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The Power of Biomedical Research

By Anthony S. Fauci

The anthrax attacks in the fall of 2001, which occurred soon after the catastrophic terrorist assaults on the World Trade Center and the Pentagon on September 11, have starkly exposed the vulnerability of the United States — and, indeed, the rest of the world — to bioterrorism.

In response, the U.S. government has committed an extraordinary sum (nearly \$6.0 billion in fiscal year 2003) to develop strategies and countermeasures to protect Americans from further attacks by bioterrorists. This funding has enabled a multifaceted and comprehensive approach to civilian biodefense, involving the Department of Homeland Security and agencies of the Department of Health and Human Services, including the Center for Disease Control, the Food and Drug Administration and the National Institutes of Health (NIH).

The resources appropriated to the NIH alone for the conduct of biomedical research leading to the development of countermeasures against agents of bioterror were more than \$1.5 billion in fiscal year 2003.

With this infusion of resources to the research enterprise come enormous responsibilities, which are taken very seriously. At NIH, we have rapidly accelerated research devoted to the prevention, diagnosis and treatment of diseases caused by potential agents of bioterrorism. While our efforts have focused on the "Category A" agents considered to be the most likely and potentially devastating bioterror threats (smallpox, anthrax, botulinum toxin, plague, tularemia and hemorrhagic fever viruses such as ebola), research is also being conducted on a much longer list of potential bioterror agents that pose significant threats to human health, as well as on chemical and radiological threats.

NIH has long sought to translate basic research findings into real-world interventions, but the path to product development has not been central to our research strategy. The terrible terrorist events in the fall of 2001 compelled us to change our approach. We remain committed to conducting the basic research that has served and will continue to serve as the underpinning of applied research — and that approach has long been the strong suit of NIH, through its own scientists, grantees and contractors. However, given our vulnerability to terrorism in the post-September 11 world, we now have taken a proactive leadership role in facilitating the transition from basic to translational research and product development, and now think in terms of time frames that are uncharacteristically brief for biomedical research. In essence, we have developed an expanded paradigm, one in which we strike a balance between the time-honored goals of pursuing basic scientific research as the true foundation of all

our objectives, and the need for leadership in the pursuit of applied research to develop rapidly biodefense countermeasures.

In order to develop rapidly such countermeasures, we must engage our partners in industry in creative ways, and significantly bolster our interactions with the private sector, including both smaller biotechnology companies and large pharmaceutical corporations. Many of the products that need to be developed to protect our citizens do not of themselves provide sufficient incentives for industry to become involved. The federal government will likely be the only major customer for biodefense countermeasures, and hence the potential profit margin for these products is tenuous. Furthermore, there is no guarantee that such products would ever be utilized; many might simply be stockpiled with the hope they would never be used. Therefore, it is critical for the federal government to push more aggressively the margins of basic research into the realm of pre-clinical and pre-advanced development of countermeasures, and to seek nontraditional collaborations with industry and provide them with assurances that, if they join forces with the federal government in good faith and provide the advanced development of relevant countermeasures, their products will be purchased.

This concept was articulated by President Bush in his announcement of Project BioShield in his State of the Union address on Jan. 28 of this year, and is now being considered for authorizing legislation by Congress. The BioShield bill is designed to speed the development and availability of medical countermeasures in response to the threats that our nation faces. The goals of Project BioShield are: 1) to expedite government research on countermeasures; 2) to create incentives for private companies by providing secure sources of funding to develop countermeasures for inclusion in the stockpile; and, 3) to give the government the authority to make these products widely available quickly, in a public health emergency prior to classic licensure. The importance of this legislation to the nation's homeland security strategy cannot be overstated.

As we consider an expanded paradigm for biodefense research, it is important to remember that the fruits of these efforts will provide benefits far beyond protection from deliberate acts of bioterrorism. Nature herself is the worst bioterrorist, as we have seen with the emergence of HIV/AIDS and, more recently, West Nile virus, SARS and monkeypox infections in the Western Hemisphere. The research facilities, activities and intellectual capital directed to the study of bioterror agents, together with the rejuvenation of our public health infrastructure, will undoubtedly help in the fight against other emerging and re-emerging diseases as well.

The reality of bioterrorism is one we cannot ignore. Together, with our academic and industrial partners, the federal government is aggressively pursuing the rapid development of medical countermeasures against bioterrorism. If we do the job as it can and should be done, the biodefense response we are mounting will have many positive implications for the defense of our nation and for health in general, for decades to come.

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