January 20, 2023

RFI Response: National Biotechnology and Biomanufacturing Initiative
White House Office of Science and Technology Policy
87 FR 77901; Document Number: 2022-27600

The Center for Security and Emerging Technology (CSET) offers the following submission for consideration by the Office of Science and Technology Policy. CSET is a policy research organization within Georgetown University's Walsh School of Foreign Service. We provide decision-makers with data-driven analysis on the security implications of emerging technologies. In response to this Request for Information, we have provided recommendations and specific feedback organized by each sub-area mentioned in the RFI. We appreciate the opportunity to offer these comments and look forward to continued engagement with OSTP.

Area: Harnessing Biotechnology and Biomanufacturing R&D To Further Societal Goals

1c. For any of the four categories outlined above (health, climate and energy, food and agriculture, and supply chain resilience): How can the Government engage with and incentivize the private sector and other organizations to achieve the goals outlined in (a)?

To prepare for current and future threats, including potential pandemics, growing antimicrobial resistance, and the potential misuse of biological agents, the United States needs a proactive biomanufacturing strategy that supports the entire lifecycle of medical countermeasure (MCM) development, including basic and clinical research, development, manufacturing and a streamlined regulatory process. This can be accomplished through sustained investment over time, fostering a technically proficient workforce, and developing an incentive structure that supports advancement in areas with long development timelines and smaller profit margins. Specific areas to focus on include:

- **R&D Funding:** An initial look at research on pathogens of pandemic potential indicates that research in this area is reactionary, not proactive.[1] Supporting research across a wide range of pathogens of pandemic potential will fill this gap.
- **Corporate Tax Incentives**: The tax code can be used to incentivize R&D investments by allowing startups and small businesses to qualify for limited tax credits.

[1] CSET webinar: The Biotechnology Landscape. September 2022; additional analysis also forthcoming.

- **Public Procurement:** The U.S. government has used the power of federal procurement dollars to promote the development of nascent industries and help them reach economies of scale and commercialize their products.
- **Talent Development:** The U.S. government has supported workforce development programs to bolster technology development efforts. In the biomanufacturing area, this does not always equate with a college degree but with training programs.[2]

Area: Data for the Bioeconomy

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?

Genomics and multiomic[3] big data, such as genomic sequences and clinical outcomes – and the computing power needed to integrate, analyze, and access the data – will be critical for next-generation biomedical research and development. As a way to advance many aspects of the bioeconomy, the United States should develop and support foundational resources that enable the integration of multiple kinds of data, make it accessible and usable to U.S. researchers, and protect it against theft and misuse. Currently this is not available in standardized and usable formats. China leverages its massive standardized genetic data holdings to drive their own personalized medicine initiatives and bioeconomy. Previous government investments have driven discovery in this key sector. For example, the genomics part of the bioeconomy alone is estimated to have had an over $250 billion economic impact in the United States since the completion of the Human Genome Project.[4]

Area: Building a Vibrant Domestic Biomanufacturing Ecosystem

5. What is the current state of the U.S. and global biomanufacturing capacity for health and industrial sectors and what are the limits of current practice?

[2] NIIMBL, "Innovation of the Biopharmaceutical Manufacturing Pipeline," October 2022
[3] Multiomics are large-scale analyses of many datasets that can include the proteome, epigenome, transcriptome, microbiome, etc.
[4] Tripp and Grueber, "The Economic Impact and Functional Applications of Human Genetics & Genomics," ASHG, May 2021

The United States currently lacks both capacity and redundancy in biomanufacturing and is dependent on foreign suppliers for nearly half of the FDA-approved vaccines available for use in the United States.[5] The reliance on foreign-made vaccines limits the country's ability to quickly produce vaccines in a public health emergency and necessitates healthcare spending flowing out of the United States to purchase these products. The United States should emphasize reshoring vaccine production to alleviate these vulnerabilities.

6. What can the Federal Government do to expand and scale domestic biomanufacturing capacity and infrastructure? What level of investment would be meaningful and what incentive structures could be employed?

A healthy and robust biomanufacturing ecosystem is dependent on talent, the ability to quickly respond to changes in demand, and increasingly on the capacity to protect both the data and manufacturing facilities. Federal action and incentivization of public-private partnerships[6] can achieve the following to scale biomanufacturing capacity:

- The United States needs to invest in a technically proficient workforce. This should include developing nationally- and regionally-recognized biomanufacturing training programs, including programs to reach non-traditional candidates such as high school graduates and displaced workers from other manufacturing industries. Currently, industry experts note that the United States biomanufacturing workforce is at an inflection point where industry growth is far outpacing the supply of trained talent.[7]
- Biomanufacturing capacity and infrastructure in the United States is currently limited and lacks the ability to respond quickly to a crisis. The cost of building new facilities, lengthy regulatory approval processes, and lack of flexibility in existing product lines contribute to this situation. The United States could mitigate this risk by investing in flexible manufacturing facilities including contract development and manufacturing organizations (CDMOs) and streamlining the regulatory process for updating existing product lines.
- The U.S. government should designate biomanufacturing as a critical infrastructure and build both physical and virtual protections into the development of new facilities, as well as implementing insider threat programs.

[5] CSET analysis; publication forthcoming
[6] These partnerships can include federal, state and local governments, philanthropic organizations, regional organizations, academic institutions, and commercial entities.
[7] NIIMBL, "Innovation of the Biopharmaceutical Manufacturing Pipeline," October 2022

Area: Measuring the Bioeconomy

14. What quantitative indicators, economic or otherwise, are currently used to measure the contributions of the U.S. bioeconomy? Are there new indicators that should be developed?

A critical indicator of the health of the bioeconomy that should be developed is the domestic capacity to produce vaccines and pharmaceuticals. The information needed to better understand this part of the bioeconomy includes the manufacturing locations of both drug substances and drug products and the volume of product that is manufactured at each facility. This indicator will give insight into the many far-reaching impacts of a robust domestic pharmaceutical supply, from creating good biomanufacturing jobs to ensuring a rapid therapy supply in a public health emergency.

Area: Reducing Risk by Advancing Biosafety and Biosecurity

12. What can the Federal Government do to support applied biosafety research and biosecurity innovation to reduce risk while maximizing benefit throughout the biotechnology and biomanufacturing lifecycles?

The Federal Government should expand current biosafety programs to ensure comprehensive and integrated oversight of all high-containment infectious pathogen research. Such research provides numerous benefits, including to vaccine and therapy development and pandemic prevention. Current U.S. policies, programs, and regulations, the Federal Select Agent Program and the National Institute of Health's Biosafety and Recombinant DNA Policy, capture only a fraction of domestic pathogenic research because they are responsible only for specific high-containment situations.[8] These programs could be expanded and integrated to further regulatory biosecurity oversight of high-containment pathogens in the United States.

Thank you for considering our insight on these issues and our recommendations for the National Biotechnology and Biomanufacturing Initiative. If you have any questions or would like clarification on our comments, please contact: Caroline Schuerger: cs2004@georgetown.edu, Steph Batalis: stephanie.batalis@georgetown.edu, Vikram Venkatram: vv135@georgetown.edu.

[8] Schuerger, Abdulla, and Puglisi, "Mapping Biosafety Level-3 Laboratories by Publications," Center for Security and Emerging Technology, August 2022