventory Request" in the subject line. All comments and/or recommendations for improvement to the inventory grid should be made on the Comment Revision Form enclosed with the inventory document. Comments and/or recommendations are to be submitted to the NBSB's e-mail box at [NBSB@hhs.gov](mailto:NBSB@hhs.gov) with "M&S-WG Inventory Comments" in the subject line and should be received no later than October 30, 2009.

## **NBSB Markets & Sustainability Work Group**

**18 May 09**

### **Observations, Adapted from June 08 NBSB Meeting**

#### ***Business Planning:***

- Contracting with some portions of the USG can be slow, unwieldy, expensive, and opaque.
- Lack of clarity increases industry risk.
  - Procurement size, warm-base requirements, length of review, etc.
- Lack of transparency increases industry risk.
  - Contract review process, rate of issuance of new proposals, requirement generation
- With a contract in place, situation improves.
  - HHS viewed as cooperative, helpful, responsible and responsive.
- Perceived lack of coordination between development activities and regulatory responsibilities remains a concern to industry.

#### ***Regulatory:***

- Lack of clarity regarding usable product definitions, seeming differences in FDA approaches to providing guidance to industry.
- Industry reliance upon USG for key components of licensure submissions can lead to lack of accountability.
  - Disease studies, toxicology reports, etc.

#### ***Funding, Stability, Reliability, Predictability:***

- Advanced Development needs more dedicated funding, separate from BioShield funding.
  - BioShield remains a funded procurement device, not an advanced-development mechanism.
- Advanced development efforts would benefit from contracting flexibility.
  - Cost-plus-fee contracting flexibility is appropriate for advanced development and would reduce risk.
- Multiyear funding.

- Drug development and corporate investment/planning is long-term process, *multiyear funding with carry-over authority, with multi-year contracting authority* would signal USG commitment and increase industry sense of long-term stability.
- Project BioShield expires in 2013 and will need to be reauthorized and funded.
  - Five years not a long time in drug-development process.
  - BioShield funds should not be diverted to fund other initiatives.
  - Inadequate funding delays the journey to MCM licensure.
  - Initiate additional program against emerging diseases, modeled after pandemic program.

***Next Steps for WG :***

- Continue to identify obstacles to greater industry participation in MCM development.
  - *Make recommendations where appropriate.*
- Identify incentives to encourage greater industry participation in MCM development.
  - *Make recommendations where appropriate.*
- Consider alternative models for MCM development.
  - *Do other models ensure national and public-health security while more efficiently using limited resources?*

**Barriers Hindering Partnership:** Opportunity cost (distractions from commercial business), economics (e.g., margins, volumes), product liability, uncertainty over sustained funding, ambiguous governance, competing public-health alternatives (e.g., needs of developing world), finite human capital, complexity of working with USG, obligations during crisis.

**Incentives Encouraging Partnership:** Reliable access to excess capacity (e.g., for redundant capacity or developing-world projects), tax credits, patent-term extensions, grants, priority-review vouchers, preferred customer/vendor status with USG, product licensing rights, larger pool of scientists and engineers, public good, long-term contracts, intellectual-property development.

## Inventory of Issues Constraining or Enabling Industrial Involvement with Medical Countermeasure Development

18 May 09

| FINANCIAL ELEMENTS |  |  |  |   |
|--------------------|--|--|--|---|
|                    | Column #1  | Column #2  | Column #3  | Column #4   |
| Row #              | Problem / Category   | Potential Solution   | Approach / Advantages / Action   | Problem / Limitation  |
| 1                  | Row 1; Column 1  | Row 1; Column 2  | Row 1; Column 3  | Row 1; Column 4   |
|                    | <b>Capital requirements to establish safety, efficacy, validated manufacture</b> | <p>Increase financial return after risking capital to industry-standard rates</p> <p>Reduce requirement for private capital for advanced development</p> | <p>Increased federal funding for advanced development, in the form of cost-reimbursement contracts and rewarding private-capital investments with milestone payments and at procurement.</p> | <p>Risk of distraction of large industry partners from commercial mission or dilution of effort [potential conflict with fiduciary responsibility to shareholders of publicly-traded companies]</p> |
| 2                  | Row 2; Column 1  | Row 2; Column 2a   | Row 2; Column 3a   | Row 2; Column 4   |
|                    | <b>Risk of technical failure of vaccine development effort</b>                   | <p>Decentralized discovery / centralized development and manufacture</p>   | <p>Reimbursement of development costs at cost+15%, with return-on-working-capital at 22%, and cost-of-money-for-capital at 15%</p>   | <p>Lack of interest, given opportunity costs Congressional tolerance for anticipatable frustrations is unknown</p>  |
|                    |  | Row 2; Column 2b   | Row 2; Column 3b   |   |
|                    |  | Evaluation of whether indirect-  | Provides support early   |   |

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|   |  | cost reimbursement greater than 100% may be appropriate.<br>Assistance with calculating indirect cost rates (for companies that have never done so before).  | in process.  |  |
| 3 | Row 3; Column 1<br><br>Tax incentives                                      | Row 3; Column 2a<br><br>Enhance current incremental R&D tax credit (increase, make refundable)   | Row 3; Column 3a<br><br>Currently, 20% for qualified R&D expenses and 50% for clinical-trial expenses  |  |
|   |  | Row 3; Column 2b<br><br>New investment tax credit (20%) for construction of new R&D and manufacturing facilities for biosecurity and emerging-infectious disease purposes (with refundable and/or transferable provisions) | Row 3; Column 3b<br><br>Enhance net revenue  | Row 3; Column 4<br><br>Not yet authorized  |
| 4 | Row 4; Column 1<br><br>Revenue enhancements based on Intellectual Property | Row 4; Column 2<br><br>Enhance current product or use patent-term restoration and/or extension (revise formula)<br><br>Allow full patent-term extension for licensed   | Row 4; Column 3<br><br>Current statutory formula: Patent extension supplemented by [1/2 time from IND to filing BLA + full time from BLA filing to FDA | Row 4; Column 4<br><br>Note: Orphan drug tax credit applies to vaccines only if less than 200,000 vaccinated recipients anticipated. |

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|   |  | <p>products that gain CBRN or emerging disease application (akin to adding pediatric indication).</p> <p>Allow transfer of patent-term extension to another product or company ("wildcard")</p> <p>Market exclusivity: Increase term of market exclusivity to ~ 12-15 years and extend it to biologicals (as does Orphan Drug Act).</p> | <p>approval/licensure]</p> <p>Currently, 5 years of market exclusivity is provided to New Chemical Entities (NCEs) but not biologicals via Hatch-Waxman Act and 7 years of market exclusivity is provided via Orphan Drug Act.</p>   |   |
| 5 | <p><b>Row 5; Column 1</b></p> <p><b>Priority-Review Vouchers (PRV)</b></p> | <p><b>Row 5; Column 2</b></p> <p>Make applicable to biosecurity products.</p>   | <p><b>Row 5; Column 3</b></p> <p>A PRV is a tradable certificate awarded to a developer of a treatment for a neglected tropical disease that gains licensure from FDA. It entitles holder to a priority review (a speedier review time) for a future product of their choosing, potentially shortening the review process by 6 to 12 months. First PRV awarded to Novartis for <i>Coartem</i> malaria treatment (artemether and lumefantrine) in Apr 09.</p> | <p><b>Row 5; Column 4</b></p> <p>Predictability: Would a priority-review voucher simply accelerate a "no" or "not yet" response?</p> <p>2007 law: Text at:<br/> <a href="http://www.bvgh.org/documents/HR3580-CompromiseFDA-PDUFABill.pdf">www.bvgh.org/documents/HR3580-CompromiseFDA-PDUFABill.pdf</a><br/> Draft FDA guidance:<br/> <a href="http://www.fda.gov/cber/gdlns/tropicaldisease.htm">www.fda.gov/cber/gdlns/tropicaldisease.htm</a></p> |

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| <b>6</b> | <b>Row 6; Column 1</b>   | <b>Row 6; Column 2a</b>  | <b>Row 6; Column 3a</b>   | <b>Row 6; Column 4a</b>  |
|          | <b>Limited market size (development costs &gt;&gt; market potential)</b>   | Acquisition RFPs should state minimum quantities (total and to each successful awardee) to increase market certainty to potential bidders and their investors. | Publication of requirements along with advanced-development RFPs. It may be possible to more widely describe procurement requirements, in contrast to the more sensitive value of treatment requirements. | Requirements are not static and can be expected to change based on threat assessments and discoveries during product development. Requirements may signal USG threat recognition, so may not be appropriate for public release |
|          | <b>Row 6; Column 2b</b>  | <b>Row 6; Column 3b</b>  | <b>Row 6; Column 4b</b>   |  |
|          | Contract terms allowing manufacturers access to allied foreign governments and other authorized customers outside the US, as well as civilian first responders, hospitals, and travel-vaccine providers within the US. | Treaty allies represent additional markets.  | Allies have not made substantial independent purchases to date. Some may hope/expect USG to share stockpile when attack occurs.   |  |
|          | <b>Row 6; Column 2c</b>  |  | <b>Row 6; Column 4c</b>   |  |
|          | Add biodefense and other adult vaccines to Standardized Equipment List (SEL) and Authorized Equipment List (AEL), so state and local first-responders can use federal (DHS) grant funds to pay for vaccinations.       |  | Currently only drugs, antidotes, and various treatments are covered, but not vaccines for prophylaxis in the first place.   |  |

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| 7                           | <p><b>Row 7; Column 1</b></p> <p><b>Surge issues</b></p>   | <p><b>Row 7; Column 2</b></p> <p>Compensation if commercial product(s) displaced during emergencies (e.g., lost sales, market share, delayed licensing).</p>   | <p><b>Row 7; Column 3</b></p> <p>Define "compensation" in initial contract or agree to a dispute-resolution mechanism.</p>   | <p><b>Row 7; Column 4</b></p> <p>Potential compensation may need to include delay of a new product or loss of market share to a competitor. Level difficult to determine <i>a priori</i>.</p>  |
| <b>LEGISLATIVE ELEMENTS</b> |  |  |  |  |
|                             | <b>Column #1</b>   | <b>Column #2</b>   | <b>Column #3</b>   | <b>Column #4</b>   |
| <b>Row #</b>                | <b>Problem / Category</b>  | <b>Potential Solution</b>  | <b>Approach / Advantages / Action</b>  | <b>Problem / Limitation</b>  |
| 8                           | <p><b>Row 8; Column 1</b></p> <p><b>Predictability, consistency adequacy of Congressional appropriations</b></p> | <p><b>Row 8; Column 2a</b></p> <p>Increase annual NIAID appropriation increases for early-stage MCM development to offset flat funding since 2001 anthrax attacks. Insufficient funds now allocated for advanced development for CBRN.</p> <p>Increase BARDA appropriations for advanced development of CBRN MCMs and continued long-term funding for both CBRN and pandemic countermeasures, to offset recent funding shortfalls.</p> | <p><b>Row 8; Column 3a</b></p> <p>Multi-year contracting authority (for large molecules, due to complex manufacturing and limited use) and multi-year funding with carry-over authority for R&amp;D and procurement initiatives.</p> <p>Manage funding as a "national portfolio" that mitigates risk by a broad set of target products, with multiple MCMs per disease.</p> <p>Base metrics on portfolio</p> | <p><b>Row 8; Column 4a</b></p> <p>Limited track record. Partial analogies: Aerospace industry in early 1940s. Consistent procurement of aircraft carriers since 1940s.</p> <p>Congressional long-term recognition of threat (natural and malicious) and tolerance for MCM technical failure unknown.</p> |

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|  |  |  | <p>performance, rather than individual candidate countermeasures. Long-term funding and ongoing government procurement (10 years or longer) is essential to maintain warm-base MCM manufacturing and surge capacity.</p> |  |
|  |  | <p><b>Row 8; Column 2b</b></p> <p>Need significantly expanded federal funding under BioShield for advanced development and procurement activities (BioShield reauthorization and funding).<br/>         Stop and reverse Congressional diversion of BioShield Reserve Fund for other initiatives (\$412M in FY09 = \$137M for pandemic + \$275M for PAHPA implementation),<br/>         Need long-term funding for acquisition of FDA-approved/licensed MCMs for Strategic National Stockpile.</p> | <p><b>Row 8; Column 3b</b></p> <p>Solution: a blend of indefinite mandatory funding authority with caveats to assure good-faith performance and sufficient ongoing discretionary appropriations.</p>                     |  |

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| <p style="text-align: center;"><b>9</b></p>  | <p style="text-align: center;"><b>Row 9; Column 1</b></p> <p><b>Funding stream</b></p>                  | <p style="text-align: center;"><b>Row 9; Column 3</b></p> <p>Provide for greater flexibility in milestone-driven payment schedules under PAHPA and BioShield, to account for the unpredictability of vaccine R&amp;D technical difficulties and progress.</p>                               | <p style="text-align: center;"><b>Row 9; Column 3</b></p> <p>PAHPA (2006) authorized \$1B to BARDA for advanced development of MCMs, in addition to BioShield Reserve Fund.</p> <p>Avoids rPA102 scenario (risk of repayment upon cancellation).</p>   | <p style="text-align: center;"><b>Row 9; Column 4</b></p> <p>Would likely require BARDA to use Other Transaction Authority (OTA) (not used to date).</p> |
| <p style="text-align: center;"><b>10</b></p> | <p style="text-align: center;"><b>Row 10; Column 1</b></p> <p><b>Untrodden development pathways</b></p> | <p style="text-align: center;"><b>Row 10; Column 2</b></p> <p>Cooperative R&amp;D Agreements (CRADAs) allow collaboration with respect for intellectual property.</p> <p>US Gov't and sponsor agree on defined development pathway at early stages to achieve a target product profile.</p> | <p style="text-align: center;"><b>Row 10; Column 3</b></p> <p>Enhanced recognition that changes in product requirements can be expected to increase the cost and time required to achieve a useable product.</p> <p>Requires enhanced integration of efforts by each USG entity (notably BARDA, NIAID, CDC, FDA, DoD, InterAgency Board)</p> |  |

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| 11                            | <p>Row 11; Column 1</p> <p><b>Facilitating technology transfer from basic to advanced development</b></p> | <p>Row 11; Column 2</p> <p>Streamline process to support integration of disciplines needed for successful scale-up of manufacturing processes.</p> <p>Increase US Gov't funding for applied bioscience, material sciences and biopharmaceutical processes.</p> | <p>Row 11; Column 3</p> <p>Offer innovator an option of (a) a milestone payment ("prize") as a single fee to license the intellectual property for further development or (b) continue involvement in development in exchange for the possibility of royalties after FDA licensure achieved.</p> | <p>Row 11; Column 4</p> <p>Milestone payments could be used on a multiple of private paid-in capital (variable) or a fixed amount per drug.</p> |
| <b>HUMAN CAPITAL ELEMENTS</b> |   |  |  |   |
|                               | <b>Column #1</b>  | <b>Column #2</b>   | <b>Column #3</b>   | <b>Column #4</b>  |
| <b>Row #</b>                  | <b>Problem / Category</b>   | <b>Potential Solution</b>  | <b>Approach / Advantages / Action</b>  | <b>Problem / Limitation</b>   |
| 12                            | <p>Row 12; Column 1</p> <p><b>Human capital within industry</b></p>                                       | <p>Row 12; Column 2</p> <p>Grow the pool of science and engineering talent pool within industry needed to develop and manufacture MCMs within the US.</p>  | <p>Row 12; Column 3</p> <p>Increased range of scientific programs offers additional career-development for industrial scientists and engineers.</p> <p>DARPA model assumes industry-standard</p>   | <p>Row 12; Column 4</p> <p>Additional flexibility needed in USG agency authority to provide competitive compensation to critical employees.</p> |

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|    |  |   | <p>compensation rates.</p> <p>Congress authorized large increases for NIH grants for researcher awards, but a long-term approach is needed to sustain the industrial base.</p> |   |
| 13 | <p><b>Row 13; Column 1</b></p> <p><b>Complex, evolving regulatory requirements</b></p> | <p><b>Row 13; Column 2a</b></p> <p>Clarify expectations early in product development and minimize changes in expectations in application review (e.g., requirements under "animal rule").</p> | <p><b>Row 13; Column 3a</b></p> <p>Spill-over benefits to commercial sphere via enhanced dialog with FDA</p>   |   |
|    |  | <p><b>Row 13; Column 2b</b></p> <p>Implement best practices for quality/regulatory systems for biosecurity products</p>   | <p><b>Row 13; Column 3b</b></p> <p>Partner with experienced biopharma organization to gain access to either staff or quality systems</p>                                       | <p><b>Row 13; Column 4b</b></p> <p>Companies with extensive FDA experience not currently engaged with MCM development or manufacture.</p> |
|    |  | <p><b>Row 13; Column 2c</b></p> <p>Collaboration with FDA to meet evolving (more stringent) standards for development, manufacture, clinical trials, and "animal-rule" pathways.</p>          | <p><b>Row 13; Column 3c</b></p> <p>Centralized advanced development and manufacturing to facilitate cross-product learning and system development</p>                          |   |

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|           |  | <b>Row 13; Column 2d</b><br>Accelerated FDA review   |  |   |
| <b>14</b> | <b>Row 14; Column 1</b><br><b>Administrative requirements to comply with USG contracts</b> | <b>Row 14; Column 2</b><br>Contracting reform to relieve the regulatory and reporting burden | <b>Row 14; Column 3</b><br>Waive nonessential accounting requirements and other components of the Federal Acquisition Regulation (FAR).<br><br>BARDA should identify opportunities to use Other Transaction Authority (OTA) to enhance R&D contracts (akin to DARPA).<br><br>Explore Cooperative R&D Agreement (CRADA) approaches. | <b>Row 14; Column 4</b><br>Familiarity with Federal Acquisition Regulations (FAR) (or relief from them) |
| <b>15</b> | <b>Row 15; Column 1</b><br><b>Adequacy of review and consultation resources at FDA</b>     | <b>Row 15; Column 2</b><br>Increase appropriations to enhance FDA review and consultation.   | <b>Row 15; Column 3</b><br>More medical reviewers needed, plus research and assay development within FDA.<br><br>Increase percentage   |   |

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|                          |   |   | of personnel eligible for enhanced bonus payments or super-grades.   |  |
| <b>SOCIETAL ELEMENTS</b> |   |   |  |  |
|                          | <b>Column #1</b>  | <b>Column #2</b>  | <b>Column #3</b>   | <b>Column #4</b>   |
| <b>Row #</b>             | <b>Problem / Category</b>   | <b>Potential Solution</b>   | <b>Approach / Advantages / Action</b>  | <b>Problem / Limitation</b>  |
| <b>16</b>                | <b>Row 16; Column 1</b><br><b>Contribution to national security</b> | <b>Row 16; Column 2</b><br>Exploration of biosecurity MCMs is likely to have spill-over benefits to "natural" infectious diseases as well | <b>Row 16; Column 3</b><br>Enhanced corporate reputation   | <b>Row 16; Column 4</b><br>Increased public attention during crisis  |
| <b>LEGAL ELEMENTS</b>    |   |   |  |  |
|                          | <b>Column #1</b>  | <b>Column #2</b>  | <b>Column #3</b>   | <b>Column #4</b>   |
| <b>Row #</b>             | <b>Problem / Category</b>   | <b>Potential Solution</b>   | <b>Approach / Advantages / Action</b>  | <b>Problem / Limitation</b>  |
| <b>17</b>                | <b>Row 17; Column 1</b><br><b>Product liability</b>                 | <b>Row 17; Column 2</b><br>Expand coverage of PREP Act to additional MCMs for which Material Threat Assessments (MTAs) exist.             | <b>Row 17; Column 3</b><br>Indemnification via Public Readiness & Emergency Preparedness (PREP) Act of 2005 (PL 109-148, Dec 30, 2005) | <b>Row 17; Column 4</b><br>Not tested in practice or litigated.<br><a href="http://www.pandemicflu.gov/plan/federal/prep_act.html">www.pandemicflu.gov/plan/federal/prep_act.html</a><br>PL 109-148. PHS Act Section 319(f)(3). 42 USC § 247d-6d.<br>[see also Support Antiterrorism by Fostering Effective Technologies (SAFE-T) Act of 2002 [within Homeland Security Act, PL 107-296].] |

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| 18 | <p><b>Row 18; Column 1</b></p> <p><b>Antitrust Provisions</b></p> | <p><b>Row 18; Column 2</b></p> <p>Assess need for, plan, and implement antitrust waiver authority under PAHPA 2006 for R&amp;D and preparedness activities to allow nominally competing parties to collaborate during a public health emergency or to conduct contingency exercises before a public-health emergency. Involve DoJ and Attorney General in supervisory/compliance role.</p> | <p><b>Row 18; Column 3</b></p> <p>Need ability to develop contingency plans and preliminary communication and technical consultation.</p> <p>Continue and expand efforts such as those underway with pandemic influenza vaccine and adjuvant "mix-and-match" studies to assess safety and efficacy.</p> |  |
|----|---|--|---|--|

**COROLLARY ELEMENTS**

|              | <b>Column #1</b>   | <b>Column #2</b>  | <b>Column #3</b>  | <b>Column #4</b>            |
|--------------|--|---|---|-----------------------------|
| <b>Row #</b> | <b>Problem / Category</b>  | <b>Potential Solution</b>   | <b>Approach / Advantages / Action</b>   | <b>Problem / Limitation</b> |
| 19           | <p><b>Row 19; Column 1</b></p> <p><b>Attractiveness of commercial vaccine market for support of future R&amp;D and manufacturing</b></p> | <p><b>Row 19; Column 2</b></p> <p>Implement national policies to provide adequate reimbursement for vaccines and their administration in both the public and private sectors, to help underwrite and sustain the industrial base needed for biosecurity and global-health products.</p> | <p><b>Row 19; Column 3</b></p> <p>Consolidate Medicare coverage of all vaccines within Part B (not Part D).</p> <p>Increase administration reimbursement rates under Medicaid and Vaccines for Children</p> |                             |

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|    |  |   | <p>(VFC) beneficiaries with federal subsidies to offset increased State costs.</p> <p>Third-party payers to provide first-dollar coverage for FDA-licensed vaccines and their administration under healthcare reform.</p>   |  |
| 20 | <p><b>Row 20; Column 1</b></p> <p><b>Approaches suitable for developing-world situations (perhaps useful by analogy)</b></p> | <p><b>Row 20; Column 2</b></p> <p>Advanced Market Commitments (AMC) separately for existing vaccines and global health vaccines at R&amp;D stage.</p> | <p><b>Row 20; Column 3</b></p> <p>Examples: Guarantee a market in developing countries for pneumococcal vaccines to prevent deadly respiratory infections in children and as an incentive for development of vaccines that currently do not exist against infectious disease threats in those countries, but which may be imported into the US or threaten global security.</p> |  |

| <b>OTHER BENEFITS TO INVOLVEMENT WITH BIOSECURITY INITIATIVE.....</b> |  |   |  |  |
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|   | <b>Column #1</b>   | <b>Column #2</b>  | <b>Column #3</b>   | <b>Column #4</b>   |
| <b>Row #</b>  | <b>Problem / Category</b>  | <b>Potential Solution</b>   | <b>Approach / Advantages / Action</b>  | <b>Problem / Limitation</b>  |
| <b>21</b>   | <p><b>Row 21; Column 1</b></p> <p><b>Competitive situation</b></p>                 | <p><b>Row 21; Column 2</b></p> <p>Don't put all eggs in one basket, allow multiple technologies and product candidates to progress simultaneously through development pathways.</p> | <p><b>Row 21; Column 3</b></p> <p>Participation by manufacturer with US Gov't withholds scientific, financial, and human-capital benefit to competitors.</p> |  |
| <b>22</b>   | <p><b>Row 22; Column 1</b></p> <p><b>New intellectual property</b></p>             |   | <p><b>Row 22; Column 3</b></p> <p>IP developed in course of government contract remains with discoverer.</p>   | <p><b>Row 22; Column 4</b></p> <p>US Gov't has step-in rights if patent arising from federal government-funded research not exploited [Bayh-Dole Act of 1980 (or University &amp; Small Business Patent Procedures Act), codified in 35 USC § 200-212[1], implemented by 37 CFR 401[2]</p> |
| <b>23</b>   | <p><b>Row 23; Column 1</b></p> <p><b>Staying abreast of advancing sciences</b></p> |   | <p><b>Row 23; Column 3</b></p> <p>Access to state-of-art process analytics for wide variety of biological products</p>                                       | <p><b>Row 23; Column 4</b></p> <p>Need to understand exclusivity of access</p>   |

Citations:

Project BioShield Act of 2004: PL 108-276, [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108\\_cong\\_public\\_laws&docid=f:publ276.108.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_public_laws&docid=f:publ276.108.pdf)

BioShield II (2005):

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