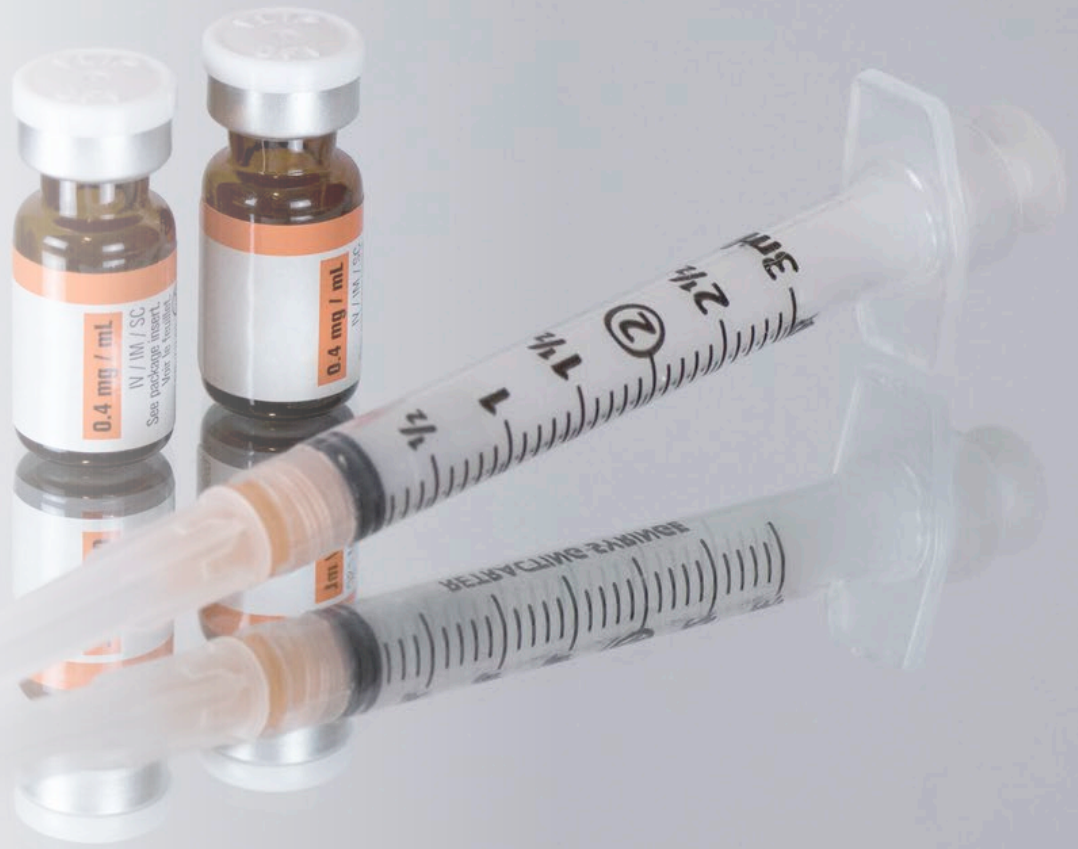
REAGAN-UDALL FOUNDATION FOR THE FDA

Naloxone Access: Answering Questions



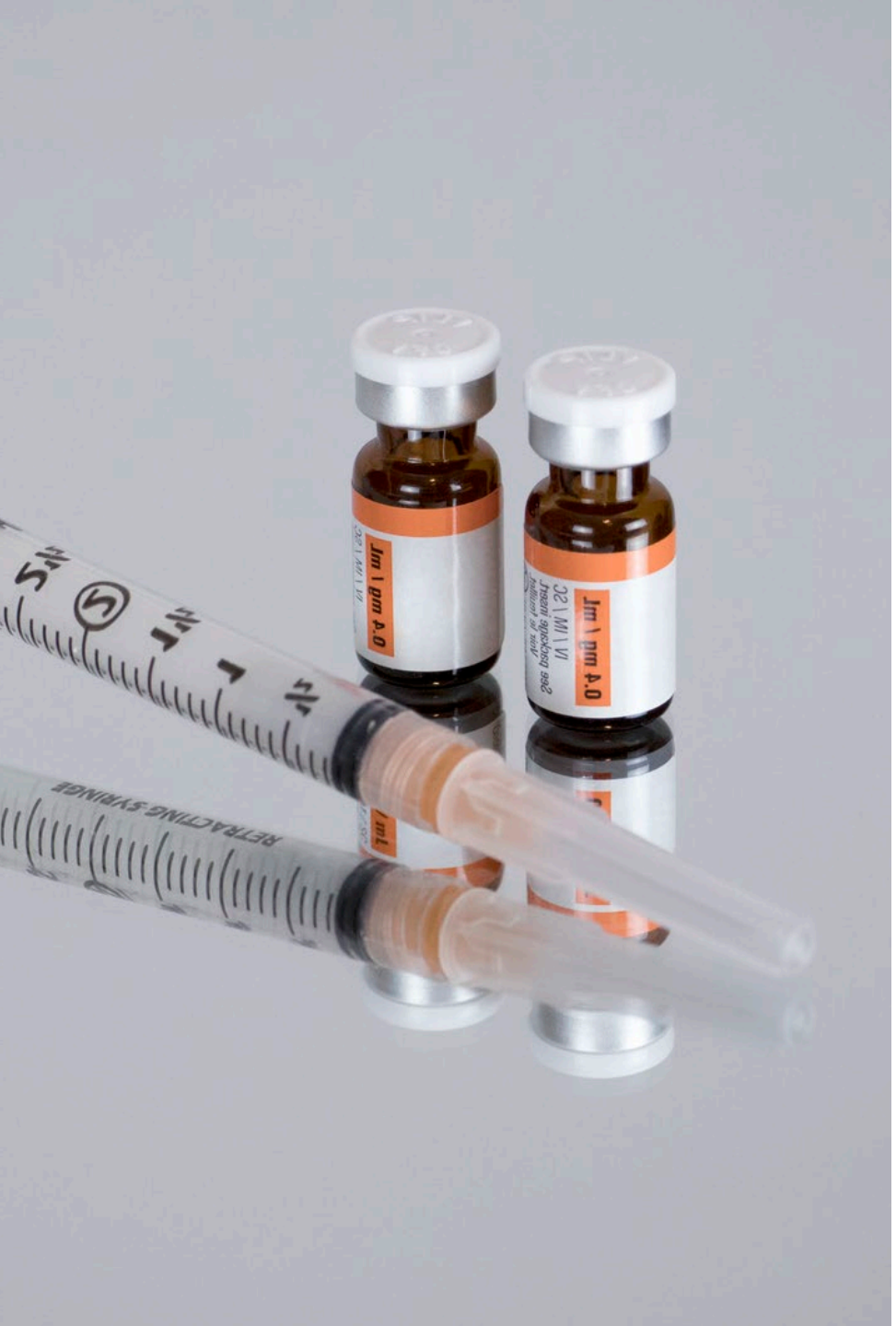
March 29, 2022
12:30-3 pm Eastern Time

[Need funding disclosure]

REAGAN-UDALL FOUNDATION FOR THE FDA

Welcome

Susan C. Winckler, RPh, Esq.
Chief Executive Officer
Reagan-Udall Foundation for the FDA



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Thank you for joining

This webinar is being recorded. The slides, transcript, and video recording will be available on the FDA Foundation website after the meeting.

If you'd like to ask a question, you may enter it in the Zoom Q&A. We will get to as many questions as time allows.

Speakers will not address questions regarding any pending regulatory action or discuss specific companies or medical products by name.

Your microphone and video will remain off during the meeting. Those who registered to present public comment will be unmuted when it is their time to speak. Reminder: public commenters should check in by 1:15pm ET.

Agenda

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12:30 p.m.	Welcome
12:35 p.m.	Opening Remarks from U.S. Food and Drug Administration
12:40 p.m.	Current Landscape of Naloxone Access
2 p.m.	Public Comment
3 p.m.	Adjournment

*Eastern Time

REAGAN-UDALL FOUNDATION FOR THE FDA

Opening Remarks

Patrizia Cavazzoni, MD
Director, Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Why are we here today?

Drug overdose persists as a major public health issue in the United States, killing 100,000 people from May 2020-April 2021.

Today, we will explore questions about access to naloxone, a drug used to reverse opioid overdoses. We will hear from harm reduction specialists, physicians, pharmacists, and regulators about the availability of this life-saving medication.

What is naloxone?

Naloxone is an opioid antagonist medication that rapidly reverses the effects of opioid overdose by blocking the effects of opioids. It is the standard treatment for overdose.

Naloxone can restore normal breathing within 2 to 3 minutes in a person whose breath has slowed, or even stopped, as a result of opioid overdose. A higher dose or more than one dose of naloxone may be required when stronger opioids like fentanyl are involved.

Naloxone is administered in a variety of ways, including via nasal spray, an autoinjector, or a vial and syringe.

Resources from HHS

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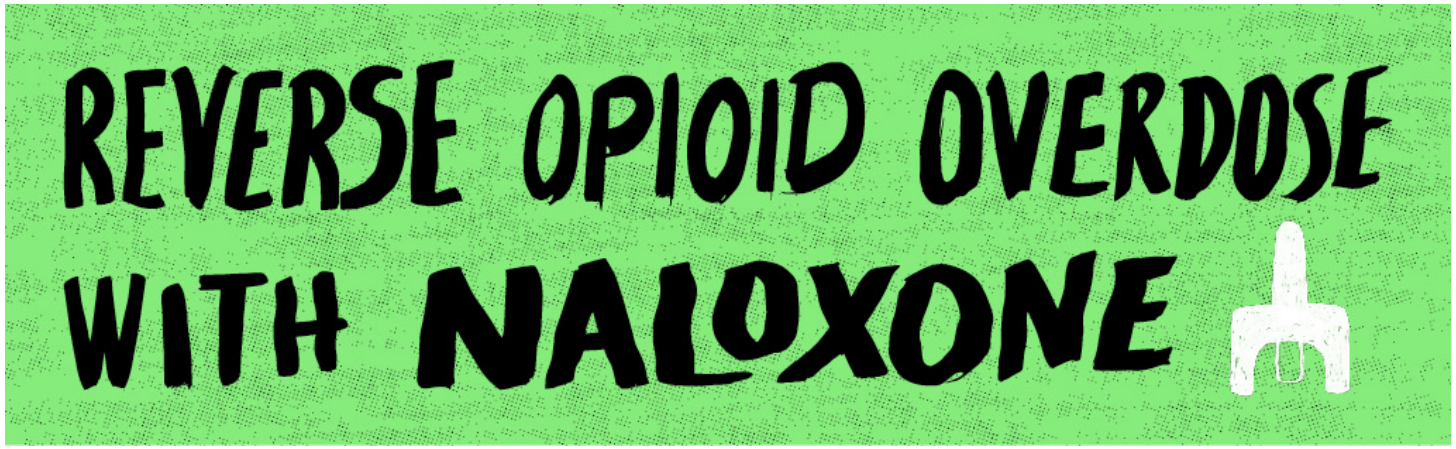
In the wake of the overdose epidemic, HHS agencies have undertaken many efforts to make this emergency treatment more readily available and more accessible. Visit their websites for more information.

FDA U.S. FOOD & DRUG ADMINISTRATION

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

SAMHSA
Substance Abuse and Mental Health Services Administration



Current Landscape of Naloxone Access

Moderator

Susan C. Winckler, RPh, Esq.

Panelists

Josh Bolin, National Association of Boards of Pharmacy

Marta Sokolowska, PhD, U.S. Food and Drug Administration

Nabarun Dasgupta, PhD, MPH, University of North Carolina

Bobby Mukkamala, MD, American Medical Association

Jeffrey Bratberg, PharmD, The University of Rhode Island

Vignette 1

What is the current federal status of naloxone?

Does FDA have the authority to change a product from prescription-only status to over-the-counter status?

What are some best practices as physicians think about whether or not to sign standing orders or other protocols to expand naloxone access?

How are pharmacists involved in expanding naloxone access?

Do you need a prescription to obtain syringes?

What flexibilities exist for states to determine who can prescribe and dispense naloxone?

Can a state make a prescription-only product available over the counter?

Vignette 2

Why do some pharmaceutical companies require signed agreements with harm reduction companies about distribution?

Is naloxone a controlled substance?

Why is it required to provide a DEA number/be a DEA registrant to prescribe naloxone?

We have heard that harm reduction organizations have to purchase naloxone from a different part of wholesale companies. How does that contribute to barriers to access?

Why is naloxone not available at some pharmacies? What is contributing to disparate distribution among pharmacies?

Vignette 3

What does an expansive naloxone standing order look like from a state pharmacy practice act/state medical practice act?

How can prescribers leverage the expertise that harm reduction organizations have related to naloxone dosing?

Are there model programs that expand pharmacy access in the U.S.?

Does FDA have regulatory authority over vending machines for naloxone?

Are there other novel approaches to increasing naloxone access that we haven't touched on yet?

What have you found effective in addressing stigma around naloxone distribution?


NALOXONE
NASAL SPRAY

Both save lives.

Allergies

Overdose

Public Comment

PLACEHOLDER FOR COUNTDOWN CLOCK

Thank You!

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