



Member Societies

The American Physiological Society
American Society for Biochemistry and Molecular Biology
American Society for Pharmacology and Experimental Therapeutics
American Society for Investigative Pathology
American Society for Nutritional Sciences
The American Association of Immunologists
American Association of Anatomists
The Protein Society
Society for Developmental Biology
American Peptide Society
Association of Biomolecular Resource Facilities
The American Society for Bone and Mineral Research
American Society for Clinical Investigation
Society for the Study of Reproduction
Teratology Society
The Endocrine Society
The American Society of Human Genetics
Society for Gynecologic Investigation
Environmental Mutagen Society
International Society for Computational Biology
American College of Sports Medicine

President

Leo Furcht, M.D.
Professor of Cancer Biology
Head, Dept. of Laboratory Medicine and Pathology
University of Minnesota
420 Delaware St. SE
760 Mayo Building
Minneapolis, MN 55455-0392
Tel: (612) 626-0622
Fax: (612) 626-2696
E-mail: furch001@umn.edu

Office of Public Affairs
9650 Rockville Pike
Bethesda, Maryland 20814-3998
Telephone: 301-634-7650
FAX: 301-634-7651
WWW: <http://opa.faseb.org/>

Federation of American Societies for Experimental Biology

----*Quality Life Through Research*----

July 12, 2006

The Honorable Richard Burr
Chairman, Subcommittee on Bioterrorism and Public Health Preparedness
Senate Committee on Health, Education, Labor and Pensions
United States Senate
Washington, DC 20510

Dear Senator Burr:

I am writing to thank you, on behalf of the Federation of American Societies for Experimental Biology (FASEB), for your efforts to strengthen our nation's biodefense through introduction of S. 2564, the Biodefense and Pandemic Vaccine and Drug Development Act of 2006. Representing 22 scientific societies and more than 84,000 biomedical researchers and clinicians, FASEB supports your view that the research funded by the National Institutes of Health (NIH) is of the highest quality, and that its translation into medical countermeasures to protect the health of our citizens is a critical issue.

FASEB is especially grateful to you and your staff director, Dr. Robert Kadlec, for your willingness to communicate with and respond to input from the scientific community. The outreach efforts you have made, and the subsequent development of the legislation, have resulted in a vision for biodefense that will substantially improve our public health preparedness. The research community spoke, you listened, and we want to express our appreciation for your consideration.

Clearly, there is a need to facilitate the development of products for procurement by funds set aside through the Project BioShield Act. Therefore, FASEB endorses the idea of a Biodefense Advanced Research and Development Authority (BARDA), within the Department of Health and Human Services (HHS), to fund activities that "are conducted after basic research and preclinical development of the product" and "are related to manufacturing the products on a commercial scale" or to meet regulatory requirements, as described in section 319L-(a)(6)(A)(i-ii) of the bill. Such an agency will facilitate industrial manufacturers' and other stakeholders' interactions with the federal government in such a way as to eliminate the current obstacles that serve to discourage advanced research, development, and production of countermeasures. Moreover, we applaud the requirement for a publicly available strategic plan; this transparency will undoubtedly assuage public fears while identifying targets and opportunities for which researchers and manufacturers might aim.

FASEB also recognizes that we exist in a time of limited federal resources. We strongly believe that the best way to strengthen and prepare the United States against outbreaks of disease, whether emerging, naturally occurring, or introduced, is through a robust and

balanced portfolio of biomedical research at NIH, including the National Institute of Allergy and Infectious Disease (NIAID). Accordingly, it is critically important that establishment of BARDA in no way impacts the lifesaving research program budget at NIH or NIAID, now or in the future. Without the foundation of fundamental knowledge generated through NIH-funded research, advanced research and development becomes a moot point. Congress and the American people have affirmed the value of NIH to the nation's health, security and well-being, and it is crucial that medical research remain a high priority.

While FASEB does not have the expertise to assess aspects of the legislation related to market exclusivity or liability, we remain concerned over the proposed disclosure exemptions in section 319L-(e)(1). FASEB understands that the technical information generated by BARDA might have public health or security implications. However, we do not believe the authority to decide what information is 'sensitive' and to whom to disclose it should be given to the Secretary of HHS, particularly without the option for judicial review. The Federal government has already created bodies and policies for the consideration of scientific information that could pose a national security risk, such as the National Science Advisory Board for Biosecurity.

Although FASEB fully agrees with and is thankful for your efforts to keep the activities of BARDA unclassified, we find the stated exemptions from the public information requirements of the United States Code (title 5, section 552) and the Federal Advisory Committee Act to be troubling and contrary to the open and innovative atmosphere of our research laboratories. Withholding scientific information could ultimately do more to harm our safety and security than protect us. As this legislation moves forward, FASEB hopes you will reconsider these provisions.

Again, FASEB praises your tremendous dedication and commitment in working to resolve our nation's challenges in biodefense. Please accept our sincere appreciation and best wishes as you lead the way towards making your vision of BARDA a reality. FASEB looks forward to working with you as we move forward in our common goal of improving the health and quality of life of all Americans.

Sincerely,

A handwritten signature in black ink, appearing to read 'Leo Furcht', written over a red horizontal line.

Leo Furcht, M.D.
FASEB President