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

## New Manufacturing USA Biotechnology Institutes: Biopharmaceutical and Biofabrication Manufacturing Innovation Institutes

The Manufacturing USA program is expanding with two new biotechnology topic manufacturing innovation institutes. The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) is sponsored by the Department of Commerce and is **dedicated to biopharmaceutical manufacturing**, focusing on the use of living cells to produce complex biotherapeutics. The technical scope of NIIMBL includes innovation for mature product classes, such as vaccines and protein therapeutics, as well as for emerging products, such as cell-based cancer immunotherapies and genetherapies. The types of cellular-based therapies within the scope of NIIMBL are those that deliver a function as <u>single, mature cells</u>. For example, mature immune cells are engineered in the lab and then administered to a patient to correct a defective gene, or to display a molecule that makes the patient's immune system attack a cancer tumor.

This is different, and complementary to the soon-to-be-announced **Advanced Tissue Biofabrication** manufacturing innovation institute (ATB) sponsored by the Department of Defense. The ATB will focus on technology innovation needed to make <u>multicellular tissues and tissue products</u>. The technical scope for Advanced Tissue Biofabrication includes innovations in materials, bioprinting and biofabrication platforms, automation, sensing of biomaterial quality and function, and preservation. Specific product classes could be in scale-up for 3D tissues, new methods for storage and shipment of bioactive products, or automation in end-to-end manufacturing processes. In addition to cells, the ATB will focus on other building blocks for tissues, such as extra-cellular biomaterials. Stem cells can be manipulated into differentiating into the many different types of cells present in various organs and tissues and are therefore a critical source of cells for biofabrication of a wide array of potential tissue products.

Innovations in growing single cell types for biopharmaceuticals will have applications to tissue biofabrication, which requires a reliable supply of high-quality cells as starting material. Although they have different products, the two types of cell manufacturing also have some common infrastructure. Both biopharmaceutical and biofabrication manufacturing will benefit from advances in cell growth and processing, and from standards for raw materials, scalable cell manufacturing methods, control of the equipment that keeps cell lines alive, and storage and transportation of cells and cell products to clinics. In these areas, the institutes will work together to gain efficiencies from each other's work and avoid duplication of efforts.

A conference on January 13, 2017 at NIST will give interested parties an opportunity to explore the synergies and differences among these two institutes. Watch the <u>NIST event calendar</u> for more details and registration.