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Submitted electronically to biotech@ostp.eop.gov

Re: **Request for Information; National Biotechnology and Biomanufacturing Initiative**

The Biotechnology Innovation Organization (BIO) is pleased to respond to the Office of Science and Technology Policy's Request for Information (RFI) regarding National Biotechnology and Biomanufacturing Initiative. Please find attached BIO's responses to several of the questions put forward in the RFI.

BIO¹ represents 1,000 members in a biotech ecosystem with a central mission: to advance public policy that supports a wide range of companies and academic research centers that are working to apply biology and technology in the energy, agriculture, manufacturing, and health sectors to improve the lives of people and the health of the planet. BIO is committed to speaking up for the millions of families around the globe who depend upon our success. We will drive a revolution that aims to cure patients, protect our climate, and nourish humanity.

BIO welcomes the opportunity to work with the administration to ensure the U.S. can advance pioneering technology breakthroughs to address climate change and improve the health and prosperity of our nation and the world.

Sincerely,

A handwritten signature in blue ink, appearing to read "John A. Murphy III".

John A. Murphy III, Esq.
Chief Policy Officer
Biotechnology Innovation Organization

¹ <https://www.bio.org/>

1 a) Transparency and communication are essential elements of successful public-private partnerships. The USG should share both short and long-term priorities openly with industry partners, continue to provide funding to support innovation, and help to sustain workforce development and innovation over time. It is critical that the government create the market conditions, including certainty around the terms of arrangements with industry, for private sector engagement.

Biotechnology innovation, particularly in niche areas of high unmet need where the government is the primary procurer, such as Medical Countermeasures (MCMs), requires both push incentives, such as government expedited development and review programs, and pull incentives, such as major milestone payments, and most significantly, consistent procurement contracts.

Government-industry partnerships with multi-year contracts that are transparent, consistent, and certain can enhance industry's ability to build expertise, and to maintain and retain a skilled workforce and surge-ready facilities. The USG and the private sector should be focused on how to build new resilience and capabilities into the manufacturing system, rather than on building new facilities which may be unutilized or underutilized. Surge manufacturing capacity needs to be operational and effective when the next pandemic occurs.

1 a i) Onshoring active pharmaceutical ingredients (API) is challenging for several reasons. Not all sources of API are distributed evenly across the globe and there are some materials that will always need to be imported. Additionally, increased environmental regulations led to much of the API that was produced in the US to be sent abroad and to be produced cheaper and to avoid the higher US standards. Taking these factors into account, the US should strive to onshore as much API production as it can, and what cannot be produced domestically should be primarily sourced from allied nations in a "near-shoring" approach.

1 b) BIO would urge the administration to support research and development that would bolster investment in biobased manufacturing processes, products and bioplastics derived from renewable or waste-based feedstocks to address the ever-increasing rise in emissions and pollution from petrochemicals and plastics and encourage the use of biobased products instead. This transition will enhance national efforts to meet a range of mitigation, adaptation, and resilience goals.

3) The convergence of big data and advances in biotechnology is unleashing a new wave of innovations, particularly from small and medium sized enterprises. Medicine will be revolutionized by better diagnostics and cures for diseases. Food security will be improved by enhanced quality and quantity in food and feedstuffs. Our ability to respond to climate change will improve by moving the world towards biobased and zero-waste economies.

Healthcare is shifting from traditional one-size-fits-all medical care to personalized medicine tailored to the genomic, molecular, and lifestyle characteristics of individual patients. Unlocking the power of health care data, including human genomic resource materials as well as digital and other related type of biomedical information, to fuel innovation in medical research is at the heart of today's health care revolution, where medicine is increasingly a collaboration between data science and clinical science realms. Harnessing data offers biopharmaceutical researchers deeper understanding of disease pathways and ultimately helps develop targeted treatments with improved efficacy and safety. The pipeline of biopharmaceutical innovation is rich with these transformative therapies that would not exist were it not for this remarkable convergence of modern biotechnology and the data sciences.

Likewise in agriculture, companies are leveraging modern biotechnology to improve plant and animal breeding and through the gathering and analyzing of atmospheric, climate, soil, and biologic data to tailored digital services to farmers looking to improve crop health and performance are being developed. Whether these crops will be used to feed humans or develop feedstock for environmentally sustainable biofuels, the convergence of data with biotechnology tools is helping to drive innovation that can have a tremendous impact on our planet.

Life sciences firms through their internal processes and investments generate a wealth of data that help to drive biotech innovation. However, life science firms also require a robust marketplace for externally generated data to innovate and draw new inferences. With respect to global clinical studies and agricultural field trials, biotech firms rely, for example, on partnering entities to collect and share key data assets from around the world. Biotech firms in other circumstances also rely on relationships with independent third parties that secure and provide valuable insights on a range of other data, such as certain environmental inputs or patient-generated medical health data.

Data, whether generated in-house by biotech companies or obtained through collaborations with external partners, is central to the innovative process. Accordingly, restrictions on biotech firms' ability to obtain and use global data sets will impact ongoing research and development endeavors and compromise the scientific advances in the biotech space.

4) Addressing cross-border data transfer rules and restrictions in key jurisdictions and to address emerging data localization policies globally is necessary to drive biotech innovation. BIO members require a robust marketplace for data to drive R&D and restrictions on ability to access, use, and transfer this data present challenges to accelerating U.S. driven biotech R&D efforts.

Our members encounter several challenges in strategic foreign jurisdictions, such as in the EU and in China. We welcome efforts of the Federal Government to work towards stronger rules to enable cross-border data flows through bilateral and multilateral engagement.

Global society depends on life science innovation to solve some of the most pressing concerns facing humanity. Strengthening scientific cooperation between U.S. biotech researchers and collaborators around the world should be a priority and can be incentivized appropriately.

Domestically, with the emergence of state privacy laws and potential federal privacy legislation, it is important to ensure that laws are not overly restrictive in a way that unnecessarily impede biotech innovation.

5) During normal market conditions the environment for biomanufacturing is stable. The issues arise during emergencies. Those emergencies could be a pandemic causing demand for countermeasures and their supplies, a natural disaster taking a key facility offline, or global trade issues leading to supply chain bottlenecks and manufacturing issues. Our lack of the ability to deliver surge capacity for medical countermeasures needs to be overcome. Similarly, we need to invest in redundancy, so that the issues a single chokepoint on the supply chain do not disrupt the entire bioeconomy.

6) The USG can invest in building surge capacity for medical countermeasures with its industry partners. These investments need to be designed with long-term sustainment in mind. The USG can pay for excess capacity, purchasing 120% for example, to ensure access to surge when needed. This also guarantees that the manufacturing of these goods remains "warm" and that the ability to produce them is not lost or delayed starting from a cold base. Additionally, the government can stockpile the API and ancillary products needed to produce medical countermeasures so that supply chain delays can be mitigated, and speed can be prioritized.

As we seek to reduce carbon and other pollutants in our environment, the U.S. government needs to make greater investments in facilities to move from fossil-based to fermentation-based productions and manufacturing, as highlighted in Schmidt Futures' April 2022 report¹. Support of the adoption of carbon capture and utilization (CCUS) biotechnologies – which aim to capture waste carbon in the form of

¹ <https://www.schmidtfutures.com/schmidt-futures-publishes-groundbreaking-new-bioeconomy-strategy-calls-for-strategic-investment-workforce-development-and-infrastructure-to-bring-innovations-from-lab-to-market/>

methane, carbon oxide emissions, or gasified wastes and convert it to renewable and low-carbon chemicals, biobased products, and biofuels is also crucial.

Encouraging and incentivizing farmers to improve the capture of soil carbon, reduce applied fertilizer needs, and improve yield through application of beneficial soil microorganisms, digital agriculture and other enhanced farming practices will promote a low-carbon economy and provide the sustainable feedstocks needed for biobased products. Supporting algae cultivation has great potential to remove carbon from the atmosphere.

Advancing biofuel innovation is also crucial to scaling up the biobased economy and enabling agriculture to be part of the solution to the climate crisis and fostering energy security. The U.S. Environmental Protection Agency (EPA) must update regulatory requirements for greenhouse gas emissions analysis to reflect the newest science and technology. Enabling the use of up-to-date modeling tools and data will permit the agency to capture improvements in agricultural efficiency, productivity, and the deployment of innovative technologies. BIO recommends EPA work with DOE to incorporate the Department's Argonne National Lab Greenhouse gases, Regulated Emissions, and Energy use in Transportation (GREET) model for measuring lifecycle emissions of transportation fuels. BIO also urges EPA to coordinate with U.S. Department of Agriculture (USDA) and utilize its practical knowledge and expertise on biofuels and innovative farming techniques. Doing so will catalyze resilient and sustainable biobased economy and drive production of sustainable biofuels and biobased manufacturing.

9) The BioPreferred Program is transforming the marketplace for biobased products through two initiatives: purchasing requirements for Federal agencies and their contractors; and voluntary product certification and labeling.

However, while federal law, the Federal Acquisition Regulation, and Presidential Executive Orders direct all federal agencies and their contractors to purchase biobased products in categories identified by the USDA through the BioPreferred Program,² oftentimes federal agencies fail to give preference to bio-based products. To ensure the BioPreferred Program drives growth of the bioeconomy, the Administration should ensure federal agencies follow through with the requirements to give preference to bio-based products and identify noncompliance.

The following recommendations put forward in An Economic Impact Analysis of the U.S. Biobased Products Industry³ can make this achievable:

- Improve the ability of the Federal Government, including the General Services Administration and other acquisition departments of federal agencies, to track the purchase of biobased products in acquisition systems. Currently, there is not a singular way of doing so, and it is difficult to accurately determine the increases in the use of biobased products by the Federal Government.
- Expand marketing and consumer education of the BioPreferred Program's USDA Certified Biobased Product label. Currently, many consumers are confused or are unaware of what a biobased product is, and they do not recognize or understand the label. While there are certainly benefits to having products labelled as USDA Certified Biobased, increased market recognition would help the biobased products industry grow and encourage more companies to pursue certification.
- Leverage the similar goals between the USDA and the DOE to cooperate on increasing the purchase of biobased products. Both agencies have similar objectives in terms of growth and less reliance on nonrenewable resources, and research supported by both agencies can provide greater power and increased success.

² <https://www.gsa.gov/governmentwide-initiatives/sustainability/buy-green-products-services-and-vehicles/buy-green-products/biobased-and-biopreferred-products>

³ <https://www.biopreferred.gov/BPResources/files/BiobasedProductsEconomicAnalysis2018.pdf>

In addition to BioPreferred, the Biorefinery, Renewable Chemical, and Biobased Product Manufacturing Assistance Program (9003 Program) can provide valuable financial assistance to companies seeking to bolster biobased manufacturing in the U.S. through capital projects. However, the lengthy timeframe of the review and the onerous application process can be daunting to growing companies that seek to take the next step towards commercialization. Streamlining the application and shortening the review process can help make 9003 Program attractive to more applicants and stay current with the pace of business and technology.

10) The private sector and the USG need to invest in jobs and training now to meet the needs of industry today, and in the future, particularly with regard to future Public Health Emergencies (PHE). Sustainable preparedness requires investment in the people who will manufacture the therapeutic or vaccine that leads us out of a future pandemic. Industry needs both a qualified manufacturing workforce now, as well as “bench strength” to meet surge requirements during a pandemic. Industry will need to devise innovative ways to train people during non-pandemic times, to maintain a cadre of skilled employees that can be deployed during a PHE. The USG should consider creative ways to incentivize a “warm base” of manufacturing, to enable industry to quickly scale-up surge production capabilities. One solution is to standardize biomanufacturing certificate programs so that industry can more easily identify qualified workers, and workers can find a short-term training program to prepare them for a new industry. BARDA is considering such a proposal and has worked with BIO to survey industry and determined that there is a need for such a change.

Additionally, onshoring and growing the domestic manufacturing capacity requires a highly skilled workforce to be successful. To enhance our capacity to address public health crises in the future as quickly and effectively as possible, the US needs to prioritize the promotion of biopharmaceutical workforce training.

The USG, industry, small companies, universities, colleges, and community colleges should consider how to partner to build the manufacturing workforce of the future. Partnerships between institutions of higher learning, the USG, and companies based in manufacturing hubs, aimed at creating a skilled workforce should be considered. Furthermore, the USG should consider workforce re- tooling programs that could support high-demand biopharmaceutical manufacturing skills training to individuals who have been displaced by the changing needs of other industries.

Finally, BIO member companies rely on the expertise and engagement of federal regulators to bring lifesaving cures and innovative, safe, healthy, nutritious, and affordable food, fuel, and fiber to market. It is essential federal agencies are staffed with well-qualified personnel who are subject to regular training opportunities to ensure that regulatory decision-making is consistent across reviewers. Moving forward it will be critical for the federal government to invest in and cultivate its workforce and recruit new talent while ensuring important institutional knowledge is maintained. Furthermore, in those instances when the federal government leverages outside expertise through federal advisory boards it is critical that the makeup of those boards include representation from subject matter experts with expertise in the biotechnology industry.

15) Critical to the development of the biobased economy is determining its value and identifying the segments which need investment and research and development. Key to this is updating the North American Industry Classification System (NAICS) codes for renewable chemicals manufacturers and biobased products manufacturers. While BIO supported language in the 2018 Farm Bill⁴ to accomplish this goal, it is yet to be implemented. BIO urges the administration to heed the calls from the U.S. Senate and follow the recommendations put forward by USDA in its comments to the 2017 NAICS Updates for 2022 to establish a measurement for biobased products.

⁴ https://republicans-agriculture.house.gov/uploadedfiles/greenwood_testimony.pdf

16) Through global collaboration and cross-border partnerships, industry success rates are underpinned by regulatory certainty, open trade, efficient supply chains, and the ability to transfer data between countries. All these obstacles are critical to address to ensure great market access to health, agricultural and other biotechnologies.

Global regulatory harmonization is essential to ensure that government supervision of the safety, efficacy and quality of innovative biotechnology products is accomplished in the most resource efficient manner while meeting high standards. BIO recommends that the U.S. Government continue its participation in the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) as well as other multilateral organizations and work with stakeholders to identify emerging areas that would benefit from harmonization efforts. One such example are cell and gene therapies (CGT). The world has already seen several approved CGT products, some of which use *ex-vivo* gene modified cell-based therapy approaches, as well as directly administered *in-vivo* gene therapies using an Adeno-Associated Virus (AAV), self-inactivating lentiviral vectors, and oncolytic viruses, among other transgene delivery methods. The impact of these groundbreaking technologies in the treatment and cure of debilitating and life-threatening disease including rare diseases, is undeniable. CGT products have the potential to cure intractable diseases, bring hope and meaningful benefit to patients in need, and change the way we approach treating disease (often addressing the underlying cause).

Nevertheless, the nonclinical development, clinical investigation, and manufacturing of CGT products can be uniquely complex, time-consuming, and resource intensive and these innovative technologies can create novel regulatory challenges that need to be addressed to bring safe and effective therapeutics to patients. As the biopharmaceutical industry continues to advance the development of safe and effective CGT products, it is critical to develop a harmonized science-based regulatory framework across all regions. In agriculture, the U.S. has successfully and safely led the world in the commercialization of biotechnology to enable more sustainable farming and industrial practices. These innovations reduce greenhouse gas emissions throughout agricultural supply chains, delivering environmentally friendly products and processes to the market and more nutritious offerings to all tables. Unfortunately, when major trading partners such as China, the European Union (EU), or Mexico, delay biotechnology risk assessments and approvals or intentionally malign technology, the global marketplace maybe reluctant to accept new technology negatively impacting U.S. access to these important innovations and limiting potential trade. BIO urges the Administration to build a proactive trade policy agenda aimed at addressing existing barriers to biotechnology, facilitate regulatory approvals critical climate technologies for agriculture and develop policies to enable producer access to innovation without reliance on foreign governments.

Open trade as well as robust and efficient supply chains support the biotechnology industry's research, development, and distribution efforts. This includes the elimination of tariffs on medicines as well as the reduction of export and import restrictions that disrupt global supply chains. The U.S Government is well placed to work bilaterally and multilaterally with countries to facilitate robust trade globally. In addition to bilateral negotiations, the World Trade Organization, G7, G20, and APEC can be productive fora for these discussions.

The Executive Order to Implement the European Union-U.S. Data Privacy Framework and the U.S.-EU Joint Statement of the Trade and Technology Council from December 5, 2022, are examples of how international cooperation can be a driver for the bioeconomy. For instance, the December 5 Statement makes clear the intent of the U.S. and the European union to "work together intensively in the appropriate for a to facilitate the exchange of health information to support research, innovation, and advancements in public health..." Cooperation of this sort and meaningful progress on resolving outstanding issues affecting the flow of data critical for biotech R&D is essential for the U.S. biotech sector.

The question of cross-border data transfers is also being addressed within IPEF, APEC, and the WTO Joint Statement Initiative on E-Commerce. The digital trade initiatives in these fora have significant impact on the U.S. biotech sector and the ability to timely and efficiently transfer key data globally to drive R&D.

17) International data transfers and the protection of intellectual property are critical to facilitate the development of biotechnology products. Uncertainties around the ability to transfer data internationally or to cultivate meaningful scientific partnerships with foreign institutions fundamentally do a disservice to science, which is increasingly globalized and interconnected. There are risks to patients, farmers, and consumers if innovation is not able to be efficiently developed and made available globally. Not only does enabling stronger global collaboration to facilitate cutting-edge biotech R&D efforts, it promotes global public and environmental health and this is of paramount importance.

Strong IP rights are also critical to ensuring meaningful global scientific collaborations. Strong and predictable IP systems cultivate partnerships around the world, enhance knowledge sharing, support the entrepreneurial journey, and ultimately ensure that innovation is resourced and funded so that technologies with the potential to deliver better care for patients and products for consumers are developed.

Most BIO's members are small and medium sized enterprises (SMEs) that currently do not have products on the market. As such, BIO's members rely heavily on the strength and scope of their IP to generate investments needed to develop and commercialize their technologies.

While the IP environment in the United States has contributed to the emergence of many biotechnology businesses and provided their first market opportunities, these businesses need to participate in the global economy in their search for innovations and rewards for transforming those innovations into products. IP reforms outside the United States would improve conditions for export of biotech products from the United States and grow American jobs, furthering a worker-centric trade policy embodied in the Build Back Better agenda.

Unfortunately, there have been many unfounded claims in international fora (WTO and WHO) and in key trading partner countries that IP has hindered the development of tools to fight COVID-19, as well as access to those tools. As a result, there have been numerous calls for the adoption of measures to weaken IP rights counter to global commitments embodied by the TRIPS Agreement. In the WTO itself, there has been an extreme proposal to waive IP commitments with respect to technologies related to COVID-19. The global IP system has been under attack, mischaracterized and misunderstood as an impediment in the face of a global pandemic. Claims that IP rights are the barriers to COVID-19 vaccine access lack objectively demonstrable support, while ignoring export and regulatory restrictions or acknowledging how poor healthcare infrastructures globally have affected the distribution of vaccines.

Despite these calls for measures to weaken IP rights, as we reflect on the incredible amount of innovation directed towards eradicating COVID-19, IP can objectively be viewed as an enabler of innovation and as a key factor in our collective ability to harness science for the public good. It is imperative that the U.S. Government work towards an international system where IP rights are protected and well-understood as enablers of scientific cooperation and a pillar of economic development.