American Society for
Biochemistry and Molecular Biology
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Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Ave. NW
Washington, D.C. 20504

RE: Office of Science and Technology Policy's Request for Information on the National Biotechnology and Biomanufacturing Initiative

The American Society for Biochemistry and Molecular Biology is an international nonprofit scientific and educational organization that represents more than 10,000 students, researchers, educators and industry professionals. The ASBMB strongly advocates for strengthening the science, technology, engineering and mathematics workforce, supporting sustainable funding for the American research enterprise, and ensuring diversity, equity and inclusion in STEM.

The White House Office of Science and Technology Policy (OSTP) published a request for information titled "National Biotechnology and Biomanufacturing Initiative" on Dec. 20 seeking input on how to advance biotechnology and biomanufacturing and support a strong bioeconomy.

The ASBMB's members contribute significantly to the bioeconomy workforce in the health, climate, energy, agriculture and other sectors. For this reason, we were motivated to submit a response. However, the short 30-day comment period required us to limit our response to focus on only four of the 17 questions.

3. **What data types and sources, to include genomic and multiomic information, are most critical to drive advances in health, climate, energy, food, agriculture, and biomanufacturing, as well as other bioeconomy-related R&D? What data gaps currently exist?**

   Recommendation 1: Require metadata during -omics data deposition into repositories.

   Metadata are the information necessary to understand the context of experimental data, such as experimental design, sample preparation and equipment details. Without this information, -omics data loses significant value and reduces confidence and reproducibility. Alarmingly, certain repositories do not require deposition of this information. In contrast, amending raw data with metadata has the potential to be an inordinately burdensome process. The ASBMB recommends requiring *a reasonable degree* of metadata that is standardized in format, interoperable across fields, and aligned with international standards.

   Recommendation 2: Ensure open-science and public-access initiatives do not exceedingly burden researchers.

   While the ASBMB strongly encourages open science and is enthused by all the potential positive effects of it, new requirements and policies, such as the National Institutes of Health data-management and -sharing policy, have the potential to place significant burden on individual scientists, laboratories and core facilities that collect large, complex datasets. The ASBMB recommends that OSTP and federal agencies continue to monitor, engage and provide updates for complying with public access policies to ensure researchers are not exceedingly burdened. It is vital for federal agencies to provide clear guidance to scientists and be receptive to feedback from the scientific community on what type of support is needed to move toward open science.

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Recommendation 3: Develop standards to reduce barriers for multiomics studies.

The validity and feasibility of incorporating some -omics data, such as metabolomics, in multiomics studies is a rapidly evolving area of research that requires further development. The most significant challenge is data integration, i.e., normalize the data of one complex technique to the output of other -omics techniques, across genomics, epigenomics, transcriptomics, metabolomics, proteomics and microbiomics. Additionally, -omics data are often heterogeneous and difficult to compare between datasets readily available in repositories. The ASBMB recommends development of gold standards for data collection, reporting, analysis and nomenclature to aid the integration of -omics data in multiomics studies. Developing these gold standards will require time and input from stakeholders across multiple fields.

4. **How can the Federal Government, in partnership with private, academic, and non-profit sectors, support a data ecosystem to drive breakthroughs for the U.S. bioeconomy? This may include technologies, software, and policies needed for data to remain high-quality, interoperable, accessible, secure, and understandable across multiple stakeholder groups.**

Recommendation 4: Modernize the technology infrastructure at MSIs, ERIs and rural areas.

As we said previously, minority-serving institutions (MSIs), emerging research institutions (ERIs) and rural communities need better technology infrastructure to access and use equitable data (as defined by the OSTP Equitable Data Working Group in its 2022 report, A Vision for Equitable Data). Ensuring that scientists at these institutions can access and use equitable data will grow the American research enterprise and support an inclusive and innovative U.S. bioeconomy. As it currently stands, MSIs, ERIs and institutions in rural areas are significantly underutilized by the American research enterprise.

To conduct research with large datasets, MSIs and ERIs need expanded broadband access and modernized technology to meet hardware, security and infrastructure requirements. In 2020, a nationwide survey demonstrated a strong need for better broadband infrastructure at MSIs. Connectivity, equipment, security and access to technology were cited as most important in supporting the goals and objectives of research programs at MSIs. Data storage, data management and data analytics were also reported as significant. Broadband must also be strengthened and expanded for the 20% to 30% of Americans in rural areas and tribal lands that lack it to ensure equitable access to data. Federal agencies must do everything that they can to help MSIs, ERIs and rural areas update their technology infrastructure to support innovative data ecosystems for the U.S. bioeconomy.

Recommendation 5: Improve repositories' deposition and retrieval processes.

The currently available software and tools for deposition and retrieval of -omics data are cumbersome. To improve these processs, we recommend that federal and public repositories have the following attributes:

(1) streamlined to minimize the burden of deposition and protect scientists' valuable time and effort

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(2) regulated to require only the data and metadata necessary to comply with the policy in a format that supports sustainability (*i.e.*, data on some file types from more than a decade ago are already inaccessible)
(3) structured to be sufficiently flexible so as to accommodate new technologies in the field and incorporate new functionalities with ease
(4) Embedded with thorough instructions on how to properly retrieve data to ensure they are correctly processed and analyzable by nonexperts

Recommendation 6: Improve and centralize access to scientific data.

Public access to decades of scientific data is sporadically available via a combination of published manuscripts and data repositories that are not centralized nor uniformly accessible (paid vs. free). The current data ecosystem is not very amenable to identifying whether a specific scientific study or dataset exists. This can lead to duplication of research and potentially wasteful allocation of scientific resources. As the OSTP develops its public access framework, it should consider strategies for and investments in the development of advanced searching capabilities within scientific research manuscripts and repositories. This would improve the efficiency of the bioeconomy and help researchers better identify current research gaps and opportunities for innovation.

Additionally, repositories require financial support to ensure they have the infrastructure and workforce necessary to validate, reformat, amend, maintain and administer data on a national scale. As an example, the Protein Data Bank is well established as a reputable resource for structural protein data that is thoroughly validated and maintained, and it generates a return on federal investment of ~1,500 times — which wouldn't have been possible without decades-long support from multiple science agencies and institutes. Notably, a 2017 study estimated that the cost to replicate the PDB would be $12 billion. To foster better data-sharing for a more robust bioeconomy, the OSTP should increase support for broad data infrastructure and repositories.

10. How can the U.S. strengthen and expand the biotechnology and biomanufacturing workforce to meet the needs of industry today and in the future? What role can government play at the local, state, and/or Federal level?

Recommendation 7: Reduce backlog and/or create new avenues for highly-skilled immigration.

There are many trained, skilled and innovative workers ready to immediately contribute to biotechnology and biomanufacturing fields from abroad. Immigration reform is needed to better streamline the migration and retention of skilled scientists to meet the increasing demands of the industry. The OSTP must clearly communicate the importance of attracting international talent and advocate for reducing visa restrictions for international students and scholars to train in the U.S. as well as increasing the retention of those students and scholars in the U.S. workforce.

By attracting international talent, the U.S. will be increasing economic growth and prosperity and ultimately supporting the growth of the bioeconomy. It is well documented that international scientists are more likely to engage in STEM entrepreneurship, patent new technology and produce more innovative research. The attraction of more international researchers into the U.S. will result in more breakthroughs, medicines and scientific products that make it to market.

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Recommendation 8: Create more opportunities and pathways for careers in biotechnology and biomanufacturing.

The ASBMB recommends the Department of Education and Department of Labor collaborate with companies to create science, technology, engineering and math apprenticeship opportunities to grow the biotechnology and biomanufacturing workforce. Establishing public–private partnerships through educational programs from K–12 to doctoral levels, such as the Student Research Apprenticeship Program and Innovatebio National Biotechnology Education Center, will ensure that the biotechnology and biomanufacturing workforce is at capacity at all work levels.

Recommendation 9: Incentivize skill-development beyond the academic lab bench.

Whether a trainee pursues a career as an independent research faculty member or an industry researcher, most Ph.D. holders find themselves responsible for navigating new responsibilities outside of laboratory experiments. The development of auxiliary skills is important for all professional science careers and should be better supported and emphasized in training programs. The ASBMB encourages all federal science agencies to consider providing recurring workshops on skills beyond the lab bench that support a more innovative bioeconomy, such as those relating to entrepreneurship, translating fundamental research into patents and commercialization, professional networking, negotiatiating, personnel management, budgeting, and diversity, equity, accessibility and inclusion.

11. **What strategies and program models have shown promise for successfully diversifying access to biomanufacturing and biotechnology jobs — including those involving Historically Black Colleges and Universities, Tribal Colleges and Universities, and other Minority Serving Institutions? What factors have stymied progress in broadening participation in this workforce?**

Recommendation 10: Increase outreach to minority-serving institutions.

The ASBMB recommends that OSTP conduct outreach to minority-serving institutions regarding biomanufacturing and biotechnology certificate programs and create a re-entry program for underrepresented groups to diversify the workforce.
Minority-serving institutions (MSIs) — including but not limited to historically black colleges and universities, tribal universities, Hispanic-serving institutions and emerging research institutions — are rapidly expanding science programs and are a valuable resource to improve and increase diversity and equity efforts. Although, they make up only 14% of degree-granting institutions, they produce one-fifth of the nation's STEM bachelor's degree holders. Expanding outreach to MSIs on programs such as the National Science Foundation–funded Innovatebio National Biotechnology Education Center to MSIs will assist in diversifying the biomanufacturing and biotechnology workforce.

Additionally, the STEM re-entry taskforce and NIH's re-entry and reintegration supplements are programs that have been successful is retaining scientists and engineers, in particular those who are women, who have left the field due to extenuating circumstances.

Recommendation 11: Establish research training programs to diversify the biotechnology and biomanufacturing workforce.

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Research training programs such as the NIH Maximizing Access to Research Careers (MARC) trains scholars from historically underrepresented groups in academic enhancement, research training and professional development skills, preparing them for careers in the biomedical science workforce. The MARC program supports the retention of underrepresented groups during undergraduate education — a period when many individuals exit the STEM pipeline — through compulsory research internships. The ASBMB suggests creating a research training program similar to the MARC program to engage trainees at the undergraduate and graduate level in biotechnology and biomanufacturing through industry internships . The NIH Broadening Experiences in Scientific Training program is one program that was successful exposing trainees to bioscience careers outside of academia while still in training.