The Biomanufacturing Excellence Act

Sens. Chris Coons (D-DE) & Ted Budd (R-NC)
Reps. Chrissy Houlahan (D-PA), Jim Baird (R-IN), David Rouzer (R-NC) & Deborah Ross (D-NC)

BACKGROUND

Biotechnology holds the potential for the United States to transform its military capabilities, strengthen food security and agricultural resilience, and cure life-threatening diseases. The National Security Commission on Emerging Biotechnology (NSCEB) highlighted the need for rapid and significant investment in U.S. biotechnology innovation in order to capture these benefits. One particular area of need for investment is in biopharmaceutical manufacturing: the commercial-scale production of medicine via biological processes. Investments in U.S. biomanufacturing would reduce dependency on unreliable foreign supply chains, improve access to life-saving medicine, and bolster our economy.

Innovation in biopharmaceutical manufacturing is stunted by the risks that come with investing in new technologies. First, regulatory approvals for products and processes are time-consuming and costly, so firms avoid iterative improvements in manufacturing. Second, few companies have access to idle manufacturing facilities that can be used to test and improve manufacturing processes.

THE BIOMANUFACTURING EXCELLENCE ACT

Implements one of the key conclusions from the NSCEB report, which recommends that the Department of Commerce "create a public-private biopharmaceutical manufacturing center of excellence focused on developing and scaling new ways to make medicines."

Authorizes the creation of a National Biopharmaceutical Manufacturing Center of Excellence to spur manufacturing innovation and catalyze commercial production of biopharmaceuticals in the United States. The center would:

- **Bring together industry professionals with academic researchers** to conduct collaborative research on new technology for scaling biopharmaceutical manufacturing.
- **House a facility that replicates industrial manufacturing conditions** and complies with FDA Current Good Manufacturing Practice (CGMP) regulations where innovators would develop and test new manufacturing processes.
- **Identify challenges and opportunities for scaling biopharmaceutical manufacturing**, especially for products important to U.S. national security, public health, and economic security.
- **Train tomorrow's biopharmaceutical manufacturing workforce** by partnering with educational, industry, and community leaders to bolster biotechnology talent.

Endorsed by: *The National Security Commission on Emerging Biotechnology, Biotechnology Innovation Organization, American Alliance for Biomanufacturing, Delaware BioScience Association, North Carolina Life Sciences Organization, North Carolina Biotechnology Center, Life Sciences Pennsylvania, and the Information Technology & Innovation Foundation.*

Please send questions and comments to Vetri_Velan@coons.senate.gov, Charlie_Hobbs@budd.senate.gov, Abigail_Lancaster@budd.senate.gov or Harrison.Jumper@mail.house.gov