**FOR IMMEDIATE RELEASE**
**September 14, 2022**

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# Fact Sheet: HHS Takes Action on Executive Order Launching a National Biotechnology and Biomanufacturing Initiative

The U.S. Department of Health and Human Services (HHS) today announced actions the department will take following the Executive Order (https://www.whitehouse.gov/briefing-room/presidential-actions/2022/09/12/executive-order-on-advancing-biotechnology-and-biomanufacturing-innovation-for-a-sustainable-safe-and-secure-american-bioeconomy/) signed September 12, 2022 by President Biden launching a National Biotechnology and Biomanufacturing Initiative (NBBI).

This initiative will help drive research and development, improve access to quality federal data, grow domestic manufacturing capacity, expand market opportunities for biobased products, train a diverse and skilled workforce, streamline regulatory processes for products of biotechnology, advance biosafety and biosecurity to reduce risk, protect the U.S. biotechnology ecosystem, and build a thriving and secure global bioeconomy with partners and allies.

In its implementation of the Executive Order, HHS intends to leverage biotechnology and biomanufacturing in order to achieve medical breakthroughs, reduce the overall burden of disease, and improve health outcomes. HHS will lead the U.S. government in strategically advancing biosafety and biosecurity innovation as part of a growing bioeconomy, to ensure biotechnology research and development and biomanufacturing infrastructure break new ground while reducing risk.

Building on the department's successes at bolstering the resilience of the domestic public health supply chain and on continued collaboration and partnership with the American private sector, HHS welcomes a whole-of-government approach to secure U.S. leadership and stewardship of an equitable, safe, and secure bioeconomy. The COVID-19 pandemic has highlighted the department's ability to foster innovative biotechnological treatments, diagnostics, and vaccines swiftly and safely as well as HHS' ability to facilitate a more flexible regulatory environment in such circumstances.

With the launch of NBBI, HHS will:

- Support development of  Food and Drug Administration (FDA) research programs for advanced manufacturing technologies, in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), fueling multiple intramural and extramural research projects (e.g., smart data analytics and novel process analytic technology for bioprocessing, and continuous manufacturing of biological products) to build a knowledge base in support of regulatory assessment, as well as scientific standard, guidance, and policy development.
- Support development of the Advanced Manufacturing Innovation Hub in the FDA's Office of Counterterrorism and Emerging Threats to facilitate creation of regulatory science benchmarks and strategies for platform technologies and to drive collaborations that affect multiple product areas (e.g., smart manufacturing, closed loop process controls).
- Support development of the FDA Center for Advancement of Manufacturing Pharmaceuticals and Biopharmaceuticals to enhance coordination and collaboration of science, regulatory, and policy activities between CDER and CBER.
- Offer additional pre-submission support for applicants looking to adopt advanced manufacturing technologies: operating and enhancing CDER's Emerging Technology Program (ETP), CBER's Advanced Technologies Team, and the FDA Center for Devices and Radiological Health's Advanced Manufacturing Clearinghouse, to provide more opportunities for drug, biologics and device manufacturers to engage with FDA.
- Lead international regulators in harmonizing requirements to promote innovation, including spearheading the development of the ICH Q13 guideline on continuous manufacturing of drug substances and drug products, the ICH Q5A guideline on viral safety evaluation of biotechnology products derived from cell lines of human or animal origin, and the ICH Q14 guideline on analytical procedure development.
- Continue to facilitate advancements in development of innovative animal products produced with biotechnology, whether intended for agricultural or biopharmaceutical use, through the Veterinary Innovation Program (https://www.fda.gov/animal-veterinary/biotechnology-products-cvm-animals-and-animal-food/vip-veterinary-innovation-program) (VIP) at the FDA's Center for Veterinary Medicine (CVM). The VIP provides greater certainty in the regulatory process, encourages development and research, and supports an efficient and predictable pathway to approval for Animal Cells, Tissues, and Cell- and Tissue-Based Products and Intentional Genomic Alterations in animals. Additionally, to assist sponsors of animal biotechnology products in understanding the regulatory process, CVM offers the Animal Biotechnology Products Resource Center (https://www.fda.gov/animal-veterinary/biotechnology-products-cvm-animals-and-animal-food/center-veterinary-medicine-cvm-animal-biotechnology-products-resource-center) .

- Collaborate with the Department of Defense to invest $1 billion in bio- industrial domestic manufacturing infrastructure over five years. This support will provide incentives that will enable private- and public-sector partners to expand manufacturing capacity for products important for defense supply chains, such as critical chemicals.
- Invest $40 million to expand the role of biomanufacturing for active pharmaceutical ingredients, antibiotics, and industrially relevant key starting materials needed to produce essential medications and respond to the current or a future pandemic.
- Continue to fund predoctoral research internships in the biotech industry through the National Institute of General Medical Sciences.
- Continue to innovate treatments using pilots such as the National Centers for Advancing Translational Sciences Platform Vector Gene Therapy (PaVe-GT) pilot program which is testing whether it is practical to use the same gene delivery system and manufacturing methods for multiple rare diseases in gene therapy clinical trial. The results from PaVe-GT will be made publicly available and can therefore be used to benefit subsequent adeno-associated virus gene therapy efforts.
- Expand cell engineering capabilities and platforms and establish synthetic biology approaches through programs such as the Biopharmaceutical Development Program at the Frederick National Lab (https://frederick.cancer.gov/news/frederick-national-laboratorys-biopharma-development-program-set) which is developing a new cell line to treat acute myeloid leukemia, a particularly aggressive form of pediatric blood cancer.
- Will launch a Biosafety and Biosecurity Innovation Initiative, in collaboration with the National Institutes of Health, to reduce risk associated with advances in biotechnology, biomanufacturing, and the bioeconomy. Along with other agencies that fund life sciences research, HHS will prioritize investments in applied biosafety and biosecurity innovation and use federal investments to incentivize and enhance biosafety and biosecurity practices throughout the United States and its partners abroad from biological incidents, whether naturally occurring, accidental, or deliberate in origin. HHS will build the U.S. innovation base for cutting-edge countermeasures, diagnostics, and biosurveillance information technologies, and advance the biomedical industries' biodefense capabilities consistent with the Bioeconomy Executive Order.

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Last revised: September 14, 2022

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