

Increasing Access to Nonprescription Drugs

Hybrid Meeting | National Press Club, Washington, D.C.

April 23, 2026

12:30 – 5:00 pm ET

Agenda

This hybrid public meeting, convened by the Duke-Margolis Institute for Health Policy under a cooperative agreement with the U.S. Food and Drug Administration, will convene drug developers, health care providers, patient and consumer representatives, and other relevant stakeholders to discuss opportunities to increase access to nonprescription drugs. The meeting will focus on the new drug application process for nonprescription drugs, which includes direct-to-nonprescription applications, prescription-to-nonprescription “switch” applications, and applications with Additional Conditions for Nonprescription Use. Participants will also discuss practical considerations related to access, innovative strategies to increase access, and how increased access may affect individual and public health outcomes.

12:30 – 12:40 pm

Welcome and Introduction

Marianne Hamilton Lopez, Duke-Margolis Institute for Health Policy

12:40 – 1:00 pm

Overview of Nonprescription Drug Regulation

Karen Murry, U.S. Food and Drug Administration

1:00 – 2:00 pm

Opportunities to Improve Public Health with Nonprescription Treatments

A presentation will analyze the potential impacts of increased nonprescription drug access on health outcomes, consumer access, and health care system costs. Panelists will discuss drug classes that are unavailable without a prescription that may be appropriate candidates for nonprescription status. Discussion will also cover the existing nonprescription and switch landscape and the potential impact of expanded use of these treatments in nonprescription settings.

Moderator: *Anna Hung*, Duke-Margolis Institute for Health Policy

Presenter:

- *Eric Brass*, University of California Los Angeles

Panelists:

- *Henry Lim*, American Academy of Dermatology Association
- *Mariana Socal*, Johns Hopkins University
- *David Spangler*, Consumer Healthcare Products Association

2:00 – 2:10 pm

Break

2:10 – 3:40 pm

Evidence Generation to Demonstrate Safety and Efficacy in the Nonprescription Setting

Panelists will discuss how clinically significant risks and benefits can be most effectively characterized to support regulatory submissions for nonprescription drugs, including consumer studies and potential, supportive use of real-world data from the U.S. or other jurisdictions. Panelists will also consider methods for ensuring safe and appropriate use in the nonprescription setting. Topics for discussion may include additional conditions for nonprescription use and how sponsors might adequately demonstrate the efficacy of these methods in regulatory submissions.

Moderator: *Valerie J. Parker*, Duke-Margolis Institute for Health Policy

Presenter:

- *Russell Bradford*, Pegus Research

Panelists:

- *Barbara Cohen*, Cohen Nonprescription Consulting
- *Ruth S. Day*, Duke University
- *Alankar Gupta*, Kenvue
- *Irene Laurora*, Perrigo
- *Michael Wolf*, Northwestern University

3:40 – 4:50 pm

Innovation to Enable Increased Access to Nonprescription Drugs

Panelists will discuss how additional conditions for nonprescription use could be implemented most effectively and consistently for different therapeutic areas with different risks. Discussion will also focus on access points across various pharmacy, retail, and online settings where consumers may purchase nonprescription drugs. Panelists will identify innovative approaches that maximize feasibility of implementation and expanded, appropriate consumer access to nonprescription drugs.

Moderator: *Thomas Rodes*, Duke-Margolis Institute for Health Policy

Panelists:

- *Michelle Cope*, National Association of Chain Drug Stores
- *Mary Alice Lawless*, Biograph by Amwell
- *Dustin Little*, AstraZeneca
- *Sue Peschin*, Alliance for Aging Research
- *Shonna Yin*, New York University

4:50 – 5:00 PM

Closing Remarks and Adjournment

Thomas Rodes, Duke-Margolis Institute for Health Policy

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