



Federation of American Societies for Experimental Biology

— *Quality Life Through Research* —

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 Nutrition
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
Environmental Mutagen Society
International Society for
Computational Biology
American College of Sports Medicine
Biomedical Engineering Society
Genetics Society of America
American Federation for Medical
Research

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April 7, 2010

M. David Hodge
Operations Manager
Office of Science and Technology Policy
Attn: Grand Challenges of the 21st Century
725 17th Street, NW
Washington, DC 20502

VIA EMAIL TO: challenge@ostp.gov

Dear Mr. Hodge:

The Federation of American Societies for Experimental Biology (FASEB) is pleased to share its thoughts on the Grand Challenges of the 21st Century. FASEB is composed of 23 societies with more than 90,000 members, making it the largest coalition of biomedical research associations in the United States. Our mission is to advance health and welfare by promoting progress and education in the biological and biomedical sciences. As such, we are deeply interested in the application of scientific research to important societal issues. Given the diversity of scientific and engineering societies that we represent, we have refrained from discussing specific grand challenge projects. However, in response to questions put forth in the RFI, we offer recommendations for systemic improvements to the U.S. biomedical research enterprise that lend themselves to the achievement of the Administration's goals.

Briefly, the recommendations of FASEB are as follows:

- Sustain support for investigator-initiated research to foster innovation
- Maintain a balanced portfolio of basic, translational, and clinical research to ensure a vibrant pipeline of discovery
- Increase and sustain investment in research training and early-career opportunities to nurture the scientists and engineers of tomorrow
- Assess the cyberinfrastructure investments that will be required to meet the grand challenges
- Ensure access to patient-consented electronic health record data to maximally leverage healthcare information technology investments
- Acknowledge the value of the use of animals models in research as crucial for the achievement of health-related grand challenges
- Reduce regulatory burden to encourage scientific and engineering progress
- Institute visa policies that support international exchange and collaboration, while protecting national security.

What existing activities in the public and private sector could the United States build on to achieve these challenges?

- **Sustained Support of Investigator-Initiated Research**

A strong emphasis on investigator-initiated research has been the cornerstone of U.S. leadership in biomedical science. The U.S. biomedical research enterprise is responsible for major advances in treatments against cancer, heart disease, HIV/AIDS, cystic fibrosis and countless other maladies. These advances were largely the products of long-term investments in investigator-initiated research. Unpredictable boom and bust funding cycles and a decline in the availability of investigator-initiated research support have made researchers and peer reviewers reluctant to pursue riskier but potentially innovative research directions. In order to nurture the technical and conceptual innovation required to achieve the grand challenges put forth by the Administration, scientists and engineers need dependable support.

- **Balancing Basic, Translational, and Clinical Research**

Although addressing the Administration's grand challenges will require applied research solutions, simultaneous investment in basic research will also be essential. Basic research lays the foundation for medical breakthroughs, whether they are breast cancer treatments or magnetic resonance imaging (MRI). However, because the commercial applications stemming from investment in basic science are uncertain, there is a disincentive for industry to support fundamental research. The federal government, therefore, plays a critical role in supporting basic, pre-competitive research and must continue to enhance that support in order to provide the foundation for achieving the grand challenges of the 21st century.

FASEB supports the Administration's health-related grand challenges. These challenges will best be met through the support across the spectrum of basic, translational, and clinical research. Basic research is the foundation for translational research and clinical advances. Maintaining a strong, balanced portfolio with a primary emphasis on investigator-initiated, basic research ensures a healthy and vigorous pipeline of discovery. The biomedical research community is concerned that an imbalanced focus will be detrimental to the Administration's goals and the medical discoveries of tomorrow.

What kinds of R&D investments (e.g. supports for individual investigators, small teams, centers, research infrastructure, etc.) should the United States Government emphasize?

- **Training of the Scientific and Engineering Workforce**

Our success at meeting the scientific and technical challenges of tomorrow depends on our ability to recruit and retain the best and brightest biomedical researchers. It is critical, therefore, that students and young investigators continue to view science as an attractive and viable career option. Unfortunately, periods of insufficient funding for medical research have had a negative impact on research training. For example, stipends for postdoctoral fellows supported on National Institutes of Health National Research Service Award training grants and fellowships have failed to keep pace with the cost of living, and compensation for postdocs is not commensurate with their education, experience, and contribution to the research enterprise. Moreover, with fewer research grants being funded, job prospects for postdocs and early career investigators are

discouraging. These conditions may deter talented individuals from pursuing research careers. Sustained investment in research training and support for scientists and engineers in the early stages of their careers are essential for nurturing the scientific innovators of tomorrow.

- **Development of Cyberinfrastructure**

It is estimated that within the next decade, researchers and healthcare providers will be able to sequence one billion bases of DNA for one dollar. In contrast, at the beginning of the Human Genome Project in 1990, it cost about five dollars to sequence a single DNA base. Now, two decades later, the cost is rapidly approaching one dollar per million bases. The development of faster and cheaper sequencing and related technologies is the foundation of the Administration's grand challenges to complete DNA sequencing of every case of cancer and to usher in the age of personalized medicine and genomics. The rapid rise in data generation is not limited to DNA sequencing; other areas, such as microscopy, remote sensing, and variety of other high throughput "-omics" approaches, are experiencing a similar acceleration. Unfortunately, the capacity to quickly generate enormous amounts of data has grown far more rapidly than our investments in mid-level cyberinfrastructure, for example, high-performance computers, mass storage, and database development and support. Because these types of tools have broad utility beyond the confines of individual funding agencies and program missions, securing external government support is often difficult. At the most general end of the spectrum of infrastructure development is building construction, which many agencies support contingent on the building's stated purpose. At present many of these cyberinfrastructure needs are being met on an ad hoc, project-by-project basis. This is not sustainable as the capacity to generate data continues to soar. With regard to mass storage, for example, the tendency to create research specific storage-islands causes redundancy, unnecessary information technology complexity, and wasted productivity. The Administration should enlist the National Academies to study these issues. In addition, trans-agency workshops should be developed to discuss near-term strategies and solutions. Spending a modest amount to understand this important problem would allow for smarter planning and development of the cyberinfrastructure architecture that the nation will need to meet the grand challenges of the 21st century.

- **Access to Patient-Consented Electronic Health Record Data**

The Administration has recently initiated a considerable effort to increase electronic health record (EHR) adoption by health care providers across the country, while increasing investment in the development of the National Health Information Infrastructure. This is a golden opportunity to connect clinical care and biomedical research on a national scale to meet several of the Administration's grand challenges and would significantly enhance the ability of scientists and engineers to develop new therapeutic treatments that lead to improved quality of care and better health outcomes.

The aggregate EHR data of hundreds of millions Americans would represent the largest health information data resource in the world and would arm researchers with unique tools to fight disease and illness. First, the large number of participants would dramatically enhance researchers' ability to detect medically relevant trends and

contributions to risk with regard to complex disease. Knowledge of specific underlying causal gene mutations can allow for more personalized therapeutic intervention. The identification of appropriately qualified candidates for clinical trials would also be greatly enhanced by the inclusion of research among the nation's health information technology strategic goals. Particularly for rare diseases, having patient-consented access to health information from a broad segment of the American public could result in increased participation among affected individuals in biomedical research studies. Similarly, this would facilitate the inclusion of minorities and other groups underrepresented in biomedical and clinical research. In addition, researcher access to patient-consented EHR information would support the real-time, post-marketing surveillance of pharmaceuticals and medical devices. Because pharmaceuticals and medical devices are approved on the basis of results of clinical trials among controlled groups of study participants, they are not always representative of the general population.

The integration of clinical care and scientific research is absolutely critical to the rapid realization of many of the Administration's biomedical grand challenges. Because of the rich resource EHR data represents, we strongly urge the government to maximally leverage emerging EHR usage by integrating biomedical research into the broader strategic goals of the nation's health information technology initiatives.

What are the ethical, legal, and societal issues raised by the pursuit of these challenges?

- **Use of Animals in Research**

FASEB affirms the essential contribution of animals in research and education aimed at improving the health of both humans and animals. The role of animals remains critical in understanding the fundamental processes of life and in developing treatments for injury and disease. Unfortunately, in recent years groups opposing the use of animal models in research have used a number of strategies to deter animal research, ranging from violent attacks against researchers and laboratories to advocating for legislative, judicial, and regulatory barriers that slow research progress without necessarily improving animal welfare.

Biomedical researchers believe that the use of animals in research and education is a privilege that imposes a major responsibility to provide for their proper care and humane treatment. However, the whittling away of their ability to humanely use animals in medical research will seriously impact our nation's ability to conquer the challenges presented by acute and chronic diseases. As an example, Congress is considering a bill, called the Great Ape Protection Act, which would eliminate the use of chimpanzees in biomedical research, and could have a major negative impact on the health-related challenges identified by the Administration. Chimpanzees have been and continue to be critical for the development of monoclonal antibody treatments, an area which holds tremendous progress for targeted cancer therapies that specifically attack cancer cells without damage to healthy tissue. Similarly, chimpanzees are excellent models for pharmacokinetics, an area of research that is helping to develop safe, effective, and individually-tailored therapies in our pursuit of personalized medicine. Regrettably, there

is evidence of a lack of understanding of the importance of animal research among policymakers and the public, as illustrated by shared congressional sponsors of both the Great Ape Protection Act and a bill to strengthen hepatitis C research (for which chimpanzees are currently the only animal model). Strong and coordinated federal acknowledgement of the value of and support for animal models in research is crucial for achievement of health-related grand challenges.

What changes in legal, regulatory, or other public policies should the U.S. be considering to achieve these challenges?

- **Reduction of Regulatory Burden**

Scientists and the institutions at which they work are subject to a wide range of regulations intended to address serious and valid concerns. Responding to a 2007 survey conducted by the Federal Demonstration Partnership, scientists estimated that 42% of the time they spend on federally funded research was devoted to administrative and regulatory activities. While FASEB has no doubt about the importance of research oversight, we fear that the cumulative burden of these regulations is having a deleterious effect on scientific and technical progress. FASEB is particularly concerned with the adverse effect of federal regulations governing human subjects research. For example, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule has had a significant, negative impact on health research, making it more difficult to design consent forms that participants can understand, increasing the cost and time associated with recruiting research participants, and contributing to bias in study samples. FASEB believes these challenges could be resolved by exempting research from HIPAA, extending the Department of Health and Human Services Common Rule to research currently covered by the Privacy Rule, and strengthening the Common Rule's data protection provisions. More generally, FASEB strongly encourages the Administration to review carefully whether the additional burdens and costs associated with proposed regulations are balanced by meaningful improvements to the current oversight system. Where new regulations are necessary, they should be harmonized with existing regulations in order to avoid unnecessary duplication, confusion, and inconsistency.

- **Visa Policy**

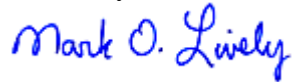
The American scientific enterprise benefits immensely from the contributions of international scientists who travel here to study and exchange knowledge. The relationships and collaborations established between U.S. scientists and their foreign colleagues have proven critical to rapid scientific advancement. We maintain our competitive edge as the world leader in science and innovation because we welcome the international scientific community to share their skills and ideas through our research institutions. However, our nation continues to struggle with significant, periodic delays in our visa processing system that sends an unwelcoming message that may encourage the world's best and brightest to seek opportunities elsewhere.

Our nation needs a visa system that supports international exchange and cooperation. We are confident that it is possible to have a system that protects national security and yet is

still timely and transparent, provides for thorough reviews of applicants, and welcomes the finest talent. In addition to increasing transparency and consistency of the visa system, FASEB recommends that the government adopt the following recommendations to achieve these goals: streamline the visa process for credentialed short-term visitors in science and technology fields; reduce repetitive processing of visa applications for those well-known researchers and scholars who regularly visit the United States; expand efforts to renegotiate visa reciprocity agreements between the United States and key sending countries in order to extend the duration of visas each country grants students and scholars of the other and to permit multiple entries on a single visa; and convene a high level interagency panel to review the full range of visa-related policies and procedures put into place after 2001.

We are pleased to have been able to share our thoughts on how best to realize the grand challenges and look forward to working with the Administration and OSTP on these issues.

Sincerely,



Mark O. Lively, Ph.D.
FASEB President