Generic Drug Repurposing: Exploring the Potential Role of the Regulator and Policy Solutions

May 29, 2025
10:00 am – 4:00 pm ET

Hybrid Public Workshop • 1201 Pennsylvania Avenue NW, Fifth Floor • Washington, DC or Virtual

Meeting Description:
This hybrid workshop will provide a forum for participants to discuss the potential role of the regulator as it relates to generic drug repurposing. Discussion will explore a range of proposed solutions that aim to address challenges in identifying drug repurposing opportunities, seeking label expansion by nontraditional developers, and ensuring labels are updated to encourage responsible drug promotion and public health benefit. The goal of this workshop is to identify priority recommendations and opportunities to address key regulatory challenges and help to unlock the full potential of generic drugs.

Workshop Agenda

10:00 am **Welcome & Opening Remarks**
Gerrit Hamre, Duke-Margolis Institute for Health Policy

10:10 am **Background and Emerging Policy Solutions**
Presentation: **Beth Boyer**, Duke-Margolis Institute for Health Policy

10:25 am **Session 1: Identifying Generic Drug Repurposing Opportunities**
Moderator: **Beth Boyer**, Duke-Margolis Institute for Health Policy

Session Overview: This session will discuss the potential roles of the regulator in identifying generic drug repurposing opportunities. Participants will discuss ways to actively identify such opportunities including expansion of current programs, setting disease specific priorities, and other policy solutions.

Presentations:
- **Heather Stone**, U.S. Food and Drug Administration
- **David Fajgenbaum**, Every Cure

Additional Panelists:
- **Christine Colvis**, National Center for Advancing Translational Sciences (NCATS)

Moderated Panel Discussion & Audience Q&A

11:35 am **Break**

11:50 am **Session 2: Regulatory Pathways for Non-Traditional Drug Developers**
Moderator: **Gerrit Hamre**, Duke-Margolis Institute for Health Policy

Session Overview: This session will examine the pathways and programs that may be used to support non-traditional developers looking to pursue regulatory approval, including solutions to encourage sponsors to collaborate with non-traditional developers. Additionally, participants will explore opportunities for new federal authorities to support trial designs that meet evidentiary requirements and initiatives that enable increased direct engagement between non-traditional developers and FDA staff.

Presentations:
- **Sara Koblitz**, Hyman, Phelps, & McNamara, P.C.
- **Devon Crittenden**, Reboot Rx

Moderated Panel Discussion & Audience Q&A

1:00 pm **Lunch Break**

2:00 pm **Session 3: Updating Labels with Established Evidence & Encouraging Responsible Promotion**
Moderator: **Beth Boyer**, Duke-Margolis Institute for Health Policy

Session Overview: This session will discuss the utilization and potential expansion of existing federal authorities to update drug labels with new indications based on established evidence from real world use.

Presentations:
- **Janet Woodcock**, Former Regulator

Moderated Discussion & Audience Q&A

2:45 pm **Break**

3:00 pm **Session 4: Additional Opportunities for Generic Drug Repurposing & Next Steps**
Moderator: **Tanisha Carino**, Duke-Margolis Institute for Health Policy

Session Overview: This session will open the floor up to participants to share new ideas and opportunities to support generic drug repurposing that have not already been discussed and potential next steps.

Open Discussion

3:50 pm **Concluding Remarks**
Beth Boyer, Duke-Margolis Institute for Health Policy

4:00 pm **Adjournment**

Funding for this project was made possible in part by Arnold Ventures LLC. The views expressed in events, written materials, or publications and by participants do not necessarily reflect the official views or endorsement by Arnold Ventures LLC.