



University of California

Office of Federal Governmental Relations • Health Forum 2002

Bioterrorism Prevention and Preparedness

- ❑ Communicate with Members of Congress and the Administration the University of California's ongoing commitment to serving the country with our bioterrorism research expertise, health care infrastructure, and unique capabilities.
- ❑ Ensure adequate funding reaches hospitals and healthcare systems and others who would be called on as first responders in the event future terrorist attacks occur.
- ❑ Ensure any new regulations do not inadvertently impede bona fide research.
- ❑ Ensure, as the new Department of Homeland Security (DHS) is developed, any changes made should not be to the detriment of research progress and efficiency.

Background

As a result of the activities surrounding the September 11, 2001 terrorist attacks and the ensuing anthrax mail scares, Congress and the Administration have focused much attention on the issues of homeland security and bioterrorism preparedness and prevention legislation. Legislation includes the "USA PATRIOT Act," which passed last fall; the Fiscal Year 2002 annual appropriations bills; a FY 2002 \$20 billion emergency supplemental appropriations bill; the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002;" and the legislation Congress is currently considering to establish a new Department of Homeland Security (DHS), which would serve as a cabinet level federal agency charged with coordinating homeland security activities.

From a UC research and healthcare perspective, these legislative measures provide additional funding opportunities for hospitals and for research related to bioterrorism countermeasures and preparedness, but these legislative measures also impose new regulatory requirements, and in the case of the new Department of Homeland Security, will likely have an impact on the current structure under which federal agencies oversee research activities.

Highlights of these various legislative vehicles follow:

USA PATRIOT Act (P.L. 107-56)

Last fall Congress passed and the President enacted the "Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act (USA PATRIOT Act) of 2001," a comprehensive anti-terrorism package designed to stiffen penalties for engaging in terrorism related activities. Several provisions were of note to UC, including a section which amended the United States Code pertaining to the handling and control of "select" biological agents and toxins. Specifically, the USA PATRIOT Act established a category of "restricted persons" who are prohibited from shipping, transporting, possessing, or receiving any of the "select agents." The list of "select agents" is comprised of biological agents and toxins that are deemed by the Centers for Disease Control as having the potential of causing extreme harm to human health ("select agents" include anthrax, smallpox, the ebola virus etc.).

The creation of the "restricted persons" categories will impact UC's research mission, to the extent it includes research on "select agents," since certain individuals will no longer be able to conduct research in this area.

Current and Future Funding For Bioterrorism Related Research and Preparedness Activities

Several appropriations bills for Fiscal Year 2002 (including a \$20 billion emergency supplemental appropriations bill) included funding for bioterrorism preparedness related activities. The spending measures include funding opportunities in the areas of bioterrorism research, vaccine development, outbreak prevention, hospital preparedness, health professions training, and laboratory security. UC's Academic Medical Centers may be able to access some of this funding for relevant programs and activities.

The Department of Health and Human Services (HHS) and other facets of the Executive Branch have been slowly releasing funding, primarily through block grants to the states to help states prepare for and respond to bioterrorist attacks. In addition, various new grant opportunities will be available to conduct research on bioterrorism preparedness and response countermeasures. It is not clear yet how the appropriated funds will be distributed and how much of the funds will be available for extramural activity (this is true for ALL of the extramural funding for Homeland Security, not just for bioterrorism related funds).

Within HHS, a new Public Health and Social Services Emergency Fund was created to serve as the primary funding source for bioterrorism activities related to healthcare. This fund has received \$2.9 billion for FY 2002. In addition, a Hospital Preparedness Bioterrorism Grants Program was established, which made \$125 million available through the Health Resources and Services Administration (HRSA) specifically for hospital preparedness activities.

Additional funding for bioterrorism related activities will likely be provided through Fiscal Year 2003 and future year appropriations bills, as well as from other sources, such as the recently enacted Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The President's budget request for FY 2003 includes a large infusion of funding for accelerated anti-bioterrorism related research through the NIH's National Institute for Allergies and Infectious Diseases (NIAID). The Administration's budget request also includes \$150 million to fund construction of BioSafety Level 3 and 4 laboratories (BSL 3 and 4 labs). UC is in regular communication with our Congressional appropriators regarding this funding in the FY 2003 Labor-HHS-Education Appropriations bills. We urge that funding for this research and construction be merit-based and competitively awarded.

Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188)

In June, President Bush signed into law the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, a comprehensive \$4 billion package to prepare the nation to respond to and prepare for bioterrorist attacks. This legislation is important to UC for several reasons: It presents new funding and grant opportunities for the University. The legislation also includes new legal requirements and authorizes the creation of significant new regulations concerning the handling and control of certain biological agents and toxins.

The legislation included \$1.6 billion in grants to states and local governments to improve state, local, and hospital preparedness to respond to bioterrorism and other public health emergencies. Hospitals are scheduled to receive up to \$520 million in FY 2003 to prepare for medical emergencies and ensure preparedness (the funds will be available through grants to states). The legislation also established a hospital funding pool for FY 2004-2006. Grants will be available for the education and training of healthcare personnel, to address shortages of health professionals, for research on priority pathogens, to evaluate new technologies, and for accelerated bioterrorism countermeasure research and development. HHS and NIH will be the lead agencies in announcing grant and funding opportunities.

Significant new legal requirements are also imposed relating to the handling and control of "select agents." These requirements will have an impact on UC's research mission to the extent UC engages in research on these specified biological agents and toxins. During the drafting of this legislation, UC led research community efforts to ameliorate language which would have resulted in unnecessarily restrictive and unintended limitations on who can conduct

research with select agents. Our efforts also resulted in the legislation specifying that in developing regulations concerning select agents, HHS should minimize disruption to current research and education projects.

The next steps in implementing this legislation will be the rulemaking process, which will be carried out by HHS and the USDA. UC Vice President for Health Affairs Dr. Michael Drake and UCSF Assistant Vice Chancellor for Research Dr. Ara Tahmassian have been instrumental in working with the Association of American Universities (AAU) and others to draft preliminary comments on the legislation for the rulemaking process. UC will continue to monitor the rulemaking process and will engage UC campuses and labs as we respond to new proposed regulations.

Proposed Department of Homeland Security

On June 6th, President Bush released a proposal to create a new cabinet level Department of Homeland Security (DHS) to oversee homeland security activities at the federal level. Under the President's proposal, certain research and development programs from five existing departments (HHS [including portions of the NIH and CDC], DOE, Commerce, USDA, and DOT) would be folded into the new DHS, which would also have primary responsibility for overseeing chemical, biological, radiological and nuclear countermeasures and research. Many in the health and research communities have raised concerns about the implications of moving certain research activities, which have traditionally been housed in other agencies to the new DHS.

Currently, the House and Senate are in the process of developing legislation to create the new DHS. It is unclear at this time how the House and Senate will treat the President's recommendations in creating a new DHS, and whether they will modify his proposal significantly. Congress has announced its intention to send the President completed legislation by as early as September 11, 2002.

UC will continue to monitor the development of the new DHS very closely and will continue to caution Congress that whatever changes take place not be to the detriment of research progress and efficiency.

Advocacy Message

The nation's hospitals and health systems, including those within the University of California system, will most certainly be part of the first line of defense if any bioterrorist or other catastrophic events occur. Medical personnel will be called on as first responders to help treat victims and provide assistance when disaster strikes, and much needs to be done to ensure that medical personnel, health facilities, and laboratories are adequately prepared to respond.

To best prevent, detect, and prepare for possible bioterrorist attacks, we must draw on the finest research capabilities in our country. Keeping research funding merit-based and competitive will help assure that we achieve results of the highest quality.