

**Your Treatment and Your Community:  
Advancing Evidence and Policy for Medical Products that Impact Others**

Virtual Public Workshop  
March 20, 2025 | 1:00 - 5:00 pm ET

**Agenda**

Many infectious diseases, such as respiratory virus infections, are easily transmissible from person to person and present a high population health burden. Because of this transmissibility, medical products to diagnose, prevent, and treat these infections have implications for both individual product users (direct effects) and their communities (indirect effects). However, the individual-level benefits and risk of medical products form the basis for marketing approval and payer reimbursement. A greater understanding of indirect effects and integrating evidence on indirect effects into decision making by regulators, payers, health care providers, and patients could reduce infectious disease burden and bolster population health.

In this convening, Duke-Margolis will present a framework on reduced transmission of infectious disease and integrating these indirect benefits for vaccines, therapeutics, and diagnostics into evidence generation and decision-making. The workshop presentations and discussions will focus on:

- Generating transparent and improved evidence for direct and indirect benefits and risks to enable voluntary and informed decision-making about treatment options;
- Advancing evidence generating infrastructure on indirect benefits to better capture the full benefits provided by vaccines, therapeutics, and diagnostics to individuals and communities;
- Elaborating on past Federal agency actions that have alluded to indirect benefits and can be expanded upon to further incentivize incorporation of indirect benefits in product approval and coverage decisions; and
- Discussing how policy approaches that stimulate the integration of indirect benefits can combine improvements to the evidence generation infrastructure with enhanced regulatory and reimbursement pathways.

**1:00 p.m.      Welcome and Overview**  
*Mark McClellan, Duke-Margolis Institute for Health Policy*

**1:10 p.m.      Session 1: Realizing a Population Health Framework**  
*Moderator: Mark McClellan, Duke-Margolis Institute for Health Policy*

*Objective:* This session will outline a framework to capture indirect benefits and population health outcomes and integrate them into current product development and access pathways. Participants will also review key regulatory and reimbursement reforms that can be taken across the product lifecycle to increase availability of and access to current and next-generation technologies.

Reactors:

- Blythe Adamson, Infectious Economics
- Mara Aspinall, Arizona State University and Illumina Ventures

**2:10 p.m.**      **Session 2: Implementing Policies to Improve Evidence Generation**  
*Moderator: Mark McClellan, Duke-Margolis Institute for Health Policy*

*Objective:* Through several use cases, panelists will discuss how stakeholders can integrate indirect benefits and population health outcomes into existing evidence generation efforts. Panelists will explore how to implement policies to define, approach and capture data on indirect benefits to understand the transmission reduction capability of vaccines, therapeutics, and diagnostics.

Panelists:

- Natalie Dean, Emory University
- Peter Marks, U.S. Food and Drug Administration
- Susan Sobolov, RIGImmune

**3:15 p.m.**      **Break**

**3:30 p.m.**      **Session 3: Implementing Policies to Clarify Regulatory and Reimbursement Pathways**  
*Moderator: Mark McClellan, Duke-Margolis Institute for Health Policy*

*Objective:* Acknowledging past FDA and CMS actions, panelists will examine legal and regulatory policy reforms that can support the incorporation of indirect benefits into regulatory and reimbursement decision-making. Panelists will discuss how to sustainably implement these reforms to increase the access and availability of transmission reducing vaccines, therapeutics, and diagnostics.

Panelists:

- Haider Andazola, Manatt, Phelps & Phillips
- Lee Fleisher, Rubrum Advising
- Joe Franklin, Covington & Burling

**4:30 p.m.**      **Fireside Chat**  
*Mark McClellan, Duke-Margolis Institute for Health Policy*  
*Scott Gottlieb, American Enterprise Institute*

**4:50 p.m.**      **Summary and Next-Steps**  
*Mark McClellan, Duke-Margolis Institute for Health Policy*

**5:00 p.m.**      **Adjournment**