

Action Needed to Protect Against Biological Attack

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Study Goals

- (1) Decrease probability that the United States sustains serious damage from a biological attack.

- (2) Decrease probability of or preempt biological attack on the United States and worldwide.



Near-Term Recommendations

RECOMMENDATION 1. The President should create a new interagency entity charged with planning, coordination, and oversight of national biodefense activities across the Intelligence Community and the Departments of Defense, Homeland Security, Health and Human Services (HHS), and Agriculture. The entity should be co-led by the Assistant to the President for Homeland Security and Counterterrorism, the Assistant to the President for Science and Technology, and the Chair of the Domestic Policy Council. The entity should have senior-level representation from all of the indicated agencies, including from within HHS, the Centers of Disease Control and Prevention (CDC), the Biomedical Advanced Research Projects Administration (BARDA), and the National Institutes of Health (NIH). The entity should be charged with:

- a. Developing, within six months, a national biodefense strategy—including short-, medium-, and long-term components—to anticipate, prepare for, and respond to all issues that arise as biotechnology continues to advance;
- b. Preparing thereafter annual public updates (with a classified annex) to the President that describe progress toward achieving the strategy and update the strategy as necessary;



Near-Term Recommendations

- c. Overseeing execution of the national biodefense strategy and holding agencies accountable for progress;
- d. Guiding requirements and taskings of the Intelligence Community (IC) and holding the IC accountable for adequate collection and analysis of current and future biological threats to the United States and for other activities of the IC that might mitigate these threats; and
- e. Ensuring coordination of efforts against new and emerging infectious diseases, antibiotic resistance, and intentional biothreats—including through the development of biosurveillance systems and the new medical-countermeasures.



Near-Term Recommendations

RECOMMENDATION 2. The President should request that Congress establish a **Public Health Emergency Response Fund** of at least \$2 billion. The fund would support mobilization of rapid Federal responses to serious, rapidly emerging natural or intentional infectious-disease events, public health interventions (CDC), scientific research (BARDA and NIH), regulatory activities (FDA), and global response (DOD/AID/CDC).

- a. The Emergency Response Fund should, analogously to FEMA's Disaster Relief Fund, consist of funds that carry over across years and can be replenished by routine and emergency appropriations.
- b. Access to funds should be contingent upon the express authorization of the President or the joint agreement of the secretaries of HHS and DHS.



Medium-Term Recommendations

RECOMMENDATION 3. As part of its national biodefense strategy, the White House should act to substantially strengthen Federal, state, and local public health infrastructure for disease surveillance, as well as promote a stronger international system of disease surveillance. The surveillance capacity should include:

- a. Laboratory networks in the United States and abroad with the capability for early detection and rapid monitoring of both manmade and natural emerging infectious agents, in public health, agricultural, and wildlife settings.
- b. The ability to routinely and rapidly employ advanced biological tools—including rapid diagnostic tests, large-scale genome sequencing and analysis, and new approaches to monitor the host immune system—for systematic evaluation of possible cases, including those presenting simply as “fevers of unknown origin” or “severe acute respiratory infections.”



Medium-Term Recommendations

RECOMMENDATION 4. The White House should set the following ambitious ten-year goals with appropriate funding (of at least \$250 million per year) for medical counter-measures preparedness. The Secretary of Health and Human Services (HHS) and the Secretary of Defense (DoD) should report annually to the White House about progress and impediments to reaching these goals:

- a. For infectious organisms for which there exist effective approaches to creating vaccines, the United States should have the ability to accomplish, within a six-month period, the complete development, manufacture, clinical testing, and licensure of a vaccine. For pandemic influenza, the goal should be 3 to 4 months to vaccine deployment.
- b. For infectious organisms that might be reasonably anticipated to lead to sudden epidemic spread that could threaten the US population or US interests overseas, the United States should have pre-tested vaccine candidates through safety and immunogenicity studies.



Medium-Term Recommendations

RECOMMENDATION 5. The United States should set as a national priority the identification and development of additional classes of broad-spectrum antibiotic and antiviral drugs. Building on progress already made pursuant to the President’s Executive Order on Combating Antibiotic Resistant Bacteria, and the corresponding National Strategy and National Action Plan, the United States should fully implement PCAST’s recommendations from its 2014 report *Combating Antibiotic Resistance* related to antibiotic development, as well as the analogous strategies for antiviral development:

- a. Expand fundamental research relevant to developing antibiotics for human healthcare and other approaches to treating bacterial infections,
- b. Establish a robust national infrastructure to support clinical trials of new antibiotics,
- c. Strengthen and expand the dedicated existing regulatory efforts for MCMs and develop new regulatory pathways to evaluate urgently needed antibiotics, and
- d. Significantly increase economic incentives for developing urgently needed antibiotics.



Medium-Term Recommendations

(Recommendation 5, continued) The United States should also support the development of platform technologies for rapid production of therapeutics and preventative medicines (examples include specific immunobiologicals such as engineered antibodies, emerging nanomedicines that elicit specific and desired immune responses, and chemically modified nucleic acids with peptide adjuvants) to neutralize and block infectious organisms of natural origin or agents of biological attack.



Long-Term Recommendation

RECOMMENDATION 6. The Departments of Defense, Health and Human Services, and other government agencies should promote vigorous basic and applied research efforts in academic, industrial, and government laboratories with the goal of developing new types of countermeasures. These countermeasures should be rapidly and easily modified to target, safely and effectively, specific human-made and naturally-occurring pathogens. The delivery of approved countermeasures should be within days after the an agent's detection and characterization.

HHS and DoD should receive new funding of \$75M/year for four years to lay the foundation of this initiative. Funding for relevant agencies within HHS and DoD should then ramp up to a steady-state of at least \$250M/year.



Long-Term Recommendation

(Recommendation 6, continued) Examples of such rapid countermeasures might include approaches that: target infectious agents based on their genomes; employ optimized and tested vectors to deliver other nucleic acid-based anti-pathogen approaches to a wide range of specific human cell types; activate the immune system against classes of pathogens; target host pathways required by pathogens; rely on antigens expressed by RNA and nucleic acid analogs to stimulate protective immunity against specific pathogen epitopes; or provide immunity via antibodies and immune cells engineered to recognize pathogen-specific epitopes.