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FASEB
Federation of American Societies for Experimental Biology

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9650 Rockville Pike
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Now representing over 100,000 researchers and scientists

The American Physiological Society (APS)

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The American Association of Immunologists (AAI)

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The Protein Society

Society for Developmental Biology (SDB)

American Peptide Society (APEPS)

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The American Society for Bone and Mineral Research (ASBMR)

American Society for Clinical Investigation (ASCI)

Society for the Study of Reproduction (SSR)

Teratology Society

The Endocrine Society

The American Society of Human Genetics (ASHG)

Environmental Mutagen Society (EMS)

International Society for Computational Biology (ISCB)

American College of Sports Medicine (ACSM)

Biomedical Engineering Society (BMES)

Genetics Society of America (GSA)

American Federation for Medical Research (AFMR)

The Histochemical Society (HCS)

John P. Holdren, PhD
Director
Office of Science and Technology Policy
Executive Office of the President
725 17th Street Room 5228
Washington, DC 20502
Phone: 202.456.7116

Dear Dr. Holdren:

The Federation of American Societies for Experimental Biology (FASEB) is composed of 24 science and engineering research societies with a combined membership of over 100,000 individuals. We wholeheartedly agree with President Obama and the Office of Science and Technology Policy (OSTP) that advances in biological research hold the to key the health, food, energy, environment, and security challenges facing this nation and others around the globe. FASEB appreciates your solicitation of our advice in the development of the National Bioeconomy Blueprint.

The Request for Information (RFI) on "Building a 21st Century Bioeconomy" poses 17 questions covering a wide range of critical issues. Our recommendations for the Bioeconomy Blueprint are presented in detail below and draw upon an active program of policy development undertaken by FASEB on behalf of its member societies. FASEB's responses reflect six major themes:

- **Focus federal priorities on investigator-initiated basic research**. We recognize that the federal agencies are under unprecedented funding constraints and can no longer fund all of the highly meritorious proposals that they receive. Priority should given to programs that unleash the creative potential of scientists and engineers across the nation whose pioneering work has been the source of major discoveries in biology. Because it is hard to capture the return to basic research investment in the short term, only the federal government is in the position to fund the wide ranging, exploratory studies needed to push the frontier of science.
- **Support the efforts of basic scientists who take a more active role in the downstream development of their work**. While not all basic researchers can or should become translational or clinical researchers, they can contribute a tremendous amount to the development of new therapies and products. Indeed, many are actively engaged in such endeavors. Innovation can be expedited by expanding these efforts. We are currently in the final stages of preparing a major report on how to support and extend such activities.
- **Eschew strategies that divert funding from competitive research budgets**. In this time of scarce resources, it is important to ensure that federal funding is allocated to the most meritorious proposals. While there are many worthy proposals and a growing need for research support of all types, the competitive research programs of NIH, NSF, and other research agencies are the backbone of our scientific and engineering enterprise.

They should not be compromised for targeted, goal-directed research.

- **Provide greater flexibility in agency rules for use of SBIR/STTR funding.** Current policies limit the ability of agencies to fund larger SBIR/STTR projects and to transfer funds across program categories. Greater flexibility would be more helpful than increased set-aside targets, which come at the expense of other, valuable research needs.
- **Help graduate programs in the biological sciences provide more opportunities for students to develop a broad range of career relevant skills and experiences.** We have been strong supporters of this concept for many years, advocating expanded opportunities for skill development, greater flexibility in funding rules, and evaluation of training outcomes. Moreover, we have actively promoted the use of Individual Development Plans (IDP) to assist students and their mentors in the identification of the optimal training pathway for each person.
- **Increase efforts to reduce unnecessary regulatory burdens that decrease the productivity of researchers.** We appreciate that the Administration has undertaken several initiatives to streamline, harmonize, and reduce regulatory requirements. These efforts are commendable, and we will continue to provide guidance and support.

In the following section, we present our responses to questions 1, 2, 5, 6, 9, 13, and 15. As our membership is composed primarily of researchers, we confine our comments to the area of our strength and expertise. In addition, we have encouraged our member societies to submit their own discipline-specific comments on these and other questions.

Responses to Questions for Bioeconomy Blueprint

(1) Identify one or more grand challenges for the bioeconomy in areas such as health, energy, the environment, and agriculture, and suggest concrete steps that would need to be taken by the Federal government, companies, non-profit organizations, foundations, and other stakeholders to achieve this goal.

We are a federation of 24 independent societies, each dedicated to advancing an important area of biomedical research. We have responded to this question in two ways: 1) identifying overarching principles and 2) collecting the proposals from our member societies.

Our April 7, 2010 submission to OSTP outlined our consensus recommendations for investment in biomedical research:

- 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 animal models in research as crucial for the achievement of health-related grand challenges
- Reduce regulatory burden to encourage scientific and engineering progress and
- Institute visa policies that support international exchange and collaboration, while protecting national security.

On September 9, 2010, we submitted a detailed list of proposed challenges solicited from our member societies. The full set of statements is available on the FASEB website.

(2) Constrained Federal budgets require a focus on high-impact research and innovation opportunities. With this in mind, what should be the Federal funding priorities in research, technologies, and infrastructure to provide the foundation for the bioeconomy?

It is regrettable that, in a time of great scientific progress and unprecedented opportunity, our nation is forced to limit its investment in research. If we are unable to marshal the resources, then the benefits from increased investment may not be realized or may be captured by other nations. Faced with the need to set priorities, we strongly urge OSTP and the President to maintain funding for investigator-initiated basic research.

A strong emphasis on investigator-initiated research has been the cornerstone of U.S. leadership in science. End-users have motivation and incentives to sponsor applied research, but only an enlightened organization with a long-term horizon can afford to sponsor a broad-based, long term program of investigator-initiated basic research. At this time, only the federal government is able to assume this vital role.

Major advances in treatments against cancer, heart disease, HIV/AIDS, cystic fibrosis and countless other maladies 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 envisioned by the Administration, there must be ample support for investigator-initiated basic research.

(5) What are the barriers preventing biological research discoveries from moving from the lab to commercial markets? What specific steps can Federal agencies take to address these shortcomings? Please specify whether these changes apply to academic labs, government labs, or both.

This is an important topic, one that has generated many proposals for drastic and dramatic action. It should be noted, however, that the much discussed “empty pipeline” has recently rebounded. Nonetheless, all of us would like to see the process improved. One important way to make this happen is to increase the involvement of basic researchers in translational and applied research. To this end, FASEB sponsored a major symposium, “Engaging Basic Scientists in Translational Research.” This two day meeting brought together researchers, administrators, and students to discuss the barriers to greater involvement in translational research and to propose solutions. A final report—with recommendations on funding and training for basic scientists with an interest in translation; facilitating collaborations between basic and clinical scientists in academe and industry; and optimizing publication, tenure, and promotion policies so as to provide appropriate recognition and rewards for translational scientists—is being prepared for release in early 2012.

(6) What specific changes to Federal Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs[2] would help accelerate commercialization of federally-funded bioeconomy-related research?

Research agencies like NIH should have greater flexibility on how to use funds designated for the SBIR/STTR programs. The limits on the size of individual awards have not kept pace with the rising cost of research, and some meritorious SBIR projects are often underfunded while the agency is required to fund work with lower priority scores in order to meet set-aside levels. Arbitrary limits on funding for phase I and phase II projects are especially problematic for research requiring clinical testing. Rules defining eligibility for these programs should also be revisited, and NIH should have more flexibility to move funds around ***within*** the SBIR/STTR budget.

FASEB supports the SBIR program and recognizes the benefits of the participation of small businesses in scientific research. We do not believe, however, that there is evidence to support an increase in the SBIR/STTR set-aside. The percentage of the NIH extramural funds going to for-profit entities has increased over the past 25 years. During the 1980s, fewer than two percent of NIH research funds went to for-profit firms. This fraction rose to three percent in the late 1990s and has been four percent or greater since 2004.

At present, small (and large) businesses can compete for almost all NIH funding mechanisms. We note that there is currently no limit on SBIR funding. NIH has the discretion to fund all meritorious SBIR applications and, if the submissions warrant it, can allocate more than the current set-aside level, which is 2.5% of the agency's total budget. However, a mandatory increase in the set-aside across agencies will necessarily result in funding cuts for the other peer-reviewed basic and applied research programs that fuel innovation, improve quality of life and contribute to our country's economic growth. Rather than increasing support for one area of research at the expense of all others, we support increased funding for all research agencies, thereby increasing the total investment in SBIR and other projects.

(9) The majority of doctorate recipients will accept jobs outside of academia. What modifications should be made to professional training programs to better prepare scientists and engineers for private-sector bioeconomy jobs?

It would be a huge mistake to drastically disrupt a research training enterprise that is the envy of the world. At the same time, the system that was created for the postwar baby boom generation is in need of change, and we support this effort. The percentage of biomedical scientists in academic employment has been declining, and we expect that trend to continue. FASEB has been actively engaged in the dialog to improve the educational experience of graduate students and postdocs.

FASEB believes that the goal of biomedical training programs should be preparation of trainees for careers in the biomedical sciences, including for positions in research, science education, and science-related fields for which their research training makes them especially qualified. Scientific training should be broad-based, enabling students to pursue a wide range of scientific questions and to transition among research areas as opportunities emerge. It should also incorporate training in teaching and mentoring and preparation in professional skills, such as leadership, management, and communication.

Federal agencies could encourage effective training in all of these areas by expanding programs to help trainees and established investigators acquire training and mentoring skills, encouraging institutions to provide teacher and mentor training to students and postdocs supported on training grants, and providing funding for institutions to develop professional skills workshops. In addition, agency policy should allow all trainees—regardless of their source of funding—to devote time to these activities in the course of their research training.

It is important for funding agencies and institutions to assess the effectiveness of their training and career development efforts. We encourage NIH, NSF, and all federal science agencies to continue to evaluate their programs, including the impact they have on increasing the diversity of the biomedical research workforce. Agencies should also help institutions measure the impact of their programs by developing instruments to measure program success and providing them with funding to conduct program assessments.

For years, FASEB has championed the use of the Individual Development Plan (IDP) as a tool for mentors and students to use in identification of career goals and planning. Our leadership and staff have worked with many organizations and institutions to advise young scientists, and we are currently developing an interactive, web-based tool that will facilitate and enhance the use of IDPs.

We have been in an active dialog with the NIH Advisory Committee to the Director Working Group on the Future Biomedical Research Workforce chaired by Shirley Tilghman. In our official comments to the Tilghman Committee, we recommended that NIH:

- Evaluate the success of its training programs and consider how well trainees have been prepared for a broad range of scientific and science-related careers, not just careers as an NIH-funded investigator.
- Encourage grantee institutions to establish or expand career and professional development programs. These programs should be available to a large number of trainees and focus on the development of core competencies, including problem solving, teamwork, leadership, management, communication, professional conduct, and responsible conduct of research.
- Develop, or fund the development of, training materials that institutions could use in training programs, courses, and workshops aimed at cultivating these core competencies.
- Encourage funded investigators to develop a plan for training and mentoring graduate students and postdoctoral scholars supported on their research grants. Ideally, these plans would address how trainees would acquire the scientific knowledge and technical skills relevant to their disciplines, as well as training in the competencies listed above.
- NIH should encourage trainees to develop, in coordination with their research mentors, individual development plans in which they identify short- and long-term career goals and articulate a plan for meeting them.
- Continue to emphasize that postdoctoral scholars are trainees and should be provided with career and professional development training as well as training in research.
- Issue guidance clarifying that trainees supported on research grants can devote effort to career and professional development activities.

(13) What specific regulations are unnecessarily slowing or preventing bioinnovation? Please cite evidence that the identified regulation(s) are a) slowing innovation, and b) could be reformed or streamlined while protecting public health, safety, and the environment.

Unnecessary regulations and reporting are costly to institutions, decrease the productivity of researchers, and delay innovation. In a survey conducted by the Federal Demonstration Partnership , U.S. scientists estimated that 42 percent of the time they spent on federally funded research was devoted to administrative and regulatory activities. This results in the expenditure of $97 million in salary support for principal investigators and co-investigators for activities related to grants administration – not research.

FASEB applauds the Administration's efforts to reduce regulatory burden and we have provided comments to the National Science and Technology Council's Circular A-21 Task Force. In our statement, we proposed the following changes to the policies regulating federally-funded research:

- Eliminate effort reporting
- Minimize financial reporting requirements
- Streamline research training requirements
- Harmonize human subjects protections regulations by
    - Exempting research from the HIPAA Privacy Rule
    - Streamlining regulations and clarifying responsibilities of federal agencies and institutions
    - Holding IRBs, not institutions, accountable for regulatory compliance
- Improve regulation of laboratory animal care and use by
    - Clarifying responsibilities of federal agencies and institutions
    - Reducing the frequency of protocol review
    - Establishing an advisory committee on animal care and use
- Streamline the systems for control of hazardous agents by

    - Stratifying the select agent list[1]
    - Eliminating requirements to quantify biological agents present in a research setting
    - Harmonizing laboratory inspections by multiple agencies of jurisdiction
    - With regard to hazardous chemicals, establish separate policies and procedures for universities so that they are not using the same standards as large manufacturers
- Facilitate reporting of potential conflicts of interest
    - Develop and make available to all investigators a simple, electronic, universal reporting form to help to ensure compliance with reporting requirements while minimizing regulatory burden.

In addition to providing specific recommendations as to how the A-21 circular and related regulatory policies could be improved, we urged the Office of Management and Budget (OMB) to adopt the following guiding principles for reducing cost and burden associated with research:

- Establish mechanisms to evaluate the need for both proposed and existing regulations.
- Assess the impact that the implementation of those regulations has, or is expected to have, on the research enterprise.
- Make every effort to harmonize regulations and guidance among federal agencies.
- Develop regulations that are tiered to the level of risk presented by the situation they are intended to address.

(15) What specific improvements in the regulatory processes for drugs, diagnostics, medical devices, and agricultural biotechnology should federal agencies implement? What challenges do new or emerging technologies pose to the existing regulatory structure and what can agencies do to address those challenges?

It would be extremely beneficial for the federal government to help streamline, rationalize, and harmonize the regulations governing human subjects research. We recognize the profound importance of protecting human research participants and support efforts to strengthen those protections. The review process, however, is not calibrated to the risks of research, regulations have not kept pace with changes in the way that clinical research studies are conducted, and regulations and guidance documents are not harmonized across or within agencies. In addition, institutions and institutional review boards (IRBs) impose additional requirements beyond those that are specified in federal regulations or guidance. These are often intended to minimize the risk of liability, but they add little to the protection of participants. Taken together, these factors create unnecessary research delays, confusion, and administrative burden for investigators and, in some cases, work against the goal of protecting participants.

Recently, the Department of Health and Human Services (HHS) issued an Advance Notice of Proposed Rule Making (ANPRM), "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators." In FASEB's response to the Department, we noted that many of the changes proposed in the ANPRM would help to address some of the community's concerns, but suggested that additional changes in policy and practice are needed as well. For example, FASEB suggested exempting research from the HIPAA Privacy Rule, treating all data as potentially identifiable and strengthening standards for protecting those data, issuing guidance encouraging institutions to limit the length and complexity of consent forms and discouraging them from imposing requirements not specified in the regulations.

In conclusion, we express our strong support for the efforts of the Administration and OSTP to promote research and development in biology and recognize their strong commitment to building a better future through research. Harnessing biological research will enable us to meet the health, energy, environmental, and security challenges of the 21st century. To those ends, we hope that the National Bioeconomy Blueprint will focus federal priorities on investigator-initiated basic research, support the efforts of basic scientists who take a more

[1] We are pleased to note progress on this topic.

active role in the downstream development of their work, eschew strategies that divert funding from competitive research budgets, provide greater flexibility in agency rules for use of SBIR/STTR funding, help graduate programs in the biological sciences provide more opportunities for students to develop a broad range of career relevant skills and experiences, and increase efforts to reduce unnecessary regulatory burdens that decrease the productivity of researchers.

We look forward to working with you on these and other initiatives.

Sincerely,

Joseph C. LaManna, PhD

FASEB President