

Ensuring Sufficient Manufacturing Capacity for COVID-19 Therapeutics

Duke-Margolis Center for Health Policy

June 22, 2020

11:30am to 1:30 pm EST

11:30 am **Welcome and Overview**

Mark McClellan, Duke-Margolis Center for Health Policy

11:40 am **Session I: Ensuring Sufficient Manufacturing Capacity for COVID-19 Therapeutics**

This session will focus on understanding how to ensure that new COVID-19 treatments can be produced at scale and with minimal delay. This will include assessing the amount of manufacturing capacity that is available to produce promising treatments, collaborating with manufacturers to make capacity available as treatments are developed, and investing in additional capacity when it can be brought online quickly. As we repurpose existing manufacturing capacity towards manufacturing COVID-19 treatments, we must also ensure that we maintain our supply of critical treatments for other conditions.

Panelists:

- Michelle McMurry-Heath, BIO
- Philip Berk, Boston Consulting Group
- Patti Seymour, BioProcess Technology Group, BDO USA, LLP
- James Thomas, Just Evotec Biologics
- Cameron Durrant, Humanigen

12:35 pm **Session II: Future Policy Considerations for COVID-19 Therapeutics Manufacturing**

This session will look into the future of COVID-19 therapeutics manufacturing, focusing on short- and long-term policy implications. The U.S. Food and Drug Administration (FDA) and Biomedical Advanced Research and Development Authority (BARDA) are addressing these critical issues for access to COVID-19 treatments, but could potentially benefit from a clearer understanding of potential manufacturing-related needs and additional public-private resources to address them. New technologies, such as continuous manufacturing, may allow industry to quickly ramp up production of a new product as the need arises, but realizing the promise of these efforts will require coordination across government, pharmaceutical manufacturers, and other stakeholders.

Panelists:

- Phyllis Arthur, BIO
- Howard Sklamberg, Arnold & Porter Kaye Scholer LLP
- Frances Zipp, Lachman Consultants & ISPE
- Gil Roth, Pharma & Biopharma Outsourcing Association

1:25 pm **Closing Remarks**

Mark McClellan, Duke-Margolis Center for Health Policy