

## Improving Anaphylaxis Outcomes: Approaches for Enhancing Access to Epinephrine

Hybrid Meeting | Duke in DC Office

December 16, 2025

9:00 AM – 4:30 PM ET

### Agenda

#### Background and Event Objective

Anaphylaxis is a severe, progressive allergic reaction that can be fatal if not promptly treated with epinephrine. Failure to treat anaphylaxis within minutes can lead to airway obstruction, shock and multi-organ failure. Despite being the only effective first-line treatment approved by the Food and Drug Administration (FDA), barriers may limit access to and use of epinephrine. For example, patients and caregivers may experience challenges in determining whether and how to administer epinephrine to treat an anaphylactic reaction. Institutional barriers may also inhibit access to and use of epinephrine in community settings, such as schools, workplaces, restaurants and other public venues. Additionally, there are potential procedural barriers to obtain authorization from a health care professional before carrying epinephrine. These barriers may be magnified in communities with limited health care infrastructure, and by the cost of epinephrine products. While Federal and state legislation has sought to expand access to epinephrine by directly addressing barriers to use, additional policy and regulatory solutions may be needed to help ensure life-saving treatment for anaphylaxis is readily available when needed in an emergency to improve anaphylaxis outcomes.

This hybrid public workshop will initiate a discussion on expanding epinephrine accessibility and use, including in community settings, to reduce anaphylaxis-related morbidity and mortality. Prospective approaches intended to improve anaphylaxis outcomes include but are not limited to expanding training on use, enhancing civil liability protections for administrators of epinephrine, incentivizing availability in public spaces, and considering development of epinephrine for nonprescription use.

#### 9:00 AM Welcome and Overview

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

#### 9:10 AM FDA Opening Remarks

**Mary Thanh Hai**, U.S. Food and Drug Administration

#### 9:20 AM Session 1: Allergic Diseases, Anaphylaxis, and Treatment of Anaphylaxis in the Community Setting

This session will feature presentations on the latest clinical guidelines and current practices for diagnosing allergic diseases and anaphylaxis. Panel discussion will explore how these practices are referenced to advise individuals on when to carry and administer epinephrine. Challenges to recognizing anaphylaxis and challenges experienced by individuals carrying epinephrine or administering undesignated epinephrine will also be explored.

*Moderator:* **Paul Greenberger**, Northwestern University

*Presenters:*

**Hugh Sampson**, Icahn School of Medicine at Mount Sinai

**Julie Wang**, Icahn School of Medicine at Mount Sinai

*Panelists:*

- **Hemant Sharma**, Children's National Hospital
- **Brian Vickery**, Emory University

**10:30 AM**      **Break**

**10:45 AM**      **Session 2: Regulatory Pathways for Epinephrine Products, Including Considerations for Prescription and Nonprescription Development**

This session will cover the regulatory pathway for approval of epinephrine products for treatment of anaphylaxis in the community setting and the risk-benefit considerations for epinephrine use as a prescription or nonprescription drug. Discussion will include the available dosage forms, delivery devices, use in adults versus pediatrics, data requirements to demonstrate that a drug is appropriate for nonprescription use, including assessments of consumer behavior as well as the capacity for consumers to self-diagnose allergies associated with anaphylaxis and self-diagnose anaphylaxis.

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

*Presenters:*

**Karen Murry**, U.S. Food and Drug Administration

**Miya Paterniti**, U.S. Food and Drug Administration

*Panelists:*

- **Carla Davis**, Howard University
- **Paul Greenberger**, Northwestern University
- **Alice Hoyt**, Code Ana
- **Kelly Stone**, U.S. Food and Drug Administration

**11:50 AM**      **Lunch Break**

**1:05 PM**      **Public Comment Session**

Individuals who wish to provide remarks during this workshop will have made a request prior to the meeting. This will serve as a listening session for the audience and there will be no moderated discussion.

*Moderator:* **Brian Canter**, Duke-Margolis Institute for Health Policy

2:05 PM

### Session 3: Current Accessibility to Epinephrine for Treating Anaphylaxis

This session will include discussions on the available data to assess barriers with obtaining, carrying, and using epinephrine. Panelists will consider the institutional barriers presented in community settings and by differing state immunity laws. They will also explore why patients may decide not to use epinephrine during anaphylaxis despite carrying it. There will also be consideration for challenges in accessing care and the need for a prescription to acquire epinephrine.

*Moderator:* **Michael Pistiner**, Massachusetts General Hospital for Children

*Panelists:*

- **Kelly Cleary**, Food Allergy Research and Education
- **Ruchi Gupta**, Northwestern University
- **Linda Herbert**, Children's National Hospital
- **Charity Luiskutty**, Food Allergy & Anaphylaxis Connection Team
- **Christopher Warren**, Northwestern University

3:05 PM

**Break**

3:20 PM

### Session 4: Opportunities to Enhance Access to and Use of Epinephrine

This session will examine promising approaches to increase access to and use of epinephrine, along with the authorities governing those measures. Reflecting on prior discussions, panelists will consider how various interventions may improve epinephrine access. Potential interventions include, but are not limited to, increased availability of methods for administration and educational resources informed by the latest clinical guidelines. Panelists will also discuss the feasibility of potential policy actions and the potential impact on anaphylaxis outcomes.

*Moderator:* **Julie Wang**, Icahn School of Medicine at Mount Sinai

*Panelists:*

- **Timothy Dribin**, Cincinnati Children's Hospital Medical Center
- **Matthew Greenhawt**, Asthma and Allergy Foundation of America
- **Nissa Shaffi**, Allergy & Asthma Network
- **Marcus Shaker**, Dartmouth College

4:30 PM

### Closing Remarks and Adjournment

**Karen Murry**, U.S. Food and Drug Administration

### **Funding Acknowledgement**

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