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Biden Order Renews Spotlight On Advancement Of US Biotech

By **Jacqueline Berman and Kathleen Sanzo** (September 19, 2022, 6:03 PM EDT)

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On Sept. 12, President Joe Biden issued **an** executive order on sustainability in biotechnology and biomanufacturing.

According to the order, the president aims to "advance biotechnology and biomanufacturing towards innovative solutions in health, climate change, energy, food security, agriculture, supply chain resilience, and national and economic security" through a multipronged and collaborative approach.

Specifically, Biden announced that the Biden-Harris administration will, among other actions:

- Bolster and coordinate federal investment in biotechnology and manufacturing research and development;
- Foster a biological data ecosystem;
- Improve and expand domestic biomanufacturing;
- Train and support a diverse and skilled leadership and workforce pool;
- Clarify and streamline regulations;
- Elevate biological risk management, including by providing for research and investment in applied biosafety and biosecurity innovation;
- Promote, establish and develop standards, metrics and systems "to grow and assess the state of the bioeconomy; to better inform policy, decision-making, and investments in the bioeconomy; and to ensure equitable and ethical development of the bioeconomy";
- Employ a forward-looking, proactive approach to assess and anticipate threats and vulnerabilities;

- Partner with the private sector and other stakeholders to "mitigate risks to protect technology leadership and economic competitiveness; and

- Engage the international community to increase technological cooperation.

As part of the implementation, executive agencies are directed to consult with stakeholders and report on a variety of biotechnology topics.

Specifically, the U.S. Department of Health and Human Services is tasked with assessing how to use biotechnology and biomanufacturing to achieve medical breakthroughs, reduce the overall burden of disease and improve health outcomes.

The U.S. Department of Commerce, in consultation with the U.S. Department of Defense and HHS, is tasked with assessing how to use biotechnology and biomanufacturing to strengthen the resilience of U.S. supply chains.

The National Science Foundation is tasked with identifying high-priority fundamental and use-inspired basic research goals to advance biotechnology and biomanufacturing. Based on these reports, the administration, in conjunction with relevant experts, will develop an implementation plan for the executive agencies to follow.

The order further seeks to establish a Data for the Bioeconomy Initiative to ensure that high-quality, wide-ranging, easily accessible and secure biological data sets can drive breakthroughs for the U.S. bioeconomy.

To further this initiative, the administration will, with stakeholders, issue a report that, among other topics, identifies critical data to drive health, biomanufacturing and R&D, as well as data gaps; provide a plan to fill gaps and make new and existing public data findable, accessible, interoperable and reusable; set out a plan for data protection; and identify federal resources, authorities and actions needed to support the initiative along with an action timeline.

Department heads will also recommend cybersecurity best practices for biological data housed on federal government information systems.

As a further step, the order directs the administration to provide policy recommendations to expand domestic biomanufacturing with a focus on advancing equity, improving biomanufacturing processes and connecting relevant infrastructure. This will include steps to mitigate any risk posed by foreign adversary involvement in the biomanufacturing supply chain and to enhance biosafety, biosecurity and cybersecurity.

Agencies are directed to allocate resources toward the creation or expansion of programs that support a vibrant domestic biomanufacturing ecosystem.

In an effort to provide regulatory clarity and acknowledging that the complexity of the current regulatory system for biotechnology products can be confusing and create challenges for businesses to navigate, the order also directs the administration and regulatory agencies, including the U.S. Food and Drug Administration, to identify areas of regulatory ambiguity and gaps and to develop a unified online website through which biotechnology developers can receive coordinated guidance regarding federal regulatory requirements.

Finally, in alignment with the goal of increasing regulatory clarity, the order directs agencies to work with their foreign partners, to enhance cooperation, joint research, data sharing and regulatory alignment.

While the majority of the goals and actions of the order are forward-looking and, thus, are not likely to have an immediate impact on the life sciences and biotechnology industry, many of the goals will require substantial lead time.

For instance, within the U.S., there currently is a scarcity of biotechnology- and biopharmaceutical-ready manufacturing facilities, which will necessitate that new facilities be built, or existing facilities be repurposed. As FDA-regulated biotechnology must meet strict manufacturing quality requirements, including facility and equipment requirements, this will take time.

Moreover, even once constructed, manufacturers will need to work with the FDA to get the new facilities up and running, which will include passing FDA inspections before the facilities can be used to produce commercial products. Accordingly, manufacturers will need to budget sufficient time for facilities to be production-ready.

The order also shines a renewed spotlight on the biotechnology sector and signals that executive agencies must buckle down on their efforts to align regulatory guidance and actions with the future of biotechnology.

As many in the biotechnology industry can attest, a major roadblock to innovation is the fact that the federal government is frequently playing catch up to scientific innovation, resulting in a lack of clarity regarding regulatory pathways. This lack of clarity can hinder scientific and technological innovation by providing a disincentive to the development and funding of new technologies.

Accordingly, the order is a hopeful first step in bolstering the U.S. biotechnology industry by providing more regulatory clarity and opportunities. Its exact impact, however, will depend on the details of the implementation.

Notably, the order provides multiple avenues for industry involvement, potentially providing those that work in and interface with the life sciences industry opportunities to shape future policy. Accordingly, stakeholders should pay close attention to future actions taken under the order and opportunities for collaboration.

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