Project BioShield

TODAY’S PRESIDENTIAL ACTION

- In his State of the Union Address, President Bush announced Project BioShield -- a comprehensive effort to develop and make available modern, effective drugs and vaccines to protect against attack by biological and chemical weapons or other dangerous pathogens. Project BioShield will:
  - Ensure that resources are available to pay for “next-generation” medical countermeasures. Project BioShield will allow the government to buy improved vaccines or drugs for smallpox, anthrax, and botulinum toxin. Use of this authority is currently estimated to be $6 billion over ten years. Funds would also be available to buy countermeasures to protect against other dangerous pathogens, such as Ebola and plague, as soon as scientists verify the safety and effectiveness of these products.
  - Strengthen NIH development capabilities by speeding research and development on medical countermeasures based on the most promising recent scientific discoveries; and
  - Give FDA the ability to make promising treatments quickly available in emergency situations -- this tightly controlled new authority can make the newest treatments widely available to patients who need it in a crisis.

PROJECT BIOSHIELD – AN OVERVIEW

- Today, the country is better prepared than ever to meet the threat of terrorist attack with a biological, chemical, radiological or nuclear agent. The national stockpile of medical countermeasures is more extensive and can be accessed more rapidly than ever, and additional diagnostic tests, drugs, and vaccines are under development.

- But, the possibility of the intentional use of biological or other dangerous pathogens represents a threat to our society. Unfortunately, the medical treatments available for some types of terrorist attacks have improved little in decades, while there has been tremendous and rapid progress in the treatment of many serious naturally-occurring diseases.
  - The smallpox vaccines available today are not much different than those last used by the public in the 1960s. Some treatments for radiation and chemical exposure have not changed much since the 1970s.
  - In contrast, since the 1960s, the treatment of the vast majority of naturally-occurring illnesses has changed dramatically as a result of ongoing innovations from biomedical research and development. Heart attacks were often fatal in the 1970s, but they are much less so today. Better detection and therapeutic options have significantly increased survival rates for many kinds of cancer over the last 20 years.

- The President believes that, by bringing researchers, medical experts, and the biomedical industry together in a new and focused way, our Nation can achieve the same kind of treatment breakthroughs for bio-terrorism and other threats that have significantly reduced the threat of heart disease, cancer, and many other serious illnesses. The President's Project BioShield has three major components:
  1. Spending Authority for the Delivery of Next-Generation Medical Countermeasures. The President proposed the creation of a permanent indefinite funding authority to spur development of medical countermeasures. This authority will enable the government to purchase vaccines and other therapies as soon as experts believe that they can be made safe and effective, ensuring that the private sector devotes efforts to developing the countermeasures.
    - The Secretary of Homeland Security and the Secretary of Health and Human Services will collaborate in identifying critical medical countermeasures by evaluating likely threats, new opportunities in biomedical research and development, and public health considerations.
2. New NIH Programs to Speed Research and Development on Medical Countermeasures. The President proposed to give the NIH new authorities to speed research and development in promising areas of medical countermeasure development. NIH's usual methods for supporting research and development on conventional diseases have been extremely effective in those areas but may not always be suited to meet the urgent demands posed by the risk of terrorism. The new authorities would apply only to support research and development on bioterrorism threat agents and include the following features:

- The Director of the National Institute of Allergy and Infectious Diseases would have increased authority and flexibility to award contracts and grants for research and development of medical countermeasures. Funding awards would remain subject to rigorous scientific peer review, but expedited peer review procedures could be used when appropriate.
- This authority would also permit more rapid hiring of technical experts, and would allow NIH to quickly procure items necessary for research.

3. New FDA Emergency Use Authorization for Promising Medical Countermeasures Under Development. Some of the most promising treatments for a terrorist agent may still be under formal FDA review when an attack occurs. The President proposed an emergency use authorization to permit the effective use of such treatments in an emergency, if alternative treatments are not available. This will improve access to a potentially beneficial treatment in an emergency situation, when it is most likely to save lives, even if it has not yet been proven to be suitable for routine general use or has not completed the formal process for full FDA licensure.

- The thorough process required for FDA licensure has protected the American people and provided a supply of safe and effective drugs. The administration fully supports the thorough review FDA requires before licensing a product.
- These new authorities seek to supplement the traditional FDA licensing process to ensure that we could respond effectively in a crisis to use a medical countermeasure that experts judged to be safe and effective, but just had not completed the formal FDA process. This authority is very narrowly focused and targeted – only drugs under the direct control of the US government could be used, they could only be used after certain certifications had been made, and all civilian use would be voluntary.
- Current use of a drug prior to licensure – a so-called Investigational New Drug – has many safeguards built into it, including informed consent and extensive follow-up monitoring. These are important provisions, but in a crisis they could prevent the drug from being made available in a timely fashion to all the citizens who need it.
- The emergency use authorization would require a finding by the Secretary of Health and Human Services, based on expert analysis by FDA, that the treatment in question was expected to have benefits in the emergency situation that outweighed its expected risks.
- Unlike typical medical product approvals, the emergency use authorization may be limited to particular types of medical providers, patients, and conditions of use. Thus, the authorization would allow greater flexibility in the FDA review process to meet the circumstances of specific terrorist threats.
- The emergency use authorization would remain in effect no more than one year, unless the specific terrorist threat justifies extension of the authorization and the available evidence indicates that the countermeasure is providing important expected benefits.

- Scientific breakthroughs such as recombinant DNA technology, immunology, molecular structural engineering, genomics, and proteomics that are now protecting our health from many conventional diseases hold considerable promise against the diseases of terrorism as well. This same innovation can be applied to the challenge of protecting America by identifying the new treatments that are most needed, and providing meaningful and consistent rewards for innovators who bring these products to the American public. And, the breakthroughs resulting from Project BioShield are likely to have important spillover benefits in diagnosing and treating other diseases, and in strengthening our overall biotechnology infrastructure.

For more information on the President's initiatives, please visit www.whitehouse.gov