



## U.S. Department of Health and Human Services Assistant Secretary for Preparedness and Response

# The Public Health Emergency Medical Countermeasures Enterprise Review Fact Sheet

Emerging infectious diseases, pandemics, and bioterrorism carry the potential for catastrophic impact, and the U.S. Government has faced chronic challenges in producing medical countermeasures against such threats, as exemplified during the recent 2009-H1N1 pandemic. The President called out the renewed need for a national capability to respond to these threats in the State of the Union, and the Secretary of HHS stepped forward to address this need. The vision to combat such threats is simple: *our nation must have the nimble, flexible capability to produce medical countermeasures rapidly in the face of any attack or threat, whether known or unknown, novel or reemerging, natural or intentional.*

The business model of the current medical countermeasure development enterprise requires new, innovative approaches to meet this vision. The HHS Assistant Secretary for Preparedness and Response led an extensive review of all aspects of product development from concept to approval, calling on the scientific leaders from all federal agencies that work with medical countermeasures, the National Security Staff, state and local health departments, the National Biodefense Science Board, the President's Council of Advisors on Science and Technology, industry, and the Institute of Medicine.

The new strategy envisions a capabilities-based approach and a much more active role by the U.S. Government in forging partnerships, attacking constraints, modernizing regulatory oversight, and supporting transformative technologies. It also addresses leadership and management practices that must be addressed to produce an integrated and successful program.

The new strategy contains initiatives that focus on products, platforms and technologies with multi-use potential to transform how the Enterprise makes investments and enhances its performance by providing stronger support to our partners:

- **Emphasizing translation of medical countermeasures concepts and research produced by the National Institutes of Health (NIH)** programs through new approaches to scout for promising efforts and accelerating candidate product maturity by using the full range of NIH resources;

- **Removing barriers to innovation** and reducing the opportunity costs for the private sector by providing a full suite of testing, evaluation, product development, and manufacturing services in concert with mature pharmaceutical partners;
- **Promoting regulatory innovation and investment in regulatory science** in order to provide private sector partners with more access to regulators and greater clarity about the pathways to product approval;
- **Addressing capacity to respond quickly with products for pandemic diseases** as informed from the extensive experience gained during the 2009 H1N1 pandemic, and
- **Repositioning the U.S. Government as a strategic partner and investor** and providing meaningful financial incentives and rewards to private sector partners who succeed in developing the medical countermeasures we need.

The review findings and resulting strategy are informed by findings of the pandemic influenza review by the President's Council of Advisors on Science and Technology.

We will achieve greater productivity from our investments in biodefense and better protection from emerging infectious diseases by reducing or eliminating the inefficiencies and chokepoints that impede progress. The five elements will be pursued simultaneously, implemented in an enterprise-wide manner, and embodied in discrete but synergistic initiatives that will be announced shortly.

The strategy outlined above represents a significant departure from the U.S. Government's previous approach, and recognizes that incremental improvements will not achieve our goals. Only by taking bold steps and implementing this new transformative strategy, comprehensively and broadly, will we achieve the return on investment for which many in the Medical Countermeasure Enterprise have worked tirelessly. Our return will be measured not in dollars and cents but in the protection of the safety and security of the American people.