following changes are made to Form 323: The instructions have been revised to incorporate a definition of ''eligible entity,'' which will apply to the Commission's existing Equity Debt Plus (''EDP'') standard, one of the standards used to determine whether interests are attributable. The instructions have also been revised to update citations to the Commission's media ownership rules.

In addition, on April 8, 2009, the Commission adopted a Report and Order and Fourth Further Notice of Proposed Rulemaking (the ''323 Order'') in MB Docket Nos. 07–294, 06–121, 02–277, 01–235, 01–317, 00–244, 04–228; *FCC 09–33*. Consistent with actions taken by the Commission in the 323 Order, the following changes are made to Form 323: The instructions have been revised to state the Commission's revised Biennial filing requirements adopted in the 323 Order. The instructions and questions in all sections of the form have been significantly revised. Many questions on the form have been reworked or reordered in order to (1) Clarify the information sought in the form; (2) simplify completion of the form by giving respondents menu-style or checkbox-style options to select rather than submit a separate narrative exhibit; and (3) make the data collected on the form more adaptable for use in database programs used to prepare economic and policy studies relating to media ownership.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E9–19222 Filed 8–10–09; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than August 26, 2009.

A. Federal Reserve Bank of Atlanta (Steve Foley, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309:

1. Don Arthur Barnette, Jonesboro, Georiga; to acquire additional voting shares of CCB Financial Corporation, and thereby indirectly acquire additional voting shares of Community Capital Bank, both of Jonesboro, Georgia.

2. Odric Gregory, individually, and as Chief Manager of Gregory Investments LLC, both of Gallatin, Tennessee; to acquire additional voting shares of Macon Banctrust, Inc., and thereby indirectly acquire additional voting shares of Macon Bank and Trust Company, both of Lafayette, Tennessee.

B. Federal Reserve Bank of Dallas (E. Ann Worthy, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. Harold Ira Kane, Corpus Christi, Texas; to retain voting shares of Charter Bancshares, Inc., and thereby indirectly retain voting shares of Charter Alliance Bank (*de novo*), both of Corpus Christi, Texas, Charter IBHC, Inc., Wilmington, Delaware, and Charter Bank, Corpus Christi, Texas.

Board of Governors of the Federal Reserve System, August 6, 2009.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. E9–19172 Filed 8–10–09; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed; Correction

AGENCY: Federal Maritime Commission.

Citation of Previous Notice of Agreements Filed: 74 FR 37709, July 29, 2009.

Previous Notice of Agreements Filed Dated: July 24, 2009.

Correction to the Notice of Agreements Filed: All of the Filing Parties and the complete Synopsis of Agreement No. 201204 were not printed in the original Notice. The complete Notice should read as follows:

Agreement No.: 201204.

Title: Port of Houston Authority and Houston Marine Terminal Operators/Freight Handlers Agreement.

Parties: Port of Houston Authority; Ceres Gulf, Inc.; Chaparral Stevedoring Company of Texas, Inc.; CT Stevedoring, Inc. dba Cooper/T. Smith Stevedoring Co.; Ports America Texas, Inc.; GP Terminals LLC; Shippers Stevedoring Company; and SSA Gulf, Inc.

Filing Party: Erik A. Eriksson, Esq.; Port of Houston Authority; Executive Office; 111 East Loop; Houston, TX 77029–4327.

Synopsis: The agreement authorizes the Port of Houston Authority and seven affiliated freight handlers to discuss and voluntarily agree on matters of common interest at the Port of Houston.

Contact Person for More Information: Karen V. Gregory, Secretary, (202) 523–5725.

Tanga S. FitzGibbon,

Assistant Secretary.

[FR Doc. E9–19208 Filed 8–10–09; 8:45 am]

BILLING CODE 6730–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

The National Biodefense Science Board (NBSB), a Federal Advisory Committee to the Secretary; Request for Public Comment

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Request for public comment.

SUMMARY: The U.S. Department of Health and Human Services is hereby giving notice that the National Biodefense Science Board (NBSB) Medical Countermeasure Markets and Sustainability Working Group is requesting public comment to their working document, ''Inventory of Issues Constraining or Enabling Industry Involvement in Medical Countermeasure Efforts''. The inventory (or grid) includes factors that may discourage industry involvement or partnering with the U.S. Government 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 Working Group wishes to solicit comment, feedback, and guidance from members of industry, other government agencies, and the public at large for consideration by the Working Group to strengthen and refine the document prior to its public presentation to the NBSB at the scheduled Fall 2009 public meeting of the Board.

DATES: The public is asked to submit comments by October 30, 2009, to the NBSB e-mail box (*NBSB@hhs.gov*) in order to be considered by the Working Group in preparing the final document.

ADDRESSES:

Availability of Materials: Requests for a copy of the Inventory and accompanying ''Comment Revision Form'' should be made to the NBSB's e-mail box at *NBSB@hhs.gov* with ''M&S–WG Inventory Request'' in the subject line. All comments and/or recommendations for improvement to the Inventory should be made on the ''Comment Revision Form'' enclosed with the inventory document.

Procedures for Providing Public Input: Interested members of the public may submit written comments and/or suggestions, using the ''Comment Revision Form,'' to the NBSB's e-mail box at *NBSB@hhs.gov,* with ''M&S–WG Inventory Comments'' in the subject line and should be received no later than October 30, 2009. Individuals providing comment or suggestions will be asked to provide their name, title, and organization. All comments received will be posted without change to *http://www.hhs.gov/aspr/omsph/nbsb/,* including any personal or commercial information provided.

FOR FURTHER INFORMATION, CONTACT: Donald Malinowski, M.Sc., HHS/ASPR/NBSB, 330 C St., SW., #5118, Washington, DC 20201, 202–205–4761, *donald.malinowski@hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 319M of the Public Health Service Act (42 U.S.C. 247d–7f) and section 222 of the Public Health Service Act (42 U.S.C. 217a), the Department of Health and Human Services established the National Biodefense Science Board. The Board shall provide expert advice and guidance to the Secretary on scientific, technical, and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. The Board may also provide advice and guidance to the Secretary on other matters related to public health emergency preparedness and response.

Dated: July 29, 2009.

Nicole Lurie,

Assistant Secretary for Preparedness and Response, Rear Admiral, U.S. Public Health Service.

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 exists 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* 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* 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

Row #	Problem/category Column #1	Potential solution Column #2	Approach/ advantages/ action Column #3	Problem/limitation Column #4
		Financial Elements		
1	Row 1; Column 1 ..... Capital requirements to establish safety, efficacy, validated manufacture.	Row 1; Column 2 ..... Increase financial return after risking capital to industry-standard rates. Reduce requirement for private capital for advanced development.	Row 1; Column 3 ..... Increased federal funding for advanced development, in the form of cost-reimbursement contracts and rewarding private-capital investments with milestone payments and at procurement.	Row 1; Column 4. 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].
2	Row 2; Column 1 ..... Risk of technical failure of vaccine development effort.	Row 2; Column 2a ..... Decentralized discovery/centralized development and manufacture. Row 2; Column 2b ..... Evaluation of whether indirect-cost reimbursement greater than 100% may be appropriate. Assistance with calculating indirect cost rates (for companies that have never done so before)..	Row 2; Column 3a ..... Reimbursement of development costs at cost +15%, with return-on-working-capital at 22%, and cost-of-money-for-capital at 15%. Row 2; Column 3b. Provides support early in process.	Row 2; Column 4. Lack of interest, given opportunity costs Congressional tolerance for anticipatable frustrations is unknown.
3	Row 3; Column 1 ..... Tax incentives	Row 3; Column 2a ..... Enhance current incremental R&D tax credit (increase, make refundable). Row 3; Column 2b ..... 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 3a. Currently, 20% for qualified R&D expenses and 50% for clinical-trial expenses. Row 3; Column 3b ..... Enhance net revenue	Row 3; Column 4. Not yet authorized.
4	Row 4; Column 1	Row 4; Column 2	Row 4; Column 3	Row 4; Column 4.

INVENTORY OF ISSUES CONSTRAINING OR ENABLING INDUSTRIAL INVOLVEMENT WITH MEDICAL COUNTERMEASURE DEVELOPMENT 18 MAY 09—Continued

Row #	Problem/category Column #1	Potential solution Column #2	Approach/ advantages/ action Column #3	Problem/limitation Column #4
	Revenue enhancements based on Intellectual Property.	Enhance current product or use patent-term restoration and/ or extension (revise formula). Allow full patent-term extension for licensed products that gain CBRN or emerging disease application (akin to adding pediatric indication). Allow transfer of patent-term extension to another product or company (''wildcard''). Market exclusivity: Increase term of market exclusivity to ~ 12–15 years and extend it to biologicals (as does Orphan Drug Act).	Current statutory formula: Patent extension supplemented by [½ time from IND to filing BLA + full time from BLA filing to FDA approval/licensure]. 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.	Note: Orphan drug tax credit applies to vaccines only if less than 200,000 vaccinated recipients anticipated.
5	Row 5; Column 1 ..... Priority-Review Vouchers (PRV).	Row 5; Column 2 ..... Make applicable to biosecurity products.	Row 5; Column 3 ..... 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 Coartem malaria treatment (artemether and lumefantrine) in Apr 09.	Row 5; Column 4. Predictability: Would a priority-review voucher simply accelerate a ''no'' or ''not yet'' response? 2007 law: Text at: *http://www.bvgh.org/documents/HR3580-CompromiseFDA-PDUFABill.pdf* Draft FDA guidance: *http://www.fda.gov/cber/gdlns/tropicaldisease.htm*.
6	Row 6; Column 1 ..... Limited market size (development costs >> market potential).	Row 6; Column 2a ..... Acquisition RFPs should state minimum quantities (total and to each successful awardee) to increase market certainty to potential bidders and their investors. Row 6; Column 2b ..... 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. Row 6; Column 2c ..... 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.	Row 6; Column 3a ..... 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. Row 6; Column 3b ..... Treaty allies represent additional markets.	Row 6; Column 4a. 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. Row 6; Column 4b. Allies have not made substantial independent purchases to date. Some may hope/expect USG to share stockpile when attack occurs. Row 6; Column 4c. Currently only drugs, antidotes, and various treatments are covered, but not vaccines for prophylaxis in the first place.
7	Row 7; Column 1	Row 7; Column 2	Row 7; Column 3	Row 7; Column 4.

INVENTORY OF ISSUES CONSTRAINING OR ENABLING INDUSTRIAL INVOLVEMENT WITH MEDICAL COUNTERMEASURE DEVELOPMENT 18 MAY 09—Continued

Row #	Problem/category Column #1	Potential solution Column #2	Approach/ advantages/ action Column #3	Problem/limitation Column #4
	Surge issues	Compensation if commercial product(s) displaced during emergencies (*e.g.*, lost sales, market share, delayed licensing).	Define ''compensation'' in initial contract or agree to a dispute-resolution mechanism.	Potential compensation may need to include delay of a new product or loss of market share to a competitor. Level difficult to determine a priori.
		Legislative Elements		
8	Row 8; Column 1 Predictability, consistency adequacy of Congressional appropriations.	Row 8; Column 2a 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. 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. Row 8; Column 2b Need significantly expanded federal funding under BioShield for advanced development and procurement activities (BioShield reauthorization and funding). Stop and reverse Congressional diversion of BioShield Reserve Fund for other initiatives ($412M in FY09 = $137M for pandemic + $275M for PAHPA implementation), Need long-term funding for acquisition of FDA-approved/licensed MCMs for Strategic National Stockpile.	Row 8; Column 3a Multi-year contracting authority (for large molecules, due to complex manufacturing and limited use) and multi-year funding with carry-over authority for R&D and procurement initiatives. Manage funding as a ''national portfolio'' that mitigates risk by a broad set of target products, with multiple MCMs per disease. Base metrics on portfolio 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. Row 8; Column 3b. Solution: a blend of indefinite mandatory funding authority with caveats to assure good-faith performance and sufficient ongoing discretionary appropriations.	Row 8; Column 4a. Limited track record. Partial analogies: Aerospace industry in early 1940s. Consistent procurement of aircraft carriers since 1940s. Congressional long-term recognition of threat (natural and malicious) and tolerance for MCM technical failure unknown.
9	Row 9; Column 1 Funding stream	Row 9; Column 3 Provide for greater flexibility in milestone-driven payment schedules under PAHPA and BioShield, to account for the unpredictability of vaccine R&D technical difficulties and progress.	Row 9; Column 3 PAHPA (2006) authorized $1B to BARDA for advanced development of MCMs, in addition to BioShield Reserve Fund. Avoids rPA102 scenario (risk of repayment upon cancellation).	Row 9; Column 4. Would likely require BARDA to use Other Transaction Authority (OTA) (not used to date).
10	Row 10; Column 1	Row 10; Column 2	Row 10; Column 3..	

INVENTORY OF ISSUES CONSTRAINING OR ENABLING INDUSTRIAL INVOLVEMENT WITH MEDICAL COUNTERMEASURE DEVELOPMENT 18 MAY 09—Continued

Row #	Problem/category Column #1	Potential solution Column #2	Approach/ advantages/ action Column #3	Problem/limitation Column #4
	Untrodden development pathways.	Cooperative R&D Agreements (CRADAs) allow collaboration with respect for intellectual property. US Gov't and sponsor agree on defined development pathway at early stages to achieve a target product profile.	Enhanced recognition that changes in product requirements can be expected to increase the cost and time required to achieve a useable product. Requires enhanced integration of efforts by each USG entity (notably BARDA, NIAID, CDC, FDA, DoD, Inter-Agency Board).	
11	Row 11; Column 1 ..... Facilitating technology transfer from basic to advanced development.	Row 11; Column 2 ..... Streamline process to support integration of disciplines needed for successful scale-up of manufacturing processes. Increase U.S. Gov't funding for applied bioscience, material sciences and biopharmaceutical processes.	Row 11; Column 3 ..... 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.	Row 11; Column 4. Milestone payments could be used on a multiple of private paid-in capital (variable) or a fixed amount per drug.
		Human Capital Elements		
12	Row 12; Column 1 ..... Human capital within industry ..	Row 12; Column 2 ..... Grow the pool of science and engineering talent pool within industry needed to develop and manufacture MCMs within the US.	Row 12; Column 3 ..... Increased range of scientific programs offers additional career-development for industrial scientists and engineers. DARPA model assumes industry-standard compensation rates. Congress authorized large increases for NIH grants for researcher awards, but a long-term approach is needed to sustain the industrial base..	Row 12; Column 4 Additional flexibility needed in USG agency authority to provide competitive compensation to critical employees.
13	Row 13; Column 1 ..... Complex, evolving regulatory requirements.	Row 13; Column 2a ..... Clarify expectations early in product development and minimize changes in expectations in application review (e.g., requirements under "animal rule"). Row 13; Column 2b ..... Implement best practices for quality/regulatory systems for biosecurity products. Row 13; Column 2c ..... Collaboration with FDA to meet evolving (more stringent) standards for development, manufacture, clinical trials, and "animal-rule" pathways. Row 13; Column 2d. Accelerated FDA review.	Row 13; Column 3a. Spill-over benefits to commercial sphere via enhanced dialog with FDA. Row 13; Column 3b ..... Partner with experienced biopharma organization to gain access to either staff or quality systems. Row 13; Column 3c. Centralized advanced development and manufacturing to facilitate cross-product learning and system development.	Row 13; Column 4b. Companies with extensive FDA experience not currently engaged with MCM development or manufacture.
14	Row 14; Column 1 ..... Administrative requirements to comply with USG contracts.	Row 14; Column 2 ..... Contracting reform to relieve the regulatory and reporting burden.	Row 14; Column 3 ..... Waive nonessential accounting requirements and other components of the Federal Acquisition Regulation (FAR).	Row 14; Column 4 Familiarity with Federal Acquisition Regulations (FAR) (or relief from them).

INVENTORY OF ISSUES CONSTRAINING OR ENABLING INDUSTRIAL INVOLVEMENT WITH MEDICAL COUNTERMEASURE DEVELOPMENT 18 MAY 09—Continued

Row #	Problem/category Column #1	Potential solution Column #2	Approach/ advantages/ action Column #3	Problem/limitation Column #4
			BARDA should identify opportunities to use Other Transaction Authority (OTA) to enhance R&D contracts (akin to DARPA).. Explore Cooperative R&D Agreement (CRADA) approaches.	
15	Row 15; Column 1 ..... Adequacy of review and consultation resources at FDA.	Row 15; Column 2 ..... Increase appropriations to enhance FDA review and consultation.	Row 15; Column 3. More medical reviewers needed, plus research and assay development within FDA. Increase percentage of personnel eligible for enhanced bonus payments or supergrades.	
Societal Elements				
16	Row 16; Column 1 ..... Contribution to national security..	Row 16; Column 2 ..... Exploration of biosecurity MCMs is likely to have spillover benefits to ''natural'' infectious diseases as well.	Row 16; Column 3 ..... Enhanced corporate reputation.	Row 16; Column 4 Increased public attention during crisis.
Legal Elements				
17	Row 17; Column 1 ..... Product liability	Row 17; Column 2 ..... Expand coverage of PREP Act to additional MCMs for which Material Threat Assessments (MTAs) exist.	Row 17; Column 3 ..... Indemnification via Public Readiness & Emergency Preparedness (PREP) Act of 2005 (PL 109–148, Dec 30, 2005).	Row 17; Column 4. Not tested in practice or litigated. *http://www.pandemicflu.gov/plan/federal/prep_act.html* Public Law 109–148. PHS Act Section 319(f)(3). 42 U.S.C. 247d–6d. [See also Support Antiterrorism by Fostering Effective Technologies (SAFE-T) Act of 2002 [within Homeland Security Act, Pub. L. 107–296].]
18	Row 18; Column 1 ..... Antitrust Provisions	Row 18; Column 2 ..... Assess need for, plan, and implement antitrust waiver authority under PAHPA 2006 for R&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.	Row 18; Column 3. Need ability to develop contingency plans and preliminary communication and technical consultation. Continue and expand efforts such as those underway with pandemic influenza vaccine and adjuvant ''mix-and-match'' studies to assess safety and efficacy.	
Corollary Elements				
19	Row 19; Column 1	Row 19; Column 2	Row 19; Column 3.	

INVENTORY OF ISSUES CONSTRAINING OR ENABLING INDUSTRIAL INVOLVEMENT WITH MEDICAL COUNTERMEASURE DEVELOPMENT 18 MAY 09—Continued

Row #	Problem/category Column #1	Potential solution Column #2	Approach/ advantages/ action Column #3	Problem/limitation Column #4
	Attractiveness of commercial vaccine market for support of future R&D and manufacturing.	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.	Consolidate Medicare coverage of all vaccines within Part B (not Part D). Increase administration reimbursement rates under Medicaid and Vaccines for Children (VFC) beneficiaries with federal subsidies to offset increased State costs. Third-party payers to provide first-dollar coverage for FDA-licensed vaccines and their administration under healthcare reform.	
20	Row 20; Column 1 ..... Approaches suitable for developing-world situations (perhaps useful by analogy).	Row 20; Column 2 ..... Advanced Market Commitments (AMC) separately for existing vaccines and global health vaccines at R&D stage.	Row 20; Column 3.. 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 U.S. or threaten global security.	
Other Benefits to Involvement With Biosecurity Initiative				
21	Row 21; Column 1 ..... Competitive situation	Row 21; Column 2 ..... Don't put all eggs in one basket, allow multiple technologies and product candidates to progress simultaneously through development pathways.	Row 21; Column 3. Participation by manufacturer with U.S. Gov't withholds scientific, financial, and human-capital benefit to competitors.	
22	Row 22; Column 1 ..... New intellectual property		Row 22; Column 3 ..... IP developed in course of government contract remains with discoverer.	Row 22; Column 4. U.S. Gov't has step-in rights if patent arising from federal government-funded research not exploited [Bayh-Dole Act of 1980 (or University & Small Business Patent Procedures Act), codified in 35 U.S.C. 200–212[1], implemented by 37 CFR 401[2]].
23	Row 23; Column 1 ..... Staying abreast of advancing sciences.		Row 23; Column 3 ..... Access to state-of-art process analytics for wide variety of biological products.	Row 23; Column 4. Need to understand exclusivity of access.

Citations:

Project BioShield Act of 2004: Public Law 108–276, *http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_public_laws&docid=f:publ276.108.pdf.*

BioShield II (2005):

PAHPA, PL 109–417, Dec 19, 2006.

Bibliography:

Matheny J, Mair M, Mulcahy A, Smith BT. Incentives for biodefense countermeasure

development. *Biosecur Bioterror* 2007 Sep;5(3):228–38.

Animal Rule = U.S. Food and Drug Administration. New drug and biological drug products; evidence needed to demonstrate effectiveness of new drugs when human efficacy studies are not ethical or feasible. Final rule. *FR* 2002 May 31;67(105):37988–98. *http://frwebgate5.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=483712496781+5+2+0&WAISaction=retrieve.*

BILLING CODE 4150–37–C

Markets & Sustainability-WG "Inventory of Issues Constraining or Enabling Industry Involvement in Medical Countermeasure Efforts" Revision Form

Revisions due by 10:00 a.m. October 30, 2009

Name:	
Organization:	
Email:	

Please identify revised sections of the inventory grid by their corresponding Row and Column Numbers. Provide specific, concrete language for revision utilizing this revision form.

Row #	Column #	Comment	Recommended Revision

[FR Doc. E9–19199 Filed 8–10–09; 8:45 am]
BILLING CODE 4150–37–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission of OMB Review; Comment Request; Investigator Registration and Financial Disclosure for Investigational Trials in Cancer Treatment (NCI)

SUMMARY: In compliance with the requirement of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute, (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collected below. This proposed information collection was previously published in the **Federal Register** on June 10, 2009 (74 FR 27552), and allowed 60 days for public comment. One public comment was received regarding pharmaceutical testing. The submitter responded to the e-mail. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a valid OMB control number.

Proposed Collection: *Title:* Investigator Registration and Financial Disclosure for Investigational Trials in Cancer Treatment (NCI). *Type of Information Collection Request:* Existing Collection in Use without an OMB Number. *Need and Use of Information Collection:* Food and Drug Administration (FDA) regulations require sponsors to obtain information from the investigator before permitting the investigator to begin participation in investigational studies. The National Cancer Institute, (NCI) as a sponsor of investigational drug trials, has the responsibility to assure the FDA that investigators in its clinical trials program are qualified by training and experience as appropriate experts to investigate the drug. In order to fulfill these requirements, a standard Statement of Investigator (FDA Form 1572 modified), Supplemental Investigator Data Form, Financial Disclosure Form and Curriculum vitae (CV) are required. The NCI will accept the investigator's CV in any format. All investigators maintain a CV as part of their academic and professional practice. The data obtained from these forms allows the NCI to evaluate the qualifications of the investigator, identify appropriate personnel to receive shipment of investigational agent, ensure supplies are not diverted for inappropriate protocol or patient use and identify financial conflicts of interest. Comparisons are done with the intention of ensuring protocol, patient safety and drug compliance for patient and drug compliance for patient safety and protections. *Frequency of Response:* Annually.

Affected Public: Public sector, businesses or other for-profit that will include Federal agencies or employees, non-profit institutions and a very small number of private practice physicians. *Type of Respondents:* Investigators. The annual reporting burden is limited to those physicians who choose to participate in NCI sponsored investigational trials to identify new medicinal agents to treat and relieve those patients suffering from cancer.

The annualized respondents' burden for record keeping is estimated to require 8,564 hours (see table below).

TABLE—ESTIMATES OF ANNUAL BURDEN

Type of respondents	Form	Number of respondents	Frequency of response	Average time per response	Total hour burden
Investigators and Designee	Statement of Investigator	17,128	1	0.25 (15 minutes)	4,282
	Supplemental Investigator	17,128	1	0.167 (10 minutes)	2,855
	Financial Disclosure	17,128	1	0.083 (5 minutes)	1,427
Totals		17,128			8,564

There are no capital costs, operating costs, and maintenance cost.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information; including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Attention: NIH Desk Officer, Office of Management and Budget, at *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Charles L. Hall, Jr., Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division of the Cancer Treatment and Diagnosis, and Centers, National Cancer Institute, Executive Plaza North, Room 7148, 9000 Rockville Pike, Bethesda, MD 20892 or call non-toll-free number 301–496–5725 or E-mail your request, including your address, to: *Hallch@mail.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days following the date of this publication.

Dated: August 5, 2009.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

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