H.R. 2405, the Pandemic All-Hazard Preparedness Reauthorization Act of 2011

Section-by-Section Summary

Section 1 – Short title and table of contents

Section 2 – Reauthorization of certain provisions relating to public health preparedness

Section 2(a) – Vaccine tracking and distribution. Reauthorizes the vaccine tracking and distribution program, to be used during an influenza pandemic. The program is funded at $30.8 million each year for five years (FY12-FY16). This level of funding is equal to the program's FY11 appropriated level.

Section 2(b) – Public health preparedness grants. Reauthorizes the Public Health Emergency Preparedness Cooperative Agreement (PHEP) administered by the Centers For Disease Control and Prevention (CDC). These grants to state and local health departments have greatly improved the nation's ability to respond to many public health hazards. The program is funded at $632.9 million each year for five years (FY12-FY16). This level of funding is equal to the program's FY11 appropriated level.

Section 2(c) – Health system preparedness grants. Reauthorizes the Hospital Preparedness Program Cooperative Agreement administered by the HHS Assistant Secretary for Preparedness and Response (ASPR). These grants to states and hospitals have greatly improved our nation's preparedness for disasters that would result in a surge in the need for medical care. The program is funded at $378 million each year for five years (FY12-FY16). This level of funding is equal to the program's FY11 appropriated level.

Section 2(d) – CDC surveillance and capacity. Reauthorizes the federal, state, and local surveillance and situational awareness capacity programs. The program is funded at $160.1 million each year for five years (FY12-FY16). This level of funding is equal to the program's FY11 appropriated level.

Section 2(e) – Dental emergency responders. Incorporates dentists by name into federal and state disaster response frameworks, allowing dentists to be deployed during a natural or man-made disaster.

Section 2(f) – BioShield Special Reserve Fund. Reauthorizes the Project BioShield Special Reserve Fund (SRF), originally created in 2004. The SRF was intended to be used solely for procuring medical countermeasures in response to chemical, biological, radiological, or nuclear (CBRN) threats against the nation. Since 2004, the SRF has successfully procured medical countermeasures for the Strategic National Stockpile, protecting against threats such as anthrax and smallpox. This legislation reauthorizes the SRF at $2.8 billion over five years (FY2014-2018).

This level of funding is consistent with the SRF's original, 10-year appropriation of $5.6 billion for FY 2004-13.

- *Section 2(f)(1) – Statement of government purpose*. Requires the federal government to clearly define the purpose of a particular contract as it relates to the medical countermeasure being procured.

- *Section 2(f)(2) – Restriction on the use of SRF funds*. Prohibits SRF funds from being used for anything other than development and procurement of medical countermeasures. SRF funds cannot be used to pay any salaries or administrative expenses.

- *Section 2(f)(2) – Notice of insufficient funds*. Requires the Secretary to provide a report to Congress when funds available in the SRF go below $1.5 billion. The report would detail how the level of funding in the SRF impacts our nation's ability to develop medical countermeasures for public health threats.

- *Section 2(f)(2) – Use of SRF for advanced research and development*. Allows the Secretary to use up to 30 percent of funds available in the SRF for advanced research and development of medical countermeasures at the Biomedical Advanced Research and Development Authority (BARDA). These funds are intended to supplement, not supplant, BARDA's funding through the annual appropriations process.

Section 2(g) – Biomedical Advanced Research and Development Authority (BARDA). Reauthorizes BARDA. BARDA was created in 2006 to help bridge the "valley of death" between medical countermeasure development and procurement. BARDA has been successful in getting many early-stage medical countermeasures through the expensive, time consuming development process so that these products can be procured for the Strategic National Stockpile. BARDA is funded at $415 million each year for five years (FY12-FY16). This level of funding is equal to the program's FY11 appropriated level.

- *Section 2(g)(2) – Extension of FOIA exemptions*. Extends requirements that the Secretary withhold from FOIA disclosure specific technical data or scientific information created during the advanced research and development of a medical countermeasure that reveals vulnerabilities of existing medical or public health defenses against CBRN threats.

- *Section 2(g)(1) – Statement of government purpose*. Requires the federal government to clearly define the purpose of a particular advanced research and development contract as it relates to the medical countermeasure under contract.

Section 2(h) – National Disaster Medical System. Reauthorizes the National Disaster Medical System (NDMS), which assists in managing the federal government's medical response to major

emergencies and disasters. The program is funded at $56 million each year for five years (FY12-FY16). This level of funding is equal to the program's FY11 appropriated level.

- *Section 2(h)(1)(D) – Third party administration*. Allows the Secretary to pay third party vendor who assist in the federal response to emergencies and disasters.

Section 2(i) – Extension of anti-trust exemptions. Extends limited anti-trust exemptions for meetings regarding medical countermeasure development that include national security information.

Section 3 – Improving coordination by the Assistant Secretary for Preparedness and Response

Section 2811 of the Public Health Service Act is amended to:

- *Improve coordination.* Clarifies that the duties of the ASPR are oversight and coordination of the entire medical countermeasure enterprise throughout HHS, including the stockpiling and distribution of medical countermeasures in the Strategic National Stockpile.

- *Clarify ASPR authority.* Clarifies the operational role of the ASPR by ensuring this position has authority over BARDA and other HHS preparedness programs.

- *Streamline grants.* Requires ASPR to streamline and better coordinates HHS preparedness grants in order to avoid duplication, as well as disseminate best practices.

- *Require budget analysis.* Requires the ASPR to conduct a comprehensive five year budget analysis of the entire medical countermeasure enterprise to ensure prioritization of limited resources.

- *Remove duplication.* Requires the ASPR to identify gaps, duplication, and other inefficiencies in public health preparedness activities and the actions necessary to overcome these obstacles.

- *Require Countermeasure Implementation Plan (CIP).* Requires the ASPR to conduct a Countermeasure Implementation Plan (CIP) in order to improve transparency, accountability, and success of the entire medical countermeasure enterprise. This report requires ASPR to identify threats against the nation, create measurable goals to address these threats, report on progress of meeting these goals, identify budget and funding needs, and identify specific timelines for medical countermeasure development. The report is due to Congress 6 months after the date of enactment and annually thereafter.

- *Consultation for Emergency Use Authorizations (EUAs).* Ensures that the ASPR is one of the individuals consulted when HHS authorizes medical products for use during emergencies.

Section 4 – Eliminating duplicative Project BioShield reports

This section repeals a report included under Project BioShield that is duplicative of parts of the new Countermeasure Implementation Plan created in Section 3 above.

Section 5 – Accelerating medical countermeasure development by strengthening FDA's role in reviewing products for national security priorities

Section 4(a) – Expansion of FDA's role in reviewing medical countermeasures. Amends section 565 of the Federal, Food, Drug and Cosmetic Act to require the FDA to accelerate the development, stockpiling, and licensure of medical countermeasures. FDA is required to expand the involvement of FDA personnel in interagency activities with BARDA, CDC, NIH, and DOD.

- *Regulatory management plan*. Requires FDA and the product sponsor, for all products procured under Project BioShield, to develop a Regulatory Management Plan. This plan would identify anticipated development activities including meetings, protocols and study reports. HHS is provided authority to apply this process to other products as appropriate.

- *Agency interaction with product sponsors*. Establishes timelines for FDA to schedule meetings and provide written feedback to protocol and study report submissions identified in the Regulatory Management Plan. HHS is required to establish timelines for all products procured under Project BioShield and other products as appropriate.

- *Animal models*. Establishes a process that facilitates the development of animal models to support high priority medical countermeasures. FDA is required to undertake Special Protocol Assessments for clinical trials necessary to support licensure of products under the Animal Rule when human efficacy studies are not possible.

- *Reporting requirements*. Requires improved reporting on FDA's countermeasure development and review activities. FDA is required to report to Congress regarding the implementation of the medical countermeasure initiative on an annual basis starting on January 1, 2012.