Fact Sheet: Commerce Secretary Pritzker Announces New Biopharmaceutical Manufacturing Innovation Hub in Newark, DE

The first manufacturing innovation institute sponsored by the U.S. Department of Commerce and dedicated to biopharmaceutical manufacturing, is a partnership among more than 150 companies, educational institutions, research centers, coordinating bodies, non-profits, and manufacturing extension partnerships. It represents a public and private investment of at least $199 million for the development of a national resource for manufacturing advanced biologic therapies and workforce training. The new institute will become the eleventh institute in the Manufacturing USA network.

On Dec. 16, 2016, U.S. Secretary of Commerce Penny Pritzker announced a new innovation institute to advance U.S. leadership in biopharmaceutical manufacturing. The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) is dedicated to accelerating innovation in biopharmaceutical manufacturing, developing standards and measurement science for the industry, and creating a well-trained workforce for the field's high-paying jobs, many of which are currently unfilled. NIIMBL will be operated by a newly formed non-profit called USA Bio LLC, and comprises a team of more than 150 partners that represent all of the elements required to make a biopharmaceutical drug, from the equipment makers and suppliers of raw materials, to the companies developing new treatments and readying them for clinical trials and regulatory approval, to the clinics treating patients. The University of Delaware will administer a cooperative agreement on behalf of USA Bio in partnership with the Commerce Department's National Institute of Standards and Technology (NIST).

The demand for disease-treating biopharmaceuticals, which often succeed where traditional drug treatments have failed, is skyrocketing. Unlike traditional pharmaceutical drugs made using chemistry, biopharmaceuticals are made by living cells in a complex manufacturing environment that is still maturing technically. Innovations in biopharmaceutical manufacturing will mean that more patients have access to the most beneficial therapies. The institute will also help ensure that the nation can rapidly scale up manufacture of these advanced treatments to respond to pandemics and other biological threats, and eliminate drug shortages that can result from quality control issues in manufacturing.

With a $70 million federal investment and at least $129 million from consortium members, NIIMBL will advance the nation's competitiveness in this increasingly global industry by developing more efficient and rapid biopharmaceutical manufacturing processes and preparing students for well-paying jobs in the field. The consortium includes biopharmaceutical companies and manufacturers of the equipment upon which they rely; schools, colleges and universities; state and regional bioscience incubators; and state governments – spanning the supply chain and technology development pipeline for these critical therapies.

Background on the National Institute for Innovation in Manufacturing Biopharmaceuticals

The new institute announced today will accelerate advances in biopharmaceutical manufacturing, support the development of standards that enable more efficient and rapid manufacturing capabilities, and educate and train a world-leading biopharmaceutical manufacturing workforce. Its goals are to advance and cement U.S. leadership in this industry, foster regional economic development, and improve medical treatments.

While the U.S. leads the world in discovering and developing new biopharmaceuticals, the process of manufacturing these complex drugs has changed little in recent years. Like any other medical treatment, biopharmaceuticals must be approved by the U.S. Food and Drug Administration (FDA) and shown to be effective, safe, and offer an improvement on the current standard of care. Because a change in a production process means that a biopharmaceutical drug must be resubmitted to the FDA for approval, the cost and risks associated with developing new manufacturing methods are often too high for an individual biopharmaceutical company to incur. NIIMBL will create an environment for members to develop and validate new technologies together, and share the costs and risks of innovation.

- *Enabling process innovation for existing products*. The NIIMBL consortium members will share the risk of developing and gaining approval for new processes and share those advances with both large and small manufacturers across the whole industry. Biopharmaceutical manufacturers will have better ability to scale up production to meet the increasing demand for these life-saving, advanced therapies.

- *Right-scaled manufacturing for precision medicine.* NIIMBL will also explore new processes and equipment to allow the cost-effective manufacture of small or even single-batch biopharmaceuticals exactly matched to an individual's genetics or their disease, realizing the promise of so-called "precision medicine."

- *Industrial manufacturing for emerging product classes.* Next-generation biopharmaceuticals, such as cell-based cancer therapies, where cells rather than the proteins made by those cells are the treatment, are currently made in small batches by some clinical trial labs and smaller biotechnology companies. New standards and measurement methods will improve production efficiency and enable more small companies to succeed, as well as enable industrial-scale manufacturing.

- *Training the future workforce.* NIIMBL will advance U.S. leadership in the biopharmaceutical market, which generates about $1 billion in domestic revenue[*] and $200 billion globally. The fast-growing biopharmaceutical field has a negative unemployment rate, with more jobs available than there are qualified workers. NIIMBL's education and training programs will ensure a pipeline of skilled workers for biopharmaceutical manufacturers, where employees earn more than twice the average salary of other U.S. jobs[†].

- *Developing industry standards.* As it has for so many industries, the National Institute of Standards and Technology will enable these innovations with standards and new measurement and monitoring methods. The biopharmaceutical industry needs standards for assessing the quality of the raw materials used for biopharmaceuticals and for making processes more reliably reproducible and efficient, as well as measurement methods for monitoring quality and processes as they happen. standards also help small- and medium-sized biopharmaceutical manufacturers innovate: standards

[*] http://cellmanufacturingusa.org/sites/default/files/NCMC_Roadmap_021816_high_res-2.pdf
[†] http://phrmacdn.connectionsmedia.com/sites/default/files/pdf/The-Economic-Impact-of-the-US-Biopharmaceutical-Industry.pdf & https://www.bio.org/value-bioscience-innovation-growing-jobs-and-improving-quality-life-2016

define the parameters of success and give smaller companies an opportunity to develop innovative components or methods that fit into the larger manufacturing process.

- *Leveraging the Manufacturing USA network*. While NIIMBL's focus on the products of biological systems is unique among the Manufacturing USA institutes, the other innovation institutes offer capabilities critical to the improvement of biopharmaceutical manufacturing processes. Department of Defense (DOD) is currently reviewing applications for a manufacturing innovation institute for Advanced Tissue Biofabrication (ATB). NIIMBL's technical focus is complementary to that of the ATB, as NIIMBL's innovations in cell culture and other techniques will offer improved building blocks for creating new tissues. More details for the technical synergy between NIIMBL and ATB can be found on here.

NIIMBL will be headquartered in Newark, Delaware, and the University of Delaware will facilitate its rapid standup of communications and projects with institute members. Moving forward, NIIMBL plans to operate under USA Bio LLC, a new independent non-profit organization created to administrate this cooperative agreement with NIST's Advanced Manufacturing Office. The winning team received support from the following 103 industry members and non-profit organizations, as well as 47 additional partners across 25 states. Commerce is already bringing to bear other resources to support the Institute. NIST's MEP Center in Delaware - DEMEP - is leading a coalition of MEP centers from 14 states to connect small manufacturers to the technologies developed by the Institute.

103 Companies and Non-Profit Organizations: Agilent Technologies, AIChE, Air Liquide, Altimmune, Amgen, Amgen Foundation, Artemis Biosystems, Association of University Research Parks, ASTM, BioFactura, Biogen, BioHealth Innovation, Biologics Modular, BioPhorum Operations Group, bioVolutions, BMC Corp, Boehringer Ingelheim Fremont, California Manufacturing Technology Consulting, Celgene Corp, Charles River Laboratories, ChromaTan, Cimetrics, Colorado BioScience Association, Commissioning Agents, Inc, Connecting Connecticut's Science Community, Continuus Pharma, Corning Life Sciences, DelawareBio, DEMEP, DVIRC, Eli Lilly Research Labs, EMD Serono, FiberCell Systems, FloDesign Sonics, Fraunhofer CMB, Fraunhofer CESE, GBSI, GE Healthcare Life Sciences, Georgia Bio, Georgia Tech MEP, Grifols S.A., IBM, ILC Dover, ImmunoGen, Indiana Health Industry Forum, Institute for BioScience & Biotechnology Research, Intellia Therapeutics, IOWABio, Janssen Pharma, Juno Therapeutics, Kentucky Life Sciences Council, LakePharma, Lewa Process Technologies, Lonza Biologics Inc., Manex, MANTEC, MassBio, MassMep, MD MEP, MedImmune, MEPOL, MilliporeSigma, National Institute for Pharmaceutical Technology and Education, NC Bio, NC MEP, NEPIRC, NewYorkBIO, North Carolina Biotechnology Center, Novartis, Novo Nordisk, NYDSTI, Orochem, Pall Corp, Parental Drug Association, PBS Biotech, Pennsylvania Bio, Pfizer, Pharma Matrix, Pharyx Inc., Protein Sciences Corp, Purdue MEP, Regeneron Pharma, RepliGen, Rooster Bio, Sanofi Pasteur, SC MEP, Shire, Southwest Research Institute, SoyMeds, Stratosphere, Sudhin Biopharma, Tech Council of MD, Terumo BCT, THBI, Thrive Bioscience, University City Science Center, Unum Therapeutics, USP, Vericel Corp, Voyager Therapeutics, VWR, Waters

41 Universities, Colleges and Other Schools: Bio-Link (City College of San Francisco), Carnegie Mellon University, Clemson University, Delaware State University, Delaware Technical Community College, East Carolina University, Georgia Institute of Technology, Harvard University, IVY Tech Community College, Johns Hopkins University, MARBIONC: Marine Biotechnology in NC (UNC Wilmington), Massachusetts Institute of Technology, Memorial Sloan Kettering, MiraCosta College District, Montgomery College, Northeast Biomanufacturing Center and Collaborative, North Carolina Central University, North Carolina Community College's BioNetwork System, North Carolina State University, Pennsylvania State University, Purdue University, Quincy College, Rensselaer

Polytechnic Institute, Solano Community College, The University of Texas at Austin, Tulane University, University of California Berkeley, University of Colorado Boulder, University of Connecticut, University of Delaware, University of Georgia, University of Iowa, University of Kansas, University of Kentucky, University of Maryland, University of Massachusetts, University of Minnesota, University of North Carolina Chapel Hill, University of North Carolina Charlotte, University of Pennsylvania, University of Wisconsin

6 State Government and Regional Organizations: Commonwealth of Pennsylvania, Massachusetts Life Sciences Center, State of Delaware, State of Maryland, State of Minnesota, State of North Carolina

25 States Represented: Arizona, California, Colorado, Connecticut, Delaware, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, North Carolina, Pennsylvania, South Carolina, Texas, Washington, Washington D.C., Wisconsin

Background on the NIST Open Topic Competition

NIIMBL is the eleventh institute to join the Manufacturing USA network and the first to be awarded under the 2014 bipartisan Revitalize American Manufacturing Innovation (RAMI) Act using an "open topic" competition. This approach allows industry to propose institutes on any advanced manufacturing topic not already addressed by another institute. NIST received nearly two dozen institute proposals and all applications were subject to a rigorous due diligence process with extensive teams of technical experts, an intensive interagency panel, and for finalists in-person presentations by the proposal teams. The interagency evaluation panel rankings and recommendation by the independent Selection Official were reviewed by NIST's grants office and legal counsel. The robust scope and breadth of advanced manufacturing proposals submitted to NIST for this competition is a strong indicator of demand for future Manufacturing USA institutes. The RAMI Act and the rules governing the competition allow NIST to award additional institutes from this competition, subject to the availability of funds.